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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

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

IMMUNITYBIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**43-1979754**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3530 John Hopkins Court San Diego, California	**92121**
(Address of principal executive offices)	**(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	**IBRX**	**The 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The number of shares of the Registrant's common stock outstanding as of May 12, 2021 was 383,905,840 (excluding 163,800 shares held by a majority owned subsidiary of ours which are treated as treasury shares for accounting purposes).

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,679	$ 34,915
Marketable securities	38,594	61,146
Due from related parties	2,057	2,003
Prepaid expenses and other current assets (including amounts with related parties)	14,242	13,649
Total current assets	99,572	111,713
Marketable securities, noncurrent	1,000	950
Property, plant and equipment, net	80,875	72,541
Non-marketable equity investment (Note 4)	—	7,849
Intangible asset, net	1,438	1,463
Convertible note receivable	6,191	6,129
Operating lease right-of-use assets, net (including amounts with related parties)	18,447	18,138
Other assets (including amounts with related parties)	1,905	2,598
Total assets	$ 209,428	$ 221,381
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 20,097	$ 11,510
Accrued expenses and other liabilities	36,793	36,771
Due to related parties	17,817	14,838
Operating lease liabilities (including amounts with related parties)	5,156	5,015
Total current liabilities	79,863	68,134
Related-party notes payable	297,286	254,353
Operating lease liabilities, less current portion (including amounts with related parties)	16,554	16,179
Deferred income tax liability	170	170
Other liabilities	891	1,035
Total liabilities	394,764	339,871
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 383,067,321 and 382,243,142 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively; excluding treasury stock, 163,800 shares outstanding as of March 31, 2021 and December 31, 2020, respectively	38	38
Additional paid-in capital	1,508,958	1,495,163
Accumulated deficit	(1,694,745)	(1,615,131)
Accumulated other comprehensive (loss) income	(38)	122
Total ImmunityBio stockholders' deficit	(185,787)	(119,808)
Noncontrolling interests	451	1,318
Total stockholders' deficit	(185,336)	(118,490)
Total liabilities and stockholders' deficit	$ 209,428	$ 221,381

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

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

	Three Months Ended March 31,	
	2021	2020
Revenue	$ 139	$ 165
Operating expenses:		
Research and development (including amounts with related parties)	41,128	27,374
Selling, general and administrative (including amounts with related parties)	45,275	9,493
Total operating expenses	86,403	36,867
Loss from operations	(86,264)	(36,702)
Other income (expense):		
Interest and investment income, net	8,944	78
Interest expense (including amounts with related parties)	(3,168)	(1,889)
Other income, net (including amounts with related parties)	13	1,104
Total other income (expense)	5,789	(707)
Loss before income taxes and noncontrolling interests	(80,475)	(37,409)
Income tax expense	(6)	(18)
Net loss	(80,481)	(37,427)
Net loss attributable to noncontrolling interests, net of tax	(867)	(389)
Net loss attributable to ImmunityBio common stockholders	$ (79,614)	$ (37,038)
Net loss per ImmunityBio common share – basic and diluted	$ (0.21)	$ (0.10)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	382,741,464	371,989,232

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

ImmunityBio, Inc. and Subsidiaries
Condensed Combined Consolidated Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Net loss	$ (80,481)	$ (37,427)
Other comprehensive (loss) income, net of income taxes:		
Net unrealized losses on available-for-sale securities	(1)	(24)
Foreign currency translation adjustments	(162)	70
Reclassification of net realized losses on available-for-sale securities included in net loss	3	1
Total other comprehensive (loss) income	(160)	47
Comprehensive loss	(80,641)	(37,380)
Comprehensive loss attributable to noncontrolling interests	(867)	(389)
Comprehensive loss attributable ImmunityBio common stockholders	$ (79,774)	$ (36,991)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Combined Consolidated Statements of (Deficit) Equity
(in thousands, except share amounts)
(Unaudited)

Three Months Ended March 31, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
Balance as of December 31, 2020	382,243,142	$ 38	$ 1,495,163	$ (1,615,131)	$ 122	$ (119,808)	$ 1,318	$ (118,490)
Stock-based compensation expense	—	—	15,298	—	—	15,298	—	15,298
Exercise of stock options	690,465	—	1,121	—	—	1,121	—	1,121
Vesting of restricted stock units (RSUs)	235,725	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(102,011)	—	(2,624)	—	—	(2,624)	—	(2,624)
Other comprehensive loss	—	—	—	—	(160)	(160)	—	(160)
Net loss	—	—	—	(79,614)	—	(79,614)	(867)	(80,481)
Balance as of March 31, 2021	383,067,321	$ 38	$ 1,508,958	$ (1,694,745)	$ (38)	$ (185,787)	$ 451	$ (185,336)

Three Months Ended March 31, 2020	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total ImmunityBio Stockholders' Equity (Deficit)	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
Balance as of December 31, 2019	371,976,995	$ 37	$ 1,406,002	$ (1,393,280)	$ (87)	$ 12,672	$ 3,654	$ 16,326
Stock-based compensation expense	—	—	480	—	—	480	—	480
Vesting of RSUs	63,750	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(25,722)	—	(123)	—	—	(123)	—	(123)
Other comprehensive income	—	—	—	—	47	47	—	47
Net loss	—	—	—	(37,038)	—	(37,038)	(389)	(37,427)
Balance as of March 31, 2020	372,015,023	$ 37	$ 1,406,359	$ (1,430,318)	$ (40)	$ (23,962)	$ 3,265	$ (20,697)

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

ImmunityBio, Inc. and Subsidiaries
Condensed Combined Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	$ (80,481)	$ (37,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	15,298	480
Unrealized (gains) losses on equity securities	(8,834)	202
Non-cash interest items, net (including amounts with related parties)	3,435	1,965
Depreciation and amortization	2,972	3,461
Non-cash lease expense related to operating lease right-of-use assets	1,555	1,177
Amortization of net premiums and discounts on marketable debt securities	225	45
Deferred tax	—	(1,067)
Other	(125)	4
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(934)	(4,020)
Other assets	693	322
Accounts payable	6,497	(1,724)
Accrued expenses and other liabilities	(1,893)	8,228
Related parties	2,597	(2,411)
Operating lease liabilities	(1,474)	(342)
Net cash used in operating activities	(60,469)	(31,107)
Investing activities:		
Purchases of property, plant and equipment	(7,083)	(315)
Purchases of marketable debt securities, available-for-sale	(91)	(10,300)
Maturities of marketable debt securities	31,925	23,109
Proceeds from sales of marketable debt securities	7,094	1,500
Net cash provided by investing activities	31,845	13,994
Financing activities:		
Proceeds from issuance of related-party promissory notes	40,000	—
Proceeds from exercises of stock options	1,121	—
Net share settlement for RSUs vesting	(2,624)	(123)
Net cash provided by (used in) financing activities	38,497	(123)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(109)	89
Net change in cash, cash equivalents, and restricted cash	9,764	(17,147)
Cash, cash equivalents, and restricted cash, beginning of period	35,094	75,980
Cash, cash equivalents, and restricted cash, end of period	$ 44,858	$ 58,833

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

ImmunityBio, Inc. and Subsidiaries
Condensed Combined Consolidated Statements of Cash Flows (Continued)
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Reconciliation of cash, cash equivalents, and restricted cash, end of period:		
Cash and cash equivalents	$ 44,679	$ 58,654
Restricted cash (Note 3)	179	179
Cash, cash equivalents, and restricted cash, end of period	$ 44,858	$ 58,833
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 12	$ 7
Income taxes	$ 2	$ —
Supplemental disclosure of non-cash activities:		
Property and equipment purchases included in accounts payable, accrued expenses, and due to related parties	$ (4,267)	$ (367)
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,388	$ —
Unrealized gains on marketable debt securities	$ 14	$ 23

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

ImmunityBio, Inc. and Subsidiaries
Notes to Unaudited Condensed Combined Consolidated Financial Statements

1. Description of Business

Organization

We were incorporated in Illinois on October 7, 2002 under the name ZelleRx Corporation. On January 22, 2010, we changed our name to Conkwest, Inc. In March 2014, we formed Conkwest, Inc., our wholly-owned subsidiary in the state of Delaware, or Conkwest Delaware, for the purposes of changing the state of our incorporation to the state of Delaware. In March 2014, we merged with an into Conkwest Delaware, with Conkwest Delaware surviving the merger. On July 10, 2015, we changed our name to NantKwest, Inc. On March 9, 2021, we completed a merger with NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company) and we changed our name to ImmunityBio, Inc. Our principal executive offices are located in San Diego, California. In these notes to unaudited condensed combined consolidated financial statements, the terms "ImmunityBio," "the company," "the combined company," "we," "us," and "our" refer to ImmunityBio and subsidiaries.

We established ImmunityBio to advance the next-generation immunotherapies and to address unmet needs within oncology and infectious disease. Our platform is designed to overcome limitations of the current standards of T cell-based immunotherapies, including checkpoint inhibitors and CAR-T cells and is based on our four key modalities: (1) activating natural killer, or NK, and T cells using antibody cytokine fusion proteins, (2) activating tumoricidal macrophages using low-dose synthetic immunomodulators, (3) generating memory T cells using vaccine candidates developed with our second-generation adenovirus, or hAd5, technology, and (4) off-the-shelf natural killer cells from the NK-92 cell line and memory-like cytokine-enhanced natural killer cells (m-ceNK) from allogenic and autologous donors.

We own a broad, clinical-stage immunotherapy pipeline, including an antibody cytokine fusion protein (an IL-15 superagonist (N-803) known as Anktiva), an albumin-associated anthracycline synthetic immunomodulator (aldoxorubicin), second-generation adenovirus (hAd5) and yeast vaccine technologies (targeting tumor-associated antigens and neoepitopes), off-the-shelf genetically engineered natural killer cell lines inducing cancer and virally infected cell death through a variety of concurrent mechanisms (including innate killing, antibody-mediated killing, and CAR-directed killing), patient specific NK cell product for cancer that is an autologous Memory cytokine enhanced Natural Killer cells, macrophage polarizing peptides, and bi-specific fusion proteins targeting CD20, PD-L1, TGF-b and IL-12. Our immunotherapy clinical pipeline consists of over 40 clinical trials in Phase 1, 2, or 3 development across 19 indications in solid and liquid cancers and infectious diseases. We have an expansive clinical-stage pipeline and intellectual property portfolio with 17 first-in-human assets in 25 Phase II to III clinical trials.

In December 2019, the United States, or U.S., Food and Drug Administration, or FDA, granted Breakthrough Therapy designation to Anktiva for bacillus Calmette-Guérin, or BCG, unresponsive carcinoma in situ non-muscle invasive bladder cancer. Other indications currently with registration-potential studies include BCG unresponsive papillary bladder cancer, first- and second-line lung cancer, and metastatic pancreatic cancer.

The Merger

On December 21, 2020, we and NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company) ("NantCell") entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which we and NantCell agreed to combine our businesses. The Merger Agreement provided that a wholly-owned subsidiary of the company would merge with and into NantCell (the "Merger"), with NantCell surviving the Merger as a wholly-owned subsidiary of the company.

On March 9, 2021, we completed the Merger pursuant to the terms of the Merger Agreement. Under the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of NantCell common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time, subject to certain exceptions as set forth in the Merger Agreement, was converted automatically into a right to receive 0.8190 (the "Exchange Ratio") newly issued shares of common stock, par value $0.0001 per share, of the company ("Company Common Stock"), with cash paid in lieu of any fractional shares. At the Effective Time, each share of the company's common stock issued and outstanding immediately prior to the Effective Time, remained an issued and outstanding share of the combined company. At the Effective Time, each outstanding option, warrant or restricted stock unit to purchase NantCell common stock was converted using the Exchange Ratio into an option, warrant or restricted stock unit, respectively, on the same terms and conditions immediately prior to the Effective Time, to purchase shares of Company Common Stock.

Immediately following the Effective Time, the former stockholders of NantCell held approximately 71.5% of the outstanding shares of Company Common Stock and the stockholders of the company as of immediately prior to the Merger held approximately 28.5% of the outstanding shares of Company Common Stock. As a result of the Merger and immediately following the Effective Time, Dr. Patrick Soon-Shiong, our Executive Chairman, and his affiliates beneficially own, in the aggregate, approximately 81.8% of the outstanding shares of Company Common Stock. Following the consummation of the Merger, shares of the company's common stock are now listed on the Nasdaq Global Select Market under the symbol "IBRX."

We incurred costs totaling $23.2 million in connection with the Merger, consisting of financial advisory, legal and other professional fees, of which $12.9 million was recorded during the three months ended March 31, 2021. Merger-related costs are reported in *selling, general and administrative expense*, on the condensed combined consolidated statements of operations.

Accounting Treatment of the Merger

The Merger represents a business combination pursuant to Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 805-50, *Mergers*, which is accounted for as a transaction between entities under common control as Dr. Soon-Shiong and his affiliates were the controlling stockholders of each of the company and NantCell for all of the periods presented in this report. As a result, all of the assets and liabilities of NantCell were combined with ours at their historical carrying amounts on the closing date of the Merger. We have recast our prior period financial statements to reflect the conveyance of NantCell's common shares as if the Merger had occurred as of the earliest date of the financial statements presented. All material intercompany accounts and transactions have been eliminated in consolidation.

The following table provides the impact of the change in reporting entity on our unaudited condensed combined consolidated statements of operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31, 2021			
	NantCell	NantKwest	Intercompany Eliminations	ImmunityBio, Inc.
Revenue	$ 183	$ —	$ (44)	$ 139
Operating expenses:				
Research and development (including amounts with related parties)	21,509	19,725	(106)	41,128
Selling, general and administrative (including amounts with related parties)	24,382	20,903	(10)	45,275
Loss from operations	(45,708)	(40,628)	72	(86,264)
Other (expense) income, net (including amounts with related parties)	(848)	6,637	—	5,789
Income tax expense	—	(6)	—	(6)
Net loss	$ (46,556)	$ (33,997)	$ 72	$ (80,481)

	Three Months Ended March 31, 2020			
	NantCell	NantKwest	Intercompany Eliminations	ImmunityBio, Inc.
Revenue	$ 168	$ 21	$ (24)	$ 165
Operating expenses:				
Research and development (including amounts with related parties)	14,252	13,234	(112)	27,374
Selling, general and administrative (including amounts with related parties)	4,120	5,373	—	9,493
Loss from operations	(18,204)	(18,586)	88	(36,702)
Other (expense) income, net (including amounts with related parties)	(910)	203	—	(707)
Income tax expense	(18)	—	—	(18)
Net loss	$ (19,132)	$ (18,383)	$ 88	$ (37,427)

2. Summary of Significant Accounting Policies

There have been no material changes to our significant accounting policies from those described in the Notes to Combined Consolidated Financial Statements included in the Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) filed as Exhibit 99.2 to our Current Report on Form 8-K/A filed with the Securities and Exchange Commission, or SEC, on April 22, 2021.

Basis of Presentation

The accompanying unaudited condensed combined consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and pursuant to the rules and regulations of the SEC. The unaudited condensed combined consolidated financial statements reflect all adjustments which are, in the opinion of management, necessary for a fair presentation of our financial position and results of operations. The unaudited condensed combined consolidated financial statements do not include all information and notes required by U.S. GAAP for annual reports.

As of March 31, 2021, the company had an accumulated deficit of $1.7 billion. We also had negative cash flows from operations of $60.5 million for the three months ended March 31, 2021. The company will likely need additional capital to further fund the development of, and seek regulatory approvals for, our product candidates, and to begin to commercialize any approved products.

The condensed combined consolidated financial statements are derived from the company's and NantCell's respective historical consolidated financial statements for each period presented. Since the entities have been under common control for all periods presented, the condensed combined consolidated financial statements assume that the Merger took place at the beginning of the earliest period for which the condensed combined consolidated financial statements are presented. Accordingly, these financial statements should be read in conjunction with the audited combined consolidated financial statements and notes thereto for the fiscal year ended December 31, 2020 included in the Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) filed as Exhibit 99.2 to our Current Report on Form 8-K/A filed with the SEC on April 22, 2021. Interim operating results are not necessarily indicative of operating results for the full year.

The condensed combined 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 of our ability to continue as a going concern. As a result of continuing anticipated operating cash outflows, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. However, we believe our existing cash, cash equivalents, and investments in marketable securities, together with capital to be raised through equity offerings, including but not limited to the offering, issuance and sale by us of up to a maximum aggregate offering of $500.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement with Jefferies LLC, or the ATM, and our potential 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 primarily upon our Executive Chairman's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt. 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 our product candidates in development, we may need additional funds to meet our needs sooner than planned.

Principles of Consolidation

The accompanying unaudited condensed combined consolidated financial statements include the accounts of the company and its subsidiaries. All intercompany amounts have been eliminated. For consolidated entities where we have less than 100% of ownership, we record net loss attributable to noncontrolling interest in our condensed combined consolidated statements of operations equal to the percentage of the ownership interest retained in such entities by the respective noncontrolling parties.

We apply the variable interest model under 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% 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 *interest and investment income, net*, on the condensed combined 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 Topic 820, *Fair Value Measurement*, or ASC 820, we will apply the measurement alternative under ASC Topic 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.

Prior to March 31, 2021, we owned non-marketable equity securities that were accounted for using the measurement alternative under ASC 321 because the preferred stock held by us was not considered in-substance common stock and such preferred stock did not have a readily determinable fair value. All investments are reviewed for possible impairment on a regular basis. 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 combined 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 combined 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 the valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, contingent value right measurement and assessments, the measurement of right-of-use assets and lease liabilities, useful lives of long-lived assets, loss contingencies, fair value measurements, and the assessment of our ability to fund our operations for at least the next 12 months from the date of issuance of these financial statements. 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 ongoing coronavirus pandemic 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) a pandemic. To date, our operations have not been significantly disadvantaged by the pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that this pandemic may have on our financial condition and results of operations, including ongoing and planned clinical trials. More specifically, the pandemic may result in prolonged impacts that we cannot predict at this time and we expect that such uncertainties will continue to exist for the foreseeable future. The impact of the pandemic on our financial performance will depend on future developments, including the duration and spread of the outbreak, impact of potential variants and the related governmental advisories and restrictions. These developments and the impact of the ongoing pandemic 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. Moreover, we record gain contingencies only when they are realizable, and the amount is known. 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, marketable securities, and a convertible note receivable.

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

Product candidates developed by us will require approvals or clearances from the 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.

Stock-Based Compensation

We account for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. We measure the fair value of an equity-classified award at the grant date and recognize the stock-based compensation expense over the period of vesting on the straight-line basis for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period using the graded vesting method once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited.

Basic and Diluted Net Loss per Share of Common Stock

Basic net loss per share is calculated by dividing the net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed by dividing net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares, including the number of additional shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

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

	As of March 31,	
	2021	2020
	(Unaudited)	
Outstanding stock options	4,978,314	6,080,483
Outstanding RSUs	7,636,132	1,102,528
Outstanding related-party warrants	1,638,000	1,638,000
Total	14,252,446	8,821,011

Amounts in the table above reflect the common stock equivalents of the noted instruments, including awards issued under the NantKwest 2015 Equity Incentive Plan (the "2015 Plan"), the NantKwest 2014 Equity Incentive Plan (the "2014 Plan"), and awards issued under the NantCell, Inc. 2015 Stock Incentive Plan (the "NC 2015 Plan") that, in the case of March 31, 2021, were outstanding immediately prior to the Effective Time of the Merger and in the case of March 31, 2020 have been adjusted to include the combined NC 2015 Plan and NantCell warrants then outstanding (in both cases adjusted using the Merger Exchange Ratio of 0.8190). See Note 11, *Stock-Based Compensation*, for further information.

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Not Yet Adopted

In June 2016, the FASB issued Accounting Standards Update, or ASU, 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. 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 an 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, including us, 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 continue to evaluate the impact that this new standard and its related amendments will have on our consolidated financial statements and we do not intend to early 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 SEC during the three months ended March 31, 2021 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, 2021 and December 31, 2020, prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2021 (Unaudited)	December 31, 2020
Prepaid preclinical and clinical trial services – with related party (Note 9)	$ 4,648	$ 4,626
Insurance claim receivable	2,932	2,518
Prepaid services	1,435	1,294
Prepaid license fees	1,329	801
Prepaid insurance	1,230	1,365
Insurance premium financing asset	571	1,421
Prepaid rent	569	589
Equipment deposits	375	66
Tenant improvement receivables – with related party (Note 9)	313	—
Prepaid equipment maintenance	239	243
Interest receivable – marketable debt securities	132	473
Prepaid supplies – with related party (Note 9)	131	143
Other	338	110
Prepaid expenses and other current assets	$ 14,242	$ 13,649

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. Our insurance claims receivable as of March 31, 2021 and December 31, 2020 are the result of the recovery of legal costs, which had been previously charged in prior periods to s*elling, general and administrative expense*, on the condensed combined consolidated statements of operations.

Property, plant and equipment, net

As of March 31, 2021 and December 31, 2020, property, plant and equipment, net, consist of the following (in thousands):

	March 31, 2021 (Unaudited)	December 31, 2020
Leasehold improvements	$ 52,200	$ 52,251
Equipment	38,556	34,738
Buildings	22,690	22,690
Construction in progress	8,308	1,333
Software	2,659	2,376
Furniture & fixtures	1,007	1,015
Gross property, plant and equipment	125,420	114,403
Less: Accumulated depreciation and amortization	44,545	41,862
Property, plant and equipment, net	$ 80,875	$ 72,541

Construction in progress at March 31, 2021 is related primarily to expansion of our hAd5 pharmaceutical development and manufacturing facilities, including construction of a new filling suite at our leased facilities in El Segundo, California.

Depreciation and amortization expense related to property, plant and equipment totaled $3.0 million and $3.5 million for the three months ended March 31, 2021 and 2020, respectively.

Other assets

As of March 31, 2021 and December 31, 2020, other assets consist of the following (in thousands):

	March 31, 2021	December 31, 2020
	(Unaudited)	
VAT receivable	$ 810	$ 864
Security deposits	319	634
Prepaid software license fees	227	455
Restricted cash	179	179
Due from related party	54	51
Prepaid preclinical and clinical trial services – with related party (Note 9)	—	92
Other	316	323
Other assets	$ 1,905	$ 2,598

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 and other liabilities

As of March 31, 2021 and December 31, 2020, accrued expenses and other liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
	(Unaudited)	
Accrued bonus	$ 6,947	$ 5,288
Accrued dissenting shares (Note 8)	6,854	6,769
Accrued professional and service fees	6,728	7,668
Accrued preclinical and clinical trial costs	4,656	4,339
Accrued compensation	4,349	3,891
Accrued research and development costs	2,103	4,002
Accrued construction costs	1,931	—
Accrued contingent consideration payable	822	856
Accrued laboratory equipment and supplies	681	641
Financing obligation – current portion	571	1,421
Deferred revenue	263	270
Accrued franchise, sales, use and property taxes	113	103
Accrued capital expenditures	16	337
Other	759	1,186
Accrued expenses and other liabilities	$ 36,793	$ 36,771

Interest and investment income, net

Interest and investment income, net consists of the following (in thousands):

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Unrealized gains (losses) from equity securities	$ 8,833	$ (198)
Interest income	339	322
Investment amortization expense, net	(225)	(45)
Net realized losses on investments	(3)	(1)
Interest and investment income, net	$ 8,944	$ 78

Interest income includes interest from marketable securities, convertible 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, 2021 and 2020.

4. Equity Investment in Viracta Therapeutics

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, which was initially recorded at cost. 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.

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 stock. 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 stock. 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.

Based on the level of equity investment at risk, Viracta was not a VIE and therefore was not consolidated under the VIE model. In addition, we did not hold a controlling financial interest in Viracta, and therefore we did not consolidate Viracta under the voting interest model. As the preferred stock was not considered in-substance common stock, the investment was not within the scope of accounting for the investment under the equity method. As the preferred stock did not have a readily determinable fair value and did not qualify for the practical expedient to estimate fair value in accordance with ASC 820, we had elected to apply the measurement alternative under ASC 321, pursuant to which we measured 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 December 31, 2020, our fair value assessment indicated that the offering of Viracta's Series E preferred stock in November 2020, at a lower offering price per share than the per share carrying amount of our investment in Viracta, was a directional indicator representing an observable price change in an orderly transaction for a similar investment. On December 31, 2020, we reduced the carrying value by $1.4 million due to the observable price change, which was included in *interest and investment income, net*, on the condensed combined consolidated statements of operations for the year ended December 31, 2020. As of December 31, 2020, the carrying value of our investment in Viracta, which was reflected in *non-marketable equity investment*, on the condensed combined consolidated balance sheets, was $7.8 million.

On February 24, 2021, Sunesis Pharmaceuticals, Inc., a public company, completed a business combination with Viracta. In connection with this business combination, our preferred stock investment in Viracta was converted into 1,562,604 shares of Viracta common stock effective February 25, 2021. As of March 31, 2021, the carrying value of our investment in Viracta, which is reflected in *marketable securities*, on the condensed combined consolidated balance sheets totaled $14.5 million (including an unrealized gain of $6.6 million).

5. Financial Instruments

Investments in Marketable Debt Securities

As of March 31, 2021, the amortized cost, gross unrealized gains, gross unrealized losses and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	March 31, 2021 (Unaudited)				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Corporate debt securities	0.2	$ 15,541	$ 1	$ (4)	$ 15,538
Mutual funds		35	2	—	37
Current portion		15,576	3	(4)	15,575
Noncurrent:					
Foreign bonds	5.1	861	139	—	1,000
Noncurrent portion		861	139	—	1,000
Total		$ 16,437	$ 142	$ (4)	$ 16,575

As of December 31, 2020, the amortized cost, gross unrealized gains, gross unrealized losses and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:				
Corporate debt securities	$ 54,789	$ 2	$ (19)	$ 54,772
Mutual funds	35	2	—	37
Current portion	54,824	4	(19)	54,809
Noncurrent:				
Foreign bonds	861	89	—	950
Noncurrent portion	861	89	—	950
Total	$ 55,685	$ 93	$ (19)	$ 55,759

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 as of March 31, 2021 and December 31, 2020 were as follows (in thousands):

	March 31, 2021 (Unaudited)			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	$ 13,535	$ (4)	$ —	$ —
Total	$ 13,535	$ (4)	$ —	$ —

	December 31, 2020			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	$ 42,762	$ (19)	$ —	$ —
Total	$ 42,762	$ (19)	$ —	$ —

As of March 31, 2021, a total of 14 of the securities were in unrealized loss positions. 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 these investments before recovery of their amortized cost bases. Therefore, we did not recognize any other-than-temporary impairment losses during the three months ended March 31, 2021. Realized gains and losses on sales of available-for-sale debt securities during the three months ended March 31, 2021 and 2020 were not material.

Marketable Equity Securities

We held investments in marketable equity securities with readily determinable fair values of $23.0 million and $6.3 million as of March 31, 2021 and December 31, 2020, respectively. Unrealized gains recognized on equity securities with readily determinable fair values totaled $8.8 million for the three months ended March 31, 2021, while unrealized losses recognized on equity securities with readily determinable fair values totaled $0.2 million for the three months ended March 31, 2020. There were no realized gains or losses on sales of equity securities for the three months ended March 31, 2021 and 2020.

6. Fair Value Measurements

Fair value is defined as an exit price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. 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, the valuation of these products does not entail a significant degree of judgment. Our Level 1 assets consist of bank deposits, money market funds, and marketable equity securities.
- 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.

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. The fair values of financial instruments other than marketable securities and cash and cash equivalents are determined through a combination of management estimates and third-party valuations.

Recurring Valuations

Financial assets and liabilities measured at fair value on a recurring basis are summarized below as of March 31, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurements as of March 31, 2021 (Unaudited)			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$ 44,679	$ 44,679	$ —	$ —
Equity securities (1)	23,019	23,019	—	—
Corporate debt securities	15,538	—	15,538	—
Mutual funds	37	37	—	—
Noncurrent:				
Foreign bonds	1,000	1,000	—	—
Total assets measured at fair value	$ 84,273	$ 68,735	$ 15,538	$ —
Liabilities:				
Contingent consideration obligations (2)	$ (844)	$ —	$ —	$ (844)

	Fair Value Measurements as of December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$ 34,915	$ 34,915	$ —	$ —
Corporate debt securities	54,772	—	54,772	—
Equity securities	6,337	6,337	—	—
Mutual funds	37	37	—	—
Noncurrent:				
Foreign bonds	950	950	—	—
Total assets measured at fair value	$ 97,011	$ 42,239	$ 54,772	$ —
Liabilities:				
Contingent consideration obligations (2)	$ (972)	$ —	$ —	$ (972)

(1) Our equity securities include our investment in Viracta totaling $14.5 million, which was previously accounted for by applying the measurement alternative under ASC 321. In February 2021, Viracta merged with Sunesis Pharmaceuticals, Inc., a public company. In connection with this transaction, our preferred stock investment in Viracta was converted into 1,562,604 shares of Viracta common stock effective February 25, 2021. See Note 4, *Equity Investment in Viracta Therapeutics*, for additional information.

(2) Contingent consideration obligations are recorded at their estimated fair values and are revalued each reporting period until the related contingencies are resolved. The fair value measurements of these obligations are based on inputs that are unobservable and significant to the overall fair value measurement (i.e., a Level 3 measurement within the fair value hierarchy) and are reviewed periodically by management. See Note 8, *Commitments and Contingencies*, for additional information.

Changes in the carrying amount of contingent consideration obligations were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Fair value, beginning of period	$ (972)	$ (1,725)
Net change in fair value	128	(2)
Fair value, end of period	$ (844)	$ (1,727)

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 during the three months ended March 31, 2021 and 2020.

7. Collaboration and License Agreements

National Cancer Institute

In May 2015, Etubics Corporation, or Etubics, entered into a Cooperative Research and Development Agreement, or CRADA, with the U.S. Department of Health and Human Services as represented by the National Cancer Institute, or NCI, of the National Institutes of Health, or NIH, to collaborate on the preclinical and clinical development of an adenovirus technology expressing tumor-associated antigens for cancer immunotherapy. In January 2016, we acquired all of the outstanding equity interests in Etubics and Etubics became a wholly-owned subsidiary.

Effective January 2018, we assumed the CRADA and it was amended to cover a collaboration for the preclinical and clinical development of our proprietary yeast-based Tarmogens expressing tumor-associated antigens and proprietary adenovirus technology expressing tumor-associated antigens for cancer immunotherapy. Pursuant to the CRADA, NIH provides scientific staff and other support necessary to conduct research and related activities as described in the CRADA.

During the term of the CRADA, we are required to make annual payments of $0.6 million to the NIH for support of research activities. We made a payment of $0.6 million for the three months ended March 31, 2021. The CRADA expires in May 2023.

In February 2018, we entered into an amendment to a CRADA with NIH that was originally executed between NIH and Amgen, Inc., or Amgen, in May 2012 and subsequently assigned by Amgen to the company effective as of December 17, 2015. The research goal of this CRADA, as amended, is for the non-clinical and clinical development of ganitumab, our licensed monoclonal antibody targeting insulin-like growth factor one receptor, to evaluate its safety and efficacy in patients with hematological malignancies and solid tumors. The CRADA has a five-year term commencing February 20, 2018 and expiring on February 20, 2023.

During the term of the agreement, we are required to make minimum annual payments of $0.2 million to NIH for support of research activities and additional payments for the clinical trials based on the scope and phase of the clinical trials. Unpaid research and development expense was estimated at $0.4 million and $0.6 million as of March 31, 2021 and December 31, 2020, respectively.

In February 2021, we entered into a CRADA with NIH to conduct collaborative analysis of human clinical trial samples from clinical trials utilizing our proprietary recombinant natural killer (NK) cells and/or monoclonal antibodies (mAbs) alone or in combination for the treatment of cancer and to pre-clinically study such agents. The CRADA has a two-year term commencing February 22, 2021 and expiring on February 22, 2023. During the term of the agreement, we are required to provide $0.1 million per year to NIH for support of research activities. We have $8,000 payable outstanding as of March 31, 2021 in connection with this CRADA agreement.

All CRADA agreements may be terminated at any time upon the mutual written consent of the company and NIH. Either party may unilaterally terminate either of the CRADAs at any time by providing written notice to the other party at least 60 days before the desired termination date.

Pursuant to the terms of the CRADAs, we have an option to elect to negotiate an exclusive or non-exclusive commercialization license to any inventions discovered in the performance of either of the CRADAs, whether solely by an NIH employee or jointly with a company employee for which a patent application has been filed. The parties jointly own any inventions and materials that are jointly produced by employees of both parties in the course of performing activities under the CRADAs.

Royalties and In-licensing Agreements

iosBio Ltd. Exclusive License Agreement

In August 2020, we executed an exclusive license agreement with iosBio Ltd., formerly Stabilitech Biopharma Ltd. ("iosBio"), pursuant to which we and our affiliates will receive an exclusive, worldwide license to certain of iosBio's intellectual property rights relating to the SARS-CoV-2 and successor vaccine candidates. In return, we are required to pay mid-to-high single-digit royalties on net sales of the resulting licensed products. Concurrently we entered into a non-exclusive license agreement with iosBio, which grants to iosBio and its affiliates a non-exclusive, worldwide license under the intellectual property and technology relating to our adenovirus constructs for the prevention and treatment of shingles and other infectious disease targets to be mutually agreed by the parties in good faith. As of March 31, 2021 and December 31, 2020, we accrued $0.1 million and $0.5 million payable, respectively, to iosBio for reimbursable costs related to the clinical trial activities initiated by iosBio.

8. Commitments and Contingencies

Contingent Consideration Related to Business Combinations

VivaBioCell, S.p.A.

On April 10, 2015, NantWorks, a related party, acquired a 100% interest in VivaBioCell, S.p.A., or VivaBioCell, through its wholly-owned subsidiary, VBC Holdings, LLC, or VBC Holdings, for $0.7 million, less working capital adjustments. On June 15, 2015, NantWorks contributed its equity interest in VBC Holdings to the company, in exchange for cash consideration equal to its cost basis in the investment. VivaBioCell develops bioreactors and products based on cell culture and tissue engineering in Italy. In connection with this transaction, we are obligated to pay the former owners up to $3.7 million upon the achievement of certain sales milestones relating to scaffold technology and certain clinical and regulatory milestones relating to the GMP-in-a-Box technology. The fair value of the contingent consideration obligation decreased $0.1 million during the three months ended March 31, 2021 to $0.8 million.

Altor BioScience Corporation

In connection with our July 2017 acquisition of Altor BioScience Corporation, or Altor, we issued contingent value rights, or CVRs, under which we agreed to pay the prior stockholders of Altor approximately $304.0 million upon successful approval of the Biologics License Application, or BLA, or foreign equivalent, for Anktiva by December 31, 2022 and approximately $304.0 million upon the first calendar year before December 31, 2026 in which worldwide net sales of Anktiva exceed $1.0 billion (with amounts payable in cash or shares of our common stock or a combination thereof). Dr. Soon-Shiong and his related party hold approximately $279.5 million in the aggregate of CVRs and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. As the transaction was recorded as an asset acquisition, future CVR payments will be recorded when the corresponding events are probable of achievement or the consideration becomes payable.

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. Moreover, we record gain contingencies only when they are realizable, and the amount is known. 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.

Altor BioScience, LLC Litigation

The first action, Gray v. Soon-Shiong, et al. (Delaware Chancery Court, Case No. 2017-466-JRS), was filed on June 21, 2017, by plaintiffs Clayland Boyden Gray, or Gray, and Adam R. Waldman. The plaintiffs, two minority stockholders, asserted claims against the company and other defendants for (1) breach of fiduciary duty and (2) aiding and abetting breach of fiduciary duty and filed a motion to enjoin the merger. The court denied the motion on July 25, 2017, and permitted the merger to close. On September 1, 2017, plaintiffs (joined by two additional minority stockholders, Barbara Sturm Waldman and Douglas E. Henderson, or Henderson) filed a second amended complaint, asserting claims for (1) appraisal; (2) quasi-appraisal; (3) breach of fiduciary duty; and (4) aiding and abetting breach of fiduciary duty. On September 18, 2017, defendants moved to dismiss the second amended complaint, raising grounds that included a "standstill" agreement under which defendants maintained that Gray and Adam R. Waldman and Barbara Strum Waldman, or the Waldman's, agreed not to bring the lawsuit. In the second action, Dyad Pharmaceutical Corp. v. Altor BioScience, LLC (Delaware Chancery Court, Case No. 2017-848-JRS), commenced November 28, 2017, Dyad Pharmaceutical Corporation, or Dyad, filed a petition for appraisal in connection with the merger. Respondent moved to dismiss the appraisal petition on January 26, 2018, arguing in part that the petition was barred by the same "standstill" agreement.

On April 23, 2018, the court heard oral arguments on the motions to dismiss in both consolidated cases, and on June 26, 2018, the court converted the motions to dismiss into motions for summary judgment with regard to the "standstill" agreement argument, or the Converted Motions. The court permitted discovery into the meaning and intended scope of the "standstill" agreements, which the parties completed on December 19, 2018. The parties completed a briefing on the Converted Motions on March 15, 2019.

The court heard an oral argument on the Converted Motions on May 7, 2019, and issued an oral ruling on May 15, 2019. The court (1) dismissed all claims brought by Gray and the Waldman's except for their appraisal claims; (2) dismissed all plaintiffs' quasi-appraisal claims; (3) dismissed the disclosure-based breach of fiduciary duty claims; and (4) dismissed Altor BioScience from the action. The following claims remain: (a) the appraisal claims by all plaintiffs and Dyad (against Altor BioScience, LLC), and (b) Henderson's claims for breach of fiduciary duty and aiding and abetting breach of fiduciary duty.

On June 14, 2019, the defendants answered the second amended complaint, and the respondent answered Dyad's appraisal petition. In their answer, defendants asserted counterclaims against Gray and the Waldman's for breach of the "standstill" agreements and are seeking as damages the attorneys' fees and costs they were forced to expend as a result of the breach. On June 20, 2019, the court issued a written order implementing its ruling on the Converted Motions, or the Implementing Order. In the Implementing Order, the court confirmed that all fiduciary duty claims brought by Gray, both individually and as trustee of the Gordon Gray Trust f/b/o C. Boyden Gray, were dismissed. On July 11, 2019, Gray and the Waldman's filed answers denying the counterclaims and asserting defenses.

On September 30, 2019, plaintiffs moved for leave to file a third amended complaint. The proposed amendment sought to add two former Altor stockholders as plaintiffs and to add a fiduciary duty claim on behalf of a purported class of former Altor stockholders. On October 25, 2019, the defendants opposed the motion, and a briefing was completed on February 28, 2020. The court heard an oral argument on March 12, 2020, and granted the motion. The plaintiffs filed the third amended complaint on June 8, 2020.

On June 29, 2020, defendants answered the third amended complaint and asserted counter claims against the plaintiffs. As damages, defendants seek the attorneys' fees and costs incurred as a result of these breaches. On July 14, 2020, the plaintiffs filed an answer denying the counterclaims and asserting defenses. The trial has been set to commence in October 2021.

The shares of these former Altor stockholders met the definition of dissenting shares under the merger agreement and were not entitled to receive any portion of the merger consideration at the closing date. However, these dissenting shares will automatically be converted to receive the portion of the merger consideration they were entitled to, on the later of the closing date, and when the stockholder withdraws or loses the right to demand appraisal rights. Payment for dissenting shares will be on the same terms and conditions originally stated in the merger agreement. As of March 31, 2021 and December 31, 2020, we had accrued $6.9 million and $6.8 million related to these obligations, respectively. The accrued amount represents the estimated low-end of the range of currently estimated payout amounts in accordance with ASC Topic 450, *Contingencies*, after considering the reasonable outcomes for settling the dissenting shareholder dispute along with any accrued statutory interest. We cannot reasonably estimate a range of loss beyond the amounts recorded as of March 31, 2021 and December 31, 2020, as the dissenting stockholders have not yet provided a quantified value of their claim and, therefore, an upper end of the range of loss cannot be determined. We reassess the reasonableness of the recorded amount at each reporting period. We believe the claims lack merit and intend to continue defending the case vigorously.

Sorrento Therapeutics, Inc. Litigation

Sorrento Therapeutics, Inc. v. NantCell, Inc., et al. Sorrento Therapeutics, Inc., or Sorrento, derivatively on behalf of NANTibody, LLC, or NANTibody, filed an action in the Superior Court of California, Los Angeles County, or the Superior Court, against the company, Dr. Soon-Shiong and Charles Kim. The action alleges that the defendants improperly caused NANTibody to acquire IgDraSol, Inc. from our affiliate NantPharma, LLC, or NantPharma, and seeks to have the transaction undone, and seeks to have the purchase amount returned to NANTibody. Sorrento filed a related arbitration proceeding, or the Cynviloq arbitration, against Dr. Soon-Shiong and NantPharma; the company is not named in the Cynviloq arbitration. On May 15, 2019, we filed a demurrer to several causes of action alleged in the Superior Court action. On July 18, 2019, Sorrento filed an amended complaint, eliminating Charles Kim as a defendant and dropping the causes of action we had challenged in its demurrer.

On May 24, 2019, we and Dr. Soon-Shiong filed cross-claims in the Superior Court action against Sorrento and its Chief Executive Officer Henry Ji, asserting claims for fraud, breach of contract, breach of the covenant of good faith and fair dealing, tortious interference with contract, unjust enrichment, and declaratory relief. We and Dr. Soon-Shiong allege that Dr. Ji and Sorrento breached the terms of an exclusive license agreement between the company and Sorrento related to Sorrento's antibody library and that Sorrento did not perform its obligations under the exclusive license agreement.

On October 9, 2019, the Superior Court ruled that our claims should be pursued in arbitration and that Dr. Soon-Shiong's claims could be pursued in Superior Court.

On February 13, 2020, after a full briefing, the Superior Court heard oral argument and granted Dr. Soon-Shiong's request for a preliminary injunction barring Sorrento from pursuing claims against him in the Cynviloq arbitration. Sorrento then filed the claims it had previously asserted in arbitration against Dr. Soon-Shiong in the Superior Court on March 3, 2020, and at Sorrento's request, the arbitrator entered an order dismissing Sorrento's claims against Dr. Soon-Shiong in the Cynviloq arbitration on March 6, 2020. The hearing in the Cynviloq arbitration has been scheduled to commence in June 2021.

On October 24, 2019, we, along with NANTibody, filed an arbitration against Sorrento and Dr. Ji asserting our claims relating to the exclusive license agreement. Sorrento filed counterclaims against the company and NANTibody in the arbitration on May 4, 2020, and requested leave to file a dispositive motion on May 1, 2020.

On January 29, 2020, Sorrento sent letters purporting to terminate the exclusive license agreement with the company, and an exclusive license agreement with NANTibody and demanding the return of its confidential information and transfer of all regulatory filings and related materials. As required pursuant to the exclusive license agreements, both parties must engage in good-faith negotiations before attempting to invoke any termination provision contained in the agreement. Notwithstanding such negotiations, Sorrento sent a letter on April 10, 2020, purporting to terminate the exclusive license agreements, maintaining the negotiations did not reach a successful resolution. We believe we have cured any perceived breaches during the 90-day contractual cure period provided under the agreements. We intend to prosecute our claims, and to defend the claims asserted against us, vigorously. An estimate of the possible loss or range of loss cannot be made at this time. The hearings in the antibody arbitration commenced in April 2021 and are anticipated to be concluded in late July or early August 2021.

Shenzhen Beike Biotechnology Corporation Litigation

In July 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Shenzhen Beike Biotechnology Corporation, or Beike. The arbitration relates to a license, development, and commercialization agreement that Altor (succeeded by our wholly-owned subsidiary Altor BioScience, LLC, or Altor) entered into with Beike in September 2014, which agreement was amended and restated in September 2017, pursuant to which Altor granted to Beike an exclusive license to use, research, develop and commercialize products based on Anktiva in China for human therapeutic uses. In the arbitration, Beike is asserting a claim for breach of contract under the license agreement. Among other things, Beike alleges that we failed to use commercially reasonable efforts to deliver to Beike materials and data related to Anktiva. Beike is seeking specific performance, or in the alternative, damages for the alleged breaches. On September 25, 2020, the parties entered into a standstill and tolling agreement under which, among other things, the parties affirmed they will perform certain of their obligations under the license agreement by specified dates and agreed that all deadlines in the arbitration are indefinitely extended. The standstill agreement may be terminated by any party on ten calendar days' notice, and upon termination, the parties will have the right to pursue claims arising from the license agreement in any appropriate tribunal. The parties have been asked to provide an update to the International Chamber of Commerce by May 31, 2021 of any further developments.

Given that this action remains at the pleading stage and no discovery has occurred, it remains too early to evaluate the likely outcome of the case or to estimate any range of potential loss. We believe the claims lack merit and intend to defend the case vigorously and that we may have counterclaims.

Fox Chase Litigation

On July 21, 2020, ImmunityBio filed a declaratory judgment lawsuit in the Superior Court for San Diego County, California, naming Fox Chase Cancer Center Foundation and Institute for Cancer Research as the defendants (hereafter collectively "Fox Chase"). This litigation relates to the license with Fox Chase and includes various intellectual property rights (the "2004 License"). Our initial court filing requested that the Court find that we have not breached any material obligation under the 2004 License and that Fox Chase has not and cannot terminate the 2004 License. Fox Chase filed a Cross-Complaint raising a patent inventorship challenge and moved the case to federal court. See Part II, Item 1A., "*Risk Factors*" of this Quarterly Report on Form 10-Q for a more detailed discussion. While the litigation is in the early stage, its outcome cannot be predicted. We do not consider the 2004 License to be material to our business.

Litigation Related to the Merger with ImmunityBio, Inc.

In connection with the Merger with NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company), a Delaware corporation, via a wholly-owned subsidiary of NantKwest (the "Merger Sub"), seven complaints have been filed as individual actions in United States District Courts. Three complaints have been filed in the United States District Court for the District of Delaware against NantKwest and its directors and are captioned *Hargett v. NantKwest, Inc., et al.*, 1:21-cv-00197 (filed February 11, 2021) (the "Hargett Complaint"), *Franchi v. NantKwest, Inc., et al.*, 1:21-cv-00218 (filed February 16, 2021) (the "Franchi Complaint"), and *Gross v. NantKwest, Inc., et al.*, 1:21-cv-00223 (filed February 17, 2021) (the "Gross Complaint"). One complaint has been filed in the United States District Court for the Southern District of New York and is captioned *Leaman v. NantKwest, Inc., et al.*, 1:21-cv-01351 (filed February 16, 2021) (the "Leaman Complaint"). Two complaints have been filed in the United States District Court for the Southern District of California and are captioned *Weiss v. NantKwest, Inc., et al.*, 3:21-cv-00280 (filed February 16, 2021) (the "Weiss Complaint") and *Carlisle v. NantKwest, Inc., et al.*, 3:21-cv-00304 (filed February 19, 2021) (the "Carlisle Complaint"). One complaint has been filed in the United States District Court for the Eastern District of New York and was captioned *Shenk v. NantKwest, Inc., et al.*, 1:21-cv-00871 (filed February 18, 2021) (the "Shenk Complaint," and collectively with the Hargett Complaint, the Franchi Complaint, the Gross Complaint, the Leaman Complaint, the Weiss Complaint, and the Carlisle Complaint, the "Merger Actions"). The Shenk Complaint was voluntarily dismissed on March 10, 2021. The Franchi Complaint was voluntarily dismissed on May 6, 2021. The Leaman Complaint was voluntarily dismissed on May 7, 2021. The Hargett Complaint and the Gross Complaint also bring claims against ImmunityBio, and Merger Sub. The Merger Actions generally allege that the Definitive Proxy Statement filed with the SEC on February 2, 2021 misrepresents and/or omits certain purportedly material information relating to financial projections, analysis performed by the financial advisor to NantKwest's Special Committee, alleged past engagements of the Special Committee's financial advisor and industry consultant, and the terms of the engagement of such consultant. The Merger Actions assert violations of Sections 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-9 promulgated thereunder against all defendants and violations of Section 20(a) of the Exchange Act against NantKwest's directors. The Merger Actions seek, among other things, an injunction enjoining the stockholder vote on the Merger and the consummation of the Merger unless and until certain additional information is disclosed to NantKwest's stockholders, costs of the action, including plaintiffs' attorneys' fees and experts' fees, and other relief the Court may deem just and proper. Neither the stockholder vote on the Merger nor the Merger were enjoined and occurred on March 8 and March 9, 2021, respectively. The company cannot predict the outcome of the Merger Actions. The company believes the Merger Actions are without merit and the company and the individual defendants intend to vigorously defend against the Merger Actions and any subsequently filed similar actions. If additional similar complaints are filed, absent new or significantly different allegations, the company will not necessarily disclose such additional filings.

Lease Arrangements

Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. We have leases in multiple facilities across the U.S. and Italy, including El Segundo, California (general corporate and administrative activities, research and development and regulatory from related parties); San Diego, California (research facility and office space); Culver City, California (research and manufacturing space from a related party); Torrance, California (a research facility from a related party); Miramar, Florida (clinical development); Seattle, Washington (research and development); Louisville, Colorado (research and development and manufacturing); Woburn, Massachusetts (research facility); and Udine and Tavangnacco, Italy (GMP-in-a-Box, research facility and office space). See Note 9, *Related Party Agreements*, for further information.

Our leases generally have initial terms ranging from two to ten years and often include one or more options to renew. These renewal terms can extend the lease term from one to five years, and are included in the lease term when it is reasonably certain that we will exercise the option.

Information regarding our leases is as follows:

	March 31, 2021	December 31, 2020
	(Unaudited)	
Weighted average remaining lease term	4.6 years	3.9 years
Weighted average discount rate	9%	9%

The components of lease expense consist of the following (in thousands):

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Operating lease costs	$ 2,147	$ 1,782
Variable lease costs	666	848
Total lease costs	$ 2,813	$ 2,630

Cash paid for amounts included in the measurement of lease liabilities is as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Operating cash flows for operating leases	$ 1,679	$ 1,355

Future minimum lease payments as of March 31, 2021, including $4.9 million related to options to extend lease terms that are reasonably certain of being exercised, 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
2021 (excluding the three months ended March 31, 2021)	$ 5,193
2022	6,889
2023	5,135
2024	3,622
2025	3,183
Thereafter	2,487
Total future minimum lease payments	26,509
Less: Interest	4,799
Present value of operating lease liabilities	$ 21,710

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, LLC, a related party, whereby we leased approximately 6,883 square feet in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease runs from January 2021 through December 2027, and includes an option to extend the lease for an additional three-year term through December 2030. Base rent for the term of the lease is approximately $20,300 per month with an annual increase of 3% on January 1 of each year during the initial term and, if applicable, during the option term. In addition, under the agreement, we are required to pay our share of estimated property taxes and operating expenses. See Note 9, *Related Party Agreements*, for further information.

There have been no other material changes related to our existing lease agreements from those disclosed in Note 8 of the Notes to Combined Consolidated Financial Statements included in the Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) filed as Exhibit 99.2 to our Current Report on Form 8-K/A filed with the Securities and Exchange Commission, or SEC, on April 22, 2021.

Commitments

We did not enter into any significant contracts during the three months ended March 31, 2021, other than those disclosed in these condensed combined consolidated financial statements.

In addition, we are also a party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement. There have been no material changes in unconditional purchase commitments from those disclosed in Note 8 of the Notes to Combined Consolidated Financial Statements included in the Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) filed as Exhibit 99.2 to our Current Report on Form 8-K/A filed with the Securities and Exchange Commission, or SEC, on April 22, 2021.

9. Related Party Agreements

We conduct business with several affiliates under written agreements and informal arrangements. Below is a summary of outstanding balances and a description of significant relationships (in thousands):

	March 31, 2021 (Unaudited)	December 31, 2020
Due from related party – NantBio	$ 1,294	$ 1,294
Due from related party – NantOmics	591	591
Due from related parties – Various	172	118
Total due from related parties	$ 2,057	$ 2,003
Due to related party – NantWorks	$ 12,799	$ 10,650
Due to related party – Duley Road	3,161	2,787
Due to related party – NantBio	943	943
Due to related party – Immuno-Oncology Clinic	503	271
Due to related party – Nant Capital	224	—
Due to related party – NantPharma	187	187
Total due to related parties	$ 17,817	$ 14,838
Related-party notes payable – Nant Capital	$ 150,695	$ 109,246
Related-party notes payable – NantMobile	57,078	56,660
Related-party notes payable – NantWorks	52,165	51,546
Related-party notes payable – NCSC	37,348	36,901
Total related-party notes payable	$ 297,286	$ 254,353

Our Executive Chairman, and principal stockholder, 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 Executive Chairman.

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 of employee benefits, facilities and other direct or fairly allocated indirect costs that relate to the employees providing the services. During the three months ended March 31, 2021 and 2020, we recorded $1.8 million and $1.5 million, respectively, in *selling, general and administrative expense*, and $0.3 million and $1.0 million, respectively, of expense reimbursements under this arrangement in *research and development expense*, on the condensed combined 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.

As of March 31, 2021 and December 31, 2020, we owed NantWorks a net amount of $12.8 million and $10.7 million, respectively, for all agreements between the two affiliates, which is included in *due to related parties* on the condensed combined consolidated balance sheets. We also recorded $1.3 million and $1.1 million of prepaid expenses for services that have been passed through to the company from NantWorks as of March 31, 2021 and December 31, 2020, respectively, which are included in *prepaid expenses and other current assets* on the condensed combined consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks LLC, or NantWorks, a related party, 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 initial license was effective from May 2015 through December 2020. Base monthly rent for the initial lease term was $47,000, with annual increases of 3% beginning in January 2017. In September 2020, we amended this agreement to extend the term of this lease through December 31, 2021. Commencing January 1, 2021, the monthly rent increased by 3% to $54,500. Subsequent to December 31, 2021, the lease term will automatically renew on a month-to-month basis, terminable by either party with at least 30 days' prior written notice to the other party. In addition, we have a one-time option to extend the lease term through December 31, 2022. If we exercise the option to extend the lease through December 31, 2022, or continue on a month-to-month basis, the monthly rent will increase by 3% annually commencing on January 1 of each year. On the date of amendment, we recognized an increase of $1.2 million in both *operating lease right-of-use assets*, and *operating lease liabilities*, on the condensed combined consolidated balance sheets, reflecting our belief that we will extend the term of this lease through December 31, 2022. Lease expense for this facility totaling $0.2 million and $0.1 million for the three months ended March 31, 2021 and 2020, respectively, was recorded in *research and development expense*, on the condensed combined consolidated statements of operations.

Immuno-Oncology Clinic, Inc.

Beginning in 2017, we entered into multiple agreements with Immuno-Oncology Clinic, Inc., or the Clinic (dba Chan Soon-Shiong Institutes for Medicine, in El Segundo, California), to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by one officer of the company and NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of our officers was an investigator or sub-investigator for all of our trials conducted at the Clinic.

In July 2019, we entered into a new agreement with the Clinic (the Clinic Agreement), which became effective on July 1, 2019. The Clinic 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 Clinic Agreement also specifies certain services and related costs that are excluded from the Clinic Agreement. Prior to commencing any work under the Clinic 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 clinical trials that commenced prior to July 1, 2019, fees incurred for services performed after July 1, 2019 are covered under the Clinic Agreement and applied towards the below-mentioned prepayments. The Clinic Agreement allows for automatic renewal and additional extensions beyond the initial one-year term.

In consideration of the services to be performed under the Clinic 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 $1.88 million were paid in July 2019 and October 2019, respectively. As amended, a conditional payment of $1.88 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 the performance of services. On a quarterly basis, our prepayment is increased by an interest credit computed in accordance with terms specified in the Clinic Agreement.

To the extent any portion of the prepayments remain unearned by the Clinic on the third anniversary of the Clinic Agreement, we may elect at our sole discretion either to (i) not extend the term of the Clinic 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 Clinic 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.

In July 2019, we executed a clinical trial work order under the Clinic Agreement for an open-label, Phase I study of PD-L1.t-haNK for infusion in subjects with locally advanced or metastatic solid cancers. In July 2020, but effective on June 22, 2020, we and NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company) executed a clinical trial work order under our existing master agreement with the Clinic for an open-label, randomized, comparative Phase II study of NantCell's proprietary IL-15 superagonist (N-803) and Aldoxorubicin Hydrochloride (Aldoxorubicin) and our PD-L1.t-haNK with standard-of-care chemotherapy versus standard-of-care chemotherapy for first and second-line treatment of locally or advanced metastatic pancreatic cancer.

During the three months ended March 31, 2021 and 2020, $0.3 million and $0.1 million, respectively, was recognized in *research and development expense*, on the condensed combined consolidated statements of operations related to clinical trial and research-related activities conducted for us by the Clinic. As of March 31, 2021 and December 31, 2020, we owed the Clinic $0.5 million and $0.3 million, respectively, for services excluded from the Clinic Agreement. As of March 31, 2021 and December 31, 2020, we had prepaid balances related to the Clinic Agreement of $4.6 million and $4.7 million, respectively. We anticipate that the remaining prepayment amount as of March 31, 2021 will be utilized in future periods as the Clinic provides additional services pursuant to the Clinic Agreement.

NantBio, Inc.

In March 2016, NantBio and the National Cancer Institute, or the NCI, entered into a cooperative research and development agreement. The initial five-year agreement covered NantBio and its affiliates, including us. Under the agreement, the parties collaborated on the preclinical and clinical development of proprietary recombinant natural killer cells and monoclonal antibodies in monotherapy and combination immunotherapies. In each of the contractual years under the agreement we paid $0.6 million to the NCI as a payment for services under the agreement. We recognized research and development expense related to this agreement ratably over a 12-month period for each funding year and recorded $0.1 million of expense related to this agreement in each of the three months ended March 31, 2021 and 2020. As of March 31, 2021 and December 31, 2020, we recorded $0 and $0.1 million, respectively, in *prepaid expenses and other current assets*, on the condensed combined consolidated balance sheets related to this agreement.

In August 2018, we entered into a supply agreement with NantCancerStemCell, LLC, or NCSC, a 60% owned subsidiary of NantBio (with the other 40% owned by Sorrento). Under this agreement, we agreed to supply VivaBioCell's proprietary GMP-in-a-Box bioreactors and related consumables, made according to specifications mutually agreed to with both companies. The agreement has an initial term of five years and renews automatically for successive one-year terms unless terminated by either party in the event of material default upon prior written notice of such default and the failure of the defaulting party to remedy the default within 30 days of the delivery of such notice, or upon 90 days' prior written notice by NCSC. No revenue was recognized during the three months ended March 31, 2021 and 2020. We recorded $0.3 million and $0.4 million of deferred revenue for bioreactors that were delivered but not installed as of March 31, 2021 and December 31, 2020, respectively. As of March 31, 2021 and December 31, 2020, we recorded $0.9 million in *due to related parties*, on the condensed combined consolidated balance sheets related to this agreement.

In 2018, we entered into a shared service agreement, pursuant to which, we are charged for services at cost, without mark-up or profit for NantBio, but including reasonable allocations of employee benefits that relate to the employees providing the services. In April 2019, we agreed with NantBio to transfer certain NantBio employees and associated research and development projects, comprising the majority of NantBio's business, to the company. After the transfer, NantBio continued to make payments on our behalf for certain employee benefits and vendor costs related to the research and development projects that were transferred to the company. In addition, we settled certain employee bonuses and benefits that were accrued by NantBio for 2018. As of March 31, 2021 and December 31, 2020, we recorded a net receivable from NantBio of $1.3 million, which included $1.0 million for employee bonuses and $0.3 million for vendor costs we paid on behalf of NantBio.

NantOmics

In June 2019, we made a strategic decision and transferred certain employees from NantOmics, LLC, or NantOmics, a related party that is controlled by our Executive Chairman, to the company. After the transfer, we settled certain employee bonuses and benefits that were accrued by NantOmics for the year ended December 31, 2020 and recorded a $0.6 million receivable from NantOmics as of March 31, 2021 and December 31, 2020.

605 Doug St, LLC

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Executive Chairman, 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% which began in July 2017. Lease expense of $0.2 million for this facility for each of the three months ended March 31, 2021 and 2020, respectively, is recorded in *research and development expense*, on the condensed combined consolidated statements of operations. As of March 31, 2021 and December 31, 2020, there were no balances due between the parties.

Duley Road, LLC

In February 2017, Altor BioScience Corporation (succeeded by our wholly-owned subsidiary Altor BioScience, LLC), or Altor, through its wholly-owned subsidiary, entered into a lease agreement with Duley Road, LLC, or Duley Road, a related party, that is indirectly controlled by our Executive Chairman, for approximately 12,000 square feet of office and cGMP manufacturing facility space in El Segundo, California. The lease term is from February 2017 through October 2024. We have the option to extend the initial term for two consecutive five-year periods through July 2034. The monthly rent is $40,700 with annual increases of 3% which began in November 2018. As of March 31, 2021 and December 31, 2020, we recorded rent payable to Duley Road of $1.5 million and $1.0 million, respectively. For the three months ended March 31, 2021 and 2020, we recorded rent expense of $0.4 million and $0.1 million, respectively, which is reflected in *research and development expense*, on the condensed combined consolidated statements of operations.

Effective in January 2019, we entered into two lease agreements with Duley Road for a second building located in El Segundo, California. The first lease is for the first floor of the building with approximately 5,650 square feet. The lease has a seven-year term commencing in September 2019. The second lease is for the second floor of the building with approximately 6,488 square feet. The lease has a seven-year term commencing in July 2019. Both floors of the building are used for research and development and office space. We have options to extend the initial terms of both leases for two consecutive five-year periods through 2036. The monthly rent for the two leases is $35,800, which increases at a rate of 3% per year.

As of March 31, 2021 and December 31, 2020, we recorded $0.9 million and $0.7 million of leasehold improvement payables, respectively, and $0.8 million and $1.1 million of lease-related payables to Duley Road, which were included in *due to related parties*, on the condensed combined consolidated balance sheets. For each of the three months ended March 31, 2021 and 2020, we recorded $0.1 million of rent expense for the two leases, which is included in *research and development expense*, on the condensed combined consolidated statements of operations. The security deposits for the leases totals $0.1 million as of March 31, 2021 and December 31, 2020, which are included in *other assets*, on the condensed combined consolidated balance sheets.

605 Nash, LLC

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, LLC, a related party, whereby we leased approximately 6,883 square feet in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease runs from January 2021 through December 2027, and includes an option to extend the lease for an additional three-year term through December 2030. Base rent for the term of the lease is approximately $20,300 per month with an annual increase of 3% on January 1 of each year during the initial term and, if applicable, during the option term. In addition, under the agreement, we are required to pay our share of estimated property taxes and operating expenses.

We are responsible for the build out of the facility space and have incurred costs of approximately $7.0 million as of March 31, 2021, which is reflected as construction in progress within *property, plant and equipment, net*, on the condensed combined consolidated balance sheets. We are also entitled to a tenant improvement allowance of $0.3 million associated with the buildout costs, which is recorded in *prepaid expenses and other current assets* on the condensed combined consolidated balance sheets. For the three months ended March 31, 2021, we recorded rent expense of $0.1 million, which is reflected in *research and development expense* on the condensed combined consolidated statements of operations.

NantPharma

In 2018, Altor BioScience, LLC and GlobeImmune, Inc. purchased a total of $0.2 million in laboratory equipment from NantPharma. As of March 31, 2021 and December 31, 2020, we recorded a $0.2 million payable to NantPharma.

Related Party Notes Payable

In December 2015, we executed a demand promissory note with Nant Capital. The note bears interest at a per annum rate of 5.0%, compounded annually and computed on the basis of 365 or 366 days. In July 2020 and August 2020, we borrowed $10.0 million and $3.7 million from Nant Capital, respectively. In July 2020, this note was amended and restated to provide that all outstanding principal and accrued and unpaid interest is due and payable on September 30, 2025, and not on demand. The principal amount of advances made by the related party pursuant to these notes totaled $55.2 million, all of which was outstanding as of March 31, 2021 and December 31, 2020, respectively. Accrued and unpaid interest on this note totaled $4.0 million and $3.3 million as of March 31, 2021 and December 31, 2020, respectively. Amounts due under this promissory note are included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

In June 2017, we executed a demand promissory note with NantWorks. The note bears interest at a per annum rate of 5.0%, compounded annually and computed on the basis of 365 or 366 days. In July 2020, this note was amended and restated to provide that all outstanding principal and accrued and unpaid interest is due and payable on September 30, 2025, and not on demand. We may prepay the outstanding principal amount at any time without premium or penalty and the prior consent of NantWorks. All outstanding amounts under the note will also become immediately due and payable upon certain bankruptcy and insolvency-related events. The principal amount of advances made by the related party pursuant to these notes totaled $43.4 million, all of which was outstanding as of March 31, 2021 and December 31, 2020, respectively. Accrued and unpaid interest on this note totaled $8.8 million and $8.1 million as of March 31, 2021 and December 31, 2020, respectively. Amounts due under this promissory note are included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

In August 2018, we executed a demand promissory note with NCSC. The note bears interest at a per annum rate of 5.0%, compounded annually and computed on the basis of 365 or 366 days. In July 2020, this note was amended and restated to provide that all outstanding principal and accrued and unpaid interest is due and payable on September 30, 2025, and not on demand. All amounts outstanding under the note will also become immediately due and payable upon certain bankruptcy and insolvency-related events. The principal amount of advances made by the related party pursuant to these notes totaled $33.0 million, all of which was outstanding as of March 31, 2021 and December 31, 2020, respectively. Accrued and unpaid interest on this note amounted to $4.3 million and $3.9 million as of March 31, 2021 and December 31, 2020, respectively. Amounts due under this promissory note are included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

In December 2019, we executed a demand promissory note with NantMobile. The note bears interest at a per annum rate of 3.0%, compounded annually and computed on the basis of 365 or 366 days. In July 2020, this note was amended and restated to provide that all outstanding principal and accrued and unpaid interest is due and payable on September 30, 2025, and not on demand. We may prepay the outstanding principal amount at any time without premium or penalty and the prior consent of NantMobile. All amounts outstanding under the note will also become immediately due and payable upon certain bankruptcy and insolvency-related events. The principal amount advanced by the related party pursuant to this note was $55.0 million, all of which was outstanding as of March 31, 2021 and December 31, 2020, respectively. Accrued and unpaid interest on this note amounted to $2.1 million and $1.7 million as of March 31, 2021 and December 31, 2020, respectively. Amounts due under this promissory note are included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

In September 2020, we executed a promissory note with Nant Capital for an advance of the principal of $50.0 million, all of which was outstanding as of March 31, 2021 and December 31, 2020. The note bears interest at a per annum rate of 6.0%, compounded annually and computed on the basis of 365 or 366 days. The outstanding principal and accrued and unpaid interest are due and payable on September 30, 2025. Accrued and unpaid interest on this note amounted to $1.5 million and $0.8 million as of March 31, 2021 and December 31, 2020, respectively. Amounts due under this promissory note are included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

In February 2021, we executed a promissory note with Nant Capital. The outstanding principal amount of each advance made by Nant Capital bears interest at a per annum rate of 6.0%, compounded annually and computed based on 365 or 366 days. On February 26, 2021, we received a $40.0 million advance pursuant to this promissory note, all of which is outstanding as of March 31, 2021. The accrued interest shall be paid quarterly commencing on June 30, 2021. The outstanding principal amount and any accrued and unpaid interest are due on September 30, 2025. We may prepay the outstanding principal amount and accrued interest at any time without premium or penalty and the prior consent of Nant Capital. Accrued interest payable on this note amounted to $0.2 million as of March 31, 2021, and was included in *due to related parties*, on the condensed combined consolidated balance sheets. The principal amount due under this promissory note is included in *related-party notes payable*, on the condensed combined consolidated balance sheets.

All demand promissory notes have no equity or equity-linked convertible rights.

10. Stockholders' Deficit

Merger with NantCell

Under the terms of the Merger Agreement, at the Effective Time of the Merger, each share of NantCell common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time, subject to certain exceptions as set forth in the Merger Agreement, was converted automatically into a right to receive 0.8190 newly issued shares of common stock, par value $0.0001 per share, resulting in the issuance of approximately 273.7 million shares of Company Common Stock. From and after the Effective Time, all of such NantCell shares ceased to be outstanding, were canceled and ceased to exist. At the Effective Time, each share of our common stock issued and outstanding immediately prior to the Effective Time, remained an issued and outstanding share of the combined company.

Since the Merger has been accounted for as a transaction between entities under common control, the outstanding shares presented on the condensed combined consolidated financial statements assume that NantCell outstanding common stock was converted into shares of Company Common Stock for all periods presented, and in connection with the conversion, those shares of common stock have been recorded at the company's par value of $0.0001 per share.

Stock Repurchases

In November 2015, the board of directors approved a share repurchase program, or the 2015 Share Repurchase Program, allowing the Chief Executive officer, or CEO, or Chief Financial Officer, 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. Shares repurchased under this program are formally retired through board approval upon repurchase. No shares were repurchased during the three months ended March 31, 2021 and 2020. As of March 31, 2021, $18.3 million remained authorized for repurchase under the 2015 Share Repurchase Program.

Common Stock Reserved for Future Issuance

As of March 31, 2021, a total of approximately 12.6 million shares of common stock were reserved for issuance, including awards issued under the NC 2015 Plan that were outstanding immediately prior to the Effective Time of the Merger. At the Effective Time, all outstanding equity awards granted under the NC 2015 Plan to purchase NantCell common stock were converted into equity awards to purchase shares of Company Common Stock (using the Merger Exchange Ratio of 0.8190), on the same terms and conditions as immediately prior to the Effective Time. As of March 31, 2021, there were approximately 7.0 million RSUs and 1.3 million stock options outstanding under the NC 2015 Plan, and there were no additional shares available for future grant.

11. Stock-Based Compensation

2015 Equity Incentive Plan

In July 2015, the company's board of directors adopted, and the company's stockholders approved the 2015 Plan. As of March 31, 2021, the 2015 Plan is the only equity plan of the company available for grant of equity awards to employees, directors and consultants of the company. As of March 31, 2021, a total of approximately 6.2 million shares were available for future grant under the 2015 Plan.

Stock-based Compensation

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

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Stock-based compensation expense:		
Stock options	$ 6,355	$ 130
RSUs	8,943	350
	$ 15,298	$ 480
Stock-based compensation expense in operating expenses:		
Research and development	$ 2,888	$ 161
Selling, general and administrative	12,410	319
	$ 15,298	$ 480

On March 18, 2021, the Board of Directors approved to modify certain non-qualified stock options that were assumed in the Merger and otherwise would have expired during a period when the grantees were legally restricted from exercising these awards. The expiration date of these options was extended to thirty (30) days following our registration statement effective date. We recognized incremental stock-based compensation expense of approximately $2.7 million for this stock option modification.

On March 29, 2021, in connection with the resignation of two former directors, the Board of Directors approved the acceleration of vesting of 83,333 shares of unvested stock options of each of the former directors on the date of their respective resignations. The modified options are exercisable for ninety (90) days after the date of the modification. We recognized incremental stock-based compensation expense of approximately $2.3 million for this stock option modification.

The stock option modifications were measured as the excess of the fair value of the modified awards over the fair value of the original awards immediately before the modifications. The incremental stock-based compensation was recognized in *selling, general and administrative expenses*, on the condensed combined consolidated statements of operations during the three months ended March 31, 2021.

Stock Options

The following table summarizes stock option activity and related information for three months ended March 31, 2021:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2020	4,996,284	$ 9.96	$ 29,746	4.7
Options granted	750,000	$ 23.72		
Options exercised	(752,310)	$ 2.39		
Options forfeited	(15,660)	$ 6.27		
Outstanding at March 31, 2021	4,978,314	$ 13.21	$ 54,279	5.4
Vested and exercisable at March 31, 2021	3,815,630	$ 12.07	$ 46,363	4.2

On February 5, 2021, the compensation committee of the board of directors of the company granted Richard Adcock, our chief executive officer, a stock option award (the "Option Grant") to purchase 750,000 shares of our common stock pursuant to our 2015 Plan. The Option Grant has an exercise price of $23.72 per share, the closing price as reported on the Nasdaq on the date of grant. In addition, the Option Grant shall vest according to the following vesting schedule: one-third of the Option Grant (i.e., 250,000 options) shall vest in equal installments on each of the first, second, and third anniversaries of the date of grant, such that all shares shall be fully vested on the third anniversary of the date of grant, subject to Mr. Adcock remaining in continuous service as defined in the 2015 Plan through the applicable vesting dates. This grant of equity awards to Mr. Adcock was made in connection with his appointment as chief executive officer of the company, which was effective as of October 26, 2020, and was modified from the recommended equity grant described in Mr. Adcock's offer of employment as of that date.

As of March 31, 2021, the unrecognized compensation cost related to outstanding stock options was $13.9 million, which is expected to be recognized over a remaining weighted-average period of 2.8 years.

The total intrinsic value of stock options exercised during the three months ended March 31, 2021 was $11.1 million. Cash proceeds received from stock option exercises during the three months ended March 31, 2021 was $1.1 million. There were no stock options exercised during the three months ended March 31, 2020.

As of December 31, 2020, a total of 4,345,497 vested and exercisable shares were outstanding.

The fair value of each stock option issued was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended March 31, 2021 (Unaudited)
Expected term (in years)	6.0
Risk-free interest rate	0.6%
Expected volatility	100.5%
Dividend yield	0.0%
Weighted-average grant date fair value	$ 18.63

The expected term was estimated using the average of the contractual term and the weighted-average vesting term of the options. The risk-free interest rate was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The expected volatility was estimated based on the historical volatility of our common stock. The assumed dividend yield was based on our expectation of not paying dividends in the foreseeable future. There were no stock options granted during the three months ended March 31, 2020.

Restricted Stock Units

The following table summarizes RSU activity for the three months ended March 31, 2021:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2020	466,842	$ 2.52
Granted	7,521,110	$ 25.35
Vested	(235,725)	$ 16.34
Forfeited/canceled	(116,095)	$ 25.49
Unvested balance at March 31, 2021	7,636,132	$ 24.23

As of March 31, 2021, there was $179.2 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 3.9 years.

We may grant RSUs to both employees and directors of the company and to employees of related parties that provide shared services to the company under our shared services agreement with NantWorks as discussed in Note 9, *Related Party Agreements*.

On February 5, 2021, the compensation committee of the board of directors of the company granted Mr. Adcock two awards totaling 400,000 RSUs (each an "RSU Award" and collectively, the "RSU Awards") of our common stock pursuant to the 2015 Plan. The RSU Awards are comprised of two separate awards, one settled by issuing 150,000 shares of our common stock and the other to be settled by issuing 250,000 shares of our common stock upon vesting. The first RSU Award vested immediately on the date of grant with the company retaining shares equal in value to the company's tax withholding obligations. The second RSU Award will vest according to the following schedule: one-third (i.e. 83,333) of the shares subject to the RSU Award shall vest in equal annual installments on each of the first, second and third anniversaries of the date of grant, such that all shares shall be fully vested on the third anniversary of the date of grant, subject to Mr. Adcock remaining in continuous service as defined in the 2015 Plan through the applicable vesting dates. This grant of equity awards to Mr. Adcock was made in connection with his appointment as chief executive officer of the company, which was effective as of October 26, 2020, and was modified from the recommended equity grant described in Mr. Adcock's offer of employment as of that date.

On March 4, 2021, prior to the Merger, NantCell awarded 7,121,110 RSUs (adjusted for the exchange ratio of 0.8190) to employees and consultants of NantCell and its affiliated companies, pursuant to the NC 2015 Plan. These RSU awards were subject to a performance condition in connection with a "Liquidity Event", defined as either (i) NantCell's registration of shares for issuance on a securities offering or (ii) the closing of a corporate transaction. In addition, the vesting of certain performance-based RSU grants accelerates upon obtaining approval by the FDA of a BLA or equivalent application for approval of Anktiva for use in the treatment of non-muscle-invasive bladder cancer. These performance-based RSUs are also subject to service conditions and are scheduled to cliff vest on the last date of each tranche as defined by the individual grant agreements. On March 9, 2021, we completed the Merger with NantCell, and the performance condition related to the Liquidity Event was met.

The fair value of the RSUs was estimated based on a third-party valuation as of the grant date of March 4, 2021 and was derived primarily from the estimated probabilities of the Merger close on March 9, 2021 and the other exit assumptions. Once the liquidity event related performance condition was met as of March 9, 2021 due to the Merger, compensation expense for these RSUs began to be recognized on a graded vesting attribution approach over the requisite service period for each participant, which ranges from six-month to seventy (70)-month vesting periods. During the three months ended March 31, 2021, we recognized approximately $5.1 million of stock-based compensation expense related to these awards, of which approximately $2.9 million was recorded in *research and development expense*, and approximately $2.2 million was recorded in *selling, general and administrative expense*, respectively, on the condensed combined consolidated statements of operations.

The RSUs awarded to employees and consultants of affiliated companies were accounted for as stock-based compensation in accordance with ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, as the compensation was in exchange for continued support or services expected to be provided to the company over the vesting periods under the NantWorks shared services agreement discussed in Note 9, *Related Party Agreements*. We have evaluated the associated benefit of these awards to the affiliated companies under common control and determined that the benefit is limited to the retention of their employees. We estimated such benefit at the grant date fair value of $4.0 million and recognized $0.1 million of deemed dividends for the three months ended March 31, 2021, which was recorded in *additional paid in capital*, on the condensed combined consolidated balance sheets, with a corresponding credit to stock compensation expense.

Warrants

In connection with the Merger, warrants issued to NantWorks, a related party, in connection with NantCell's acquisition of Altor were assumed by the company. After applying the Exchange Ratio at the Effective Time of the Merger, a total of 1,638,000 warrants with an exercise price of $3.24 per share, with vesting subject to the achievement of a certain performance condition pertaining to building manufacturing capacity, were outstanding as of March 31, 2021. The fair value of $18.0 million assigned to the unvested warrants will be recognized upon achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for one of our product candidates.

12. Income Taxes

On March 9, 2021, the company completed the Merger with NantCell. The merger is accounted for as a transaction between entities under common control. The Merger is also considered a nontaxable transaction for U.S. income tax purposes and it is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The company is subject to taxation in the United States, various state, and foreign jurisdictions. Earnings from non-U.S. activities are subject to local country income tax. The company computes its quarterly income tax provision by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. No tax benefit was provided for losses incurred in the United States, Italy, and South Korea because those losses are offset by a full valuation allowance.

The difference between the federal statutory tax rate of 21% and the company's 0% tax rate is due to losses from which the company cannot benefit.

The company is no longer subject to income tax examination by the U.S. federal, state or local tax authorities for years ended December 31, 2015 or prior; however, its tax attributes, such as net operating loss ("NOL") carryforwards and tax credits, are still subject to examination in the year they are used.

13. Subsequent Events

Immuno-Oncology Clinic, Inc. Agreement

During April 2021, ImmunityBio executed two work orders under an existing master agreement with Immuno-Oncology Clinic, Inc. (the "Clinic"), a related party. Under these work orders, the parties agreed that the Clinic would serve as a site for the following multi-site clinical trials:

- A Phase I study of the safety, reactogenicity, and immunogenicity of subcutaneously- and orally-administered supplemental spike & nucleocapsid-targeted COVID-19 vaccine to enhance T cell-based immunogenicity in participants who have already received a vaccine authorized for emergency use; and
- A Phase I study of the safety, reactogenicity, and immunogenicity of a supplemental spike & nucleocapsid-targeted COVID-19 vaccine to enhance T cell-based immunogenicity in participants who have already received a vaccine authorized for emergency use.

Pursuant to our existing agreement with the Clinic, our share of qualifying expenses shall be deducted from amounts previously paid to the Clinic as described in further detail in Note 9, *Related Party Agreements*. We expect to incur up to $0.2 million of qualifying clinical trial expenses under each work order, subject to changes dependent on clinical trial enrollments and progress.

Open Market Sale Agreement

On April 30, 2021, we entered into an Open Market Sale Agreement (the "Sale Agreement") with respect to an at-the-market ("ATM") offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $500.0 million through our sales agent. We will pay our sales agent a commission of up to 3.0% of the gross sales proceeds of any shares of our common stock sold through them under the Sale Agreement, and also have provided them with customary indemnification and contribution rights.

We are not obligated to sell any shares under the Sale Agreement and may at any time suspend solicitation and offers under the Sale Agreement. The Sale Agreement may be terminated by us at any time given written notice to the sales agent for any reason or by the sales agent at any time by giving written notice to us for any reason or immediately under certain circumstances, and shall automatically terminate upon the issuance and sale of all of the shares.

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 combined consolidated financial statements and the notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained in 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;
- our ability to implement and support our COVID-19 vaccine and therapeutic programs;
- any impact of the coronavirus 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 our product candidates, including our haNK, taNK, t-haNK, MSC and ceNK product candidates;
- our expectations regarding the development, application, commercialization, marketing, prospects and use generally of our product candidates, including Anktiva, hAd5 and aldoxorubicin;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned investigational new drug, or IND; Biologics License Application, or BLA; or New Drug Application, or NDA, 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 facilities and our belief that our manufacturing is capable of being conducted in-house;
- our belief in the potential of our antibody cytokine fusion protein, vaccine technology and NK-92 and ceNK cell therapy technology, and the fact that our business is based upon the success individually and collectively of our platforms;
- our antibody cytokine fusion protein, vaccine technology and NK-92 and ceNK cell therapy technology along with other product candidate families, will require significant additional clinical testing;
- even if we successfully develop and commercialize specific product candidates like our Anktiva or haNK and t-hank, 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, maintain, protect and enforce intellectual property protection for our product candidates and technology and not infringe upon, misappropriate or otherwise violate the intellectual property of others;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property relating to our product candidates and technology;
- the impact on us, if any, if the contingent value rights, or CVRs, held by former Altor stockholders become due and payable in accordance with their terms; and
- regulatory developments in the United States, or U.S., and foreign countries.

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 on Form 10-Q, 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" of this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q.

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

This Quarterly Report on Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q, including logos, artwork and other visual displays, may appear without the ® or ™ 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 on Form 10-Q, "ImmunityBio," "the company," "the combined company," "we," "us," and "our" refer to ImmunityBio, Inc. and its subsidiaries.

Overview

We established ImmunityBio to advance the next-generation of immunotherapies and to address unmet needs within oncology and infectious disease. Our platform is designed to overcome limitations of the current standards of T cell-based immunotherapies, including checkpoint inhibitors and CAR-T cells and is based on our four key modalities: (1) activating NK and T cells using antibody cytokine fusion proteins, (2) activating tumoricidal macrophages using low-dose synthetic immunomodulators, (3) generating memory T cells using vaccine candidates developed with our second-generation adenovirus, or hAd5, technology, and (4) off-the-shelf natural killer cells from the NK-92 cell line and memory-like cytokine-enhanced natural killer cells (m-ceNK) from allogenic and autologous donors.

We own a broad, clinical-stage immunotherapy pipeline, including an antibody cytokine fusion protein (an IL-15 superagonist (N-803) known as Anktiva), an albumin-associated anthracycline synthetic immunomodulator (aldoxorubicin), second-generation adenovirus (hAd5) and yeast vaccine technologies (targeting tumor-associated antigens and neoepitopes), off-the-shelf genetically engineered natural killer cell lines inducing cancer and virally infected cell death through a variety of concurrent mechanisms (including innate killing, antibody-mediated killing, and CAR-directed killing), patient specific NK cell product for cancer that is an autologous Memory cytokine enhanced Natural Killer cells, macrophage polarizing peptides, and bi-specific fusion proteins targeting CD20, PD-L1, TGF-b and IL-12. Our immunotherapy clinical pipeline consists of over 40 clinical trials in Phase 1, 2, or 3 development across 19 indications in solid and liquid cancers and infectious diseases. We have an expansive clinical-stage pipeline and intellectual property portfolio with 17 first-in-human assets in 25 Phase II to III clinical trials.

In December 2019, the U.S. Food and Drug Administration, or FDA, granted Breakthrough Therapy designation to Anktiva for bacillus Calmette-Guérin, or BCG, unresponsive carcinoma in situ non-muscle invasive bladder cancer. Other indications currently with registration-potential studies include BCG unresponsive papillary bladder cancer, first- and second-line lung cancer, and metastatic pancreatic cancer.

The Merger

On December 21, 2020, we and NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company) ("NantCell") entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which we and NantCell agreed to combine our businesses. The Merger Agreement provided that a wholly-owned subsidiary of the company would merge with and into NantCell (the "Merger"), with NantCell surviving the Merger as a wholly-owned subsidiary of the company.

On March 9, 2021, we completed the Merger pursuant to the terms of the Merger Agreement. Under the terms of the Merger Agreement, at the effective time of the Merger (the "Effective Time"), each share of NantCell common stock, par value $0.001 per share, issued and outstanding immediately prior to the Effective Time, subject to certain exceptions as set forth in the Merger Agreement, was converted automatically into a right to receive 0.8190 (the "Exchange Ratio") newly issued shares of common stock, par value $0.0001 per share, of the company ("Company Common Stock"), with cash paid in lieu of any fractional shares. At the Effective Time, each share of the company's common stock issued and outstanding immediately prior to the Effective Time, remained an issued and outstanding share of the combined company. At the Effective Time, each outstanding option, warrant or restricted stock unit to purchase NantCell common stock was converted using the Exchange Ratio into an option, warrant or restricted stock unit, respectively, on the same terms and conditions immediately prior to the Effective Time, to purchase shares of Company Common Stock.

Immediately following the Effective Time, the former stockholders of NantCell held approximately 71.5% of the outstanding shares of Company Common Stock and the stockholders of the company as of immediately prior to the Merger held approximately 28.5% of the outstanding shares of Company Common Stock. As a result of the Merger and immediately following the Effective Time, Dr. Patrick Soon-Shiong, our Executive Chairman, and his affiliates beneficially own, in the aggregate, approximately 81.8% of the outstanding shares of Company Common Stock. Following the consummation of the Merger, shares of the company's common stock are now listed on the Nasdaq Global Select Market under the symbol "IBRX."

We incurred costs totaling $23.2 million in connection with the Merger, consisting of financial advisory, legal and other professional fees, of which $12.9 million was recorded during the three months ended March 31, 2021.

Accounting Treatment of the Merger

The Merger represents a business combination pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 805-50, *Mergers*, which is accounted for as a transaction between entities under common control as Dr. Soon-Shiong and his affiliates were the controlling stockholders of each of the company and NantCell for all the periods presented in this report. As a result, all of the assets and liabilities of NantCell were combined with ours at their historical carrying amounts on the closing date of the Merger. We have recast our prior period financial statements to reflect the conveyance of NantCell's common shares as if the Merger had occurred as of the earliest date of the condensed consolidated financial statements presented in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q. All material intercompany accounts and transactions have been eliminated in consolidation.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the novel strain of coronavirus disease (SARS-CoV-2) a pandemic. To date, our operations have not been significantly disadvantaged by the pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that this pandemic may have on our financial condition and results of operations, including ongoing and planned clinical trials. More specifically, the pandemic may result in prolonged impacts that we cannot predict at this time and we expect that such uncertainties will continue to exist for the foreseeable future. The impact of the pandemic on our financial performance will depend on future developments, including the duration and spread of the outbreak, impact of potential variants and the related governmental advisories and restrictions. These developments and the impact of the ongoing pandemic 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.

Given the unprecedented and continuously 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 pandemic. We anticipate, however, that enrollment of patients in certain studies will likely take longer than forecasted in prior Securities and Exchange Commission, or SEC, filings and that our clinical trials may require additional time to complete which would in turn impact the timeline in which we were previously forecasting BLA submissions of our product candidates and subsequent revenue generation. These factors have been accounted for in the company's anticipated upcoming milestones. 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, Good Manufacturing Practice, or GMP, manufacturing, and office facilities.

Many of our office-based employees have been working from home since mid-March 2020. 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 pandemic and resulting mitigation efforts could have an impact in the future on 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. We have addressed this in part by ensuring that we have sufficient supplies on hand to weather interruptions in our supply chain.

There is significant uncertainty about the progression and ultimate impact of the pandemic on our business and operations. While the pandemic did not materially impact our results during the periods presented in this Quarterly Report on Form 10-Q, we anticipate that it could impact our business in the future due to factors such as fewer patients accessing treatment for cancer.

Operating Results

To date, we have generated minimal revenue from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables and grant programs. We have no clinical products approved for commercial sale and have not generated any revenue from therapeutic and vaccine product candidates that are under development. We have incurred net losses in each year since our inception and, as of March 31, 2021, we had an accumulated deficit of $1.7 billion. Our net losses attributable to ImmunityBio common stockholders were $79.6 million and $37.0 million for the three months ended March 31, 2021 and 2020, respectively, and $221.9 million and $157.8 million for the years ended December 31, 2020 and 2019, respectively. Substantially all of our net losses resulted principally from 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, including stock-based compensation expense.

As of March 31, 2021, we had 475 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 Combined Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q. 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. See "*—Future Funding Requirements*" below for a discussion of our anticipated expenditures and sources of capital we expect to access to fund these expenditures.

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 immunotherapy due to our broad and vertically integrated platform and through complementary strategic partnerships. We may also enter into supply arrangements for various investigational agents to be used in our clinical trials. See Note 7, *Collaboration and License Agreements*, of the "Notes to Unaudited Condensed Combined Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q for a more detailed discussion regarding our existing collaboration and license agreements.

Agreements with Related Parties

We conduct business with several affiliates under written and informal arrangements. Our Executive Chairman, and principal stockholder, 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, to facilitate the development of new immunotherapies 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 Executive Chairman.

As of March 31, 2021, we have outstanding promissory notes with certain entities affiliated with Dr. Soon-Shiong in an aggregate amount of $297.5 million, including accrued interest. The notes bear interest at a per annum rate ranging from 3.0% to 6.0%. As of March 31, 2021, the notes provide that all outstanding principal is due and payable on September 30, 2025, and accrued and unpaid interest is payable on either the maturity date or, with respect to one of the notes, on a quarterly basis beginning June 30, 2021. We may prepay the outstanding amount of any advance under such notes, together with accrued and unpaid interest, at any time, in whole or in part, without premium or penalty.

605 Nash, LLC

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, LLC, a related party, whereby we leased approximately 6,883 square feet in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease runs from January 2021 through December 2027, and includes an option to extend the lease for an additional three-year term through December 2030. Base rent for the term of the lease is approximately $20,300 per month with an annual increase of 3% on January 1 of each year during the initial term and, if applicable, during the option term. In addition, under the agreement, we are required to pay our share of estimated property taxes and operating expenses.

Promissory Note with Nant Capital

In February 2021, we executed a promissory note with Nant Capital. The outstanding principal amount of each advance made by Nant Capital bears interest at a per annum rate of 6.0%, compounded annually and computed based on 365 or 366 days. On February 26, 2021, we received a $40.0 million advance pursuant to this promissory note, all of which is outstanding as of March 31, 2021. The accrued interest shall be paid quarterly commencing on June 30, 2021. The outstanding principal amount and any accrued and unpaid interest are due on September 30, 2025. We may prepay the outstanding principal amount and accrued interest at any time without premium or penalty and the prior consent of Nant Capital.

See Note 9, *Related Party Agreements*, of the "Notes to Unaudited Condensed Combined Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q for a more detailed discussion regarding our related party agreements.

Components of our Results of Operations

Revenue

To date, we have generated minimal revenue from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables and grant programs. We have no clinical products approved for commercial sale and have not generated any revenue from therapeutic and vaccine product candidates that are under development. 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 generally 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 technology and 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;
- expenses incurred under collaborative agreements;
- 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.

We expect our research and development expenses to continue 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.

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 12 to 24 months, 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, information technology, legal, 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 strategic business transactions and business development efforts, 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 will increase for the foreseeable future as we expand operations, build out information systems and increase our headcount to support continued research activities and the development of our clinical programs. 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 and Expense

Other income and expense consists primarily of interest income, interest expense, unrealized gains and losses on investments in equity securities, realized gains and losses on both debt and equity securities, and gains and losses on foreign currency transactions.

Income Taxes

The company is subject to taxation in the United States, various state, and foreign jurisdictions. Earnings from non-U.S. activities are subject to local country income tax. To date, we have not been required to pay U.S. federal income taxes or foreign income taxes because of our or our subsidiaries' current and accumulated net operating losses.

Results of Operations

Comparison of the three months ended March 31, 2021 and 2020

	Three Months Ended March 31,			
	2021	2020	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue	$ 139	$ 165	$ (26)	(16%)
Operating expenses:				
Research and development (including amounts with related parties)	41,128	27,374	13,754	50%
Selling, general and administrative (including amounts with related parties)	45,275	9,493	35,782	377%
Total operating expenses	86,403	36,867	49,536	134%
Loss from operations	(86,264)	(36,702)	(49,562)	135%
Other income (expense):				
Interest and investment income, net	8,944	78	8,866	11367%
Interest expense (including amounts with related parties)	(3,168)	(1,889)	(1,279)	68%
Other income, net (including amounts with related parties)	13	1,104	(1,091)	(99%)
Total other income (expense)	5,789	(707)	6,496	(919%)
Loss before income taxes and noncontrolling interests	(80,475)	(37,409)	(43,066)	115%
Income tax expense	(6)	(18)	12	(67%)
Net loss	$ (80,481)	$ (37,427)	$ (43,054)	115%

Research and Development Expense

Research and development expense increased $13.8 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The increase in research and development expense was primarily driven by higher laboratory supply expenses of $4.9 million mainly driven by our COVID-19 programs, increased stock compensation expense of $2.7 million due to new grants issued, higher compensation related expenses including shared services costs of $1.9 million driven by additional headcount needed to support our business activities, increased clinical trial expenses and regulatory costs of $1.7 million related to our COVID-19 programs, higher third party testing services of $1.3 million driven by release testing related to various product candidates, and higher manufacturing costs, including facilities expenses and equipment maintenance costs of $1.1 million related to our Anktiva and COVID-19 programs.

We expect our research and development expense 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 Expense

Selling, general and administrative expense increased $35.8 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The increase in selling, general and administrative expense was primarily attributable to higher financial advisory, legal, public company and other professional fees of $21.0 million related to our merger which was announced in December 2020 and closed in March 2021 as well as higher costs associated with ongoing litigation, contracting, trademark, and patent related legal fees and other matters, higher stock compensation expense of $12.1 million driven by stock options and RSUs granted as well as stock option modifications resulting in incremental stock based compensation expense in the first quarter of 2021, increased insurance costs of $2.0 million due mostly to higher directors' and officers' renewal rates and increased coverage related to the combined company, and higher compensation related expenses including shared services costs of $0.6 million.

Other Income and Expense

Other income increased $6.5 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. This increase was mainly due to unrealized gains of $8.8 million related to our equity investments. These gains were partially offset by a $1.3 million increase in interest expense driven primarily by additional related party borrowings and a decrease in other income of $1.1 million related to Receptome, LLC.

Liquidity and Capital Resources

Sources of Liquidity

Our principal sources of liquidity are our existing cash, cash equivalents, and marketable 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.

As of March 31, 2021, we had cash and cash equivalents, and marketable securities of $84.3 million compared to $97.0 million as of December 31, 2020. In order to complete the development of our current product candidates, and implement our business plan, we will require substantial additional funding. Furthermore, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to raise even greater amounts of funds sooner if we choose to expand more rapidly than we presently anticipate. Moreover, our fixed expenses such as rent and other contractual commitments are substantial and are expected to increase in the future.

Uses of Liquidity

In addition to the cash used to fund our operating activities discussed in "*—Future Funding Requirements*" below, we will require cash to settle the following obligations:

As of March 31, 2021, we had related-party notes payable together with accrued interest thereon of $297.5 million compared to $254.4 million as of December 31, 2020. During the three months ended March 31 2021, we received a $40.0 million advance pursuant to a related-party promissory note. Such notes bear interest at 3% to 6% per year and may be prepaid by us without penalty. The notes allow for additional advances as we may request with the consent of the applicable lender. With the exception of interest on the recent $40.0 million advance, all outstanding principal and accrued and unpaid interest on these notes are due and payable on September 30, 2025.

In connection with our acquisition of Altor, we issued CVRs under which we have agreed to pay the prior stockholders of Altor approximately $304.0 million upon successful approval of the BLA or foreign equivalent for Anktiva by December 31, 2022 and approximately $304.0 million upon the first calendar year prior to December 31, 2026 in which worldwide net sales of Anktiva exceed $1.0 billion (with payments payable in cash or shares of our common stock or a combination thereof). Dr. Soon-Shiong and his related party hold approximately $279.5 million in the aggregate of CVRs and they have both irrevocably agreed to receive shares of common stock in satisfaction of their CVRs. We may need to seek additional sources of capital to satisfy the CVR obligations if they are achieved.

Cash Flows

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

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Cash provided by (used in):		
Operating activities	$ (60,469)	$ (31,107)
Investing activities	31,845	13,994
Financing activities	38,497	(123)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(109)	89
Net change in cash, cash equivalents, and restricted cash	$ 9,764	$ (17,147)

Operating Activities

For the three months ended March 31, 2021, net cash used in operating activities of $60.5 million consisted of a net loss of $80.5 million, partially offset by $14.5 million in adjustments for non-cash items and $5.5 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of $15.3 million in stock compensation expense, $3.4 million in non-cash interest related primarily to related party loans, $3.0 million in depreciation and amortization, $1.6 million of non-cash lease expense related to operating lease right-of-use assets, and $0.2 million in amortization of net premiums and discounts on marketable debt securities, reduced by $8.8 million in unrealized gains on marketable equity securities driven primarily by an increase in the value of our investments. The change in net working capital consisted primarily of increases in accounts payable of $6.5 million, amounts due to related parties of $2.6 million, and other long-term assets of $0.7 million. These increases in net working capital were partially offset by decreases in accrued expenses and other liabilities of $1.9 million, operating lease liabilities of $1.5 million and prepaid expenses and other current assets of $0.9 million including changes related to insurance claim receivables and prepaid manufacturing services.

For the three months ended March 31, 2020, net cash used in operating activities of $31.1 million consisted of a net loss of $37.4 million, partially offset by $6.3 million in adjustments for non-cash items and $0.1 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of $3.5 million in depreciation and amortization, $2.0 million in non-cash interest items, $1.2 million of non-cash lease expense related to operating lease right-of-use assets, $0.5 million in stock compensation expense, and $0.2 million in unrealized losses on marketable equity securities, partially offset by a $1.1 million change in deferred tax liability. The changes in net working capital consisted primarily of increases related to accrued expenses of $8.2 million and other assets of $0.3 million, partially offset by decreases in prepaid expenses and other current assets of $4.0 million, due to related parties of $2.4 million, accounts payable of $1.7 million, and operating lease liabilities of $0.3 million.

Investing Activities

For the three months ended March 31, 2021, net cash provided by investing activities was $31.8 million, which included cash inflows of $31.9 million and $7.1 million from maturities and sales of marketable securities, respectively, partially offset by $7.1 million for purchases of property, plant and equipment, Our investments in property, plant and equipment related primarily to acquisitions of equipment which will be used for the manufacturing of our product candidates and expenditures related to the build out of our manufacturing facilities.

For the three months ended March 31, 2020, net cash provided by investing activities was $14.0 million, which included cash inflows of $23.1 million and $1.5 million from maturities and sales of marketable securities, respectively, partially offset by $10.3 million of purchases of marketable debt securities and $0.3 million for purchases of property, plant and equipment.

Financing Activities

For the three months ended March 31, 2021, net cash provided by financing activities was $38.5 million, which consisted of net proceeds from issuances of related party notes of $40 million and proceeds of $1.1 million resulting from exercises of stock options. Net cash used in financing activities consisted of $2.6 million related to net share settlement of vested RSUs for payment of employee payroll taxes.

For the three months ended March 31, 2020, net cash used in financing activities was minimal.

Future Funding Requirements

To date, we have generated minimal revenue, 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. We have also 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.

As a result of continuing anticipated operating cash outflows, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. To date, we have in part relied on borrowings from entities affiliated with our Executive Chairman and principal stockholder, Dr. Soon-Shiong, to fund our capital requirements. We have no lines of credit or committed sources of financing; however, we may have access to incremental draws on the promissory notes we have with entities associated with Dr. Soon-Shiong. We believe our existing cash, cash equivalents, and investments in marketable securities, together with capital to be raised through equity offerings and our potential 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 condensed combined consolidated financial statements based primarily upon our Executive Chairman's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt. 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.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to:

- progress, timing, scope and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects and manufacture Anktiva and other therapies for the treatment of patients in our ongoing, planned and potential future clinical trials;

- time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities to execute clinical trials;
- our ability to successfully commercialize any product candidates, if approved;
- our ability to have clinical and commercial products successfully manufactured consistent with FDA and European Medicines Agency regulations;
- amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- sales and marketing costs associated with commercializing any product candidates, if approved, including the cost and timing of building our marketing and sales capabilities;
- cost of building, staffing and validating our own manufacturing facilities in the U.S.;
- terms and timing of our current and any potential future collaborations, CVRs, milestones, royalties, licensing or other arrangements that we have established or may establish;
- cash requirements of any future acquisitions or the development of other product candidates;
- time and cost necessary to respond to technological, regulatory, political and market developments;
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

Unless and until we can generate a sufficient amount of revenue, we expect to seek to finance future cash needs through public or private equity offerings, license agreements, debt financings, credit facilities, collaborations, strategic alliances and marketing or distribution arrangements. In that connection we intend to issue additional shares in one or more future capital raising transactions, including but not limited to the offering, issuance and sale by us of up to a maximum aggregate offering of $500.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement with Jefferies LLC, or the ATM. Additional funds may not be available when we seek to raise capital or need funds on terms that are acceptable to us, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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

On April 30, 2021, we entered into an Open Market Sale Agreement (the “Agreement”) with respect to an at-the-market (“ATM”) offering program under which we may offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $500 million. See Note 13, *Subsequent Events*, of the “Notes to Unaudited Condensed Combined Consolidated Financial Statements” that appear in Item 1. “Financial Statements” of this Quarterly Report on Form 10-Q.

Contractual Obligations, Commitments and Contingencies

Contractual Obligations and Commitments

See Note 8, *Commitments and Contingencies – Lease Arrangements*, and Note 9, *Related Party Agreements*, of the “Notes to Unaudited Condensed Combined Consolidated Financial Statements” that appear in Item 1. “Financial Statements” of this Quarterly Report on Form 10-Q.

Contingencies

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. We are aware of complaints that have been filed regarding the Merger, but we have not been served with any of such complaints. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments

In the Notes to Combined Consolidated Financial Statements included in the Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) filed as Exhibit 99.2 and the Management's Discussion and Analysis of Financial Condition and Results of Operations of ImmunityBio, Inc. filed as Exhibit 99.3 to our Current Report on Form 8-K/A filed with the SEC on April 22, 2021, we have disclosed those accounting policies that we consider to be significant in determining our results of operations and financial condition. There have been no material changes to those policies that we consider to be significant since the filing of our Current Report on Form 8-K/A on April 22, 2021. The accounting principles used in preparing our condensed combined consolidated financial statements conform in all material respects with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Use of Estimates

The preparation of condensed combined 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 combined 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, contingent value right measurement and assessments, the measurement of right-of-use assets and lease liabilities, 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 ongoing coronavirus pandemic could have on our significant accounting estimates. Actual results could differ from those estimates.

Stock-Based Compensation

We account for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. We measure the fair value of an equity-classified award at the grant date and recognize the stock-based compensation expense over the period of vesting on the straight-line basis for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period using the graded vesting method once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited.

Recent Accounting Pronouncements

Refer to Note 2, *Summary of Significant Accounting Policies*, of the "Notes to Unaudited Condensed Combined Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q 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, equity investments, foreign currency exchange rates and inflation are described in the Combined Management's Discussion and Analysis of Financial Condition and Results of Operations of ImmunityBio, Inc. filed as Exhibit 99.3 to our Current Report on Form 8-K filed with the SEC on April 22, 2021, there have been no material changes to the financial market risks described at December 31, 2020. 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 chief executive officer, or CEO, and chief financial officer, or 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, 2021. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) of 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 SEC'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, 2021, our CEO and CFO have concluded that, as of March 31, 2021, 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) of the Exchange Act) during the fiscal quarter ended March 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, as a result of the Merger, our internal control over financial reporting may change. Our process for evaluating controls and procedures is continuous and encompasses constant improvement of the design and effectiveness of established controls and procedures and the remediation of any deficiencies, which may be identified during this process.

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.

PART II—OTHER INFORMATION

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. We are aware of complaints that have been filed regarding the Merger, but we have not been served with any of such complaints. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

See Note 8, *Commitments and Contingencies—Contingencies*, of the "Notes to Unaudited Condensed Combined Consolidated Financial Statements" included in Part I, Item 1. of this Quarterly Report for a discussion of legal matters.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, 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.

On March 9, 2021, we completed the merger with ImmunityBio, Inc., a private company referred to below as "ImmunityBio." After the completion of this merger, we (formerly known as NantKwest, Inc.) changed our name to ImmunityBio, Inc., and references below to "the company," "the combined company," "we," "us," and "our" refer to ImmunityBio, Inc. and its subsidiaries.

Risk Factor Summary

Risks Related to Our Financial Condition and Capital Requirements

- We will need additional financing to fund our operations and complete the development and commercialization of our various product candidates, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our debt could adversely affect our cash flows and limit our flexibility to raise additional capital.
- The synergies and benefits expected from the integration of our operations may not be realized within the expected time frame.
- Our businesses may not be integrated successfully, or such integration may be more difficult, time consuming or costly than expected. Operating costs, customer loss and business disruption, including difficulties in maintaining relationships with employees, customers, suppliers or vendors, may be greater than expected for the combined company. Revenues may be lower than expected for the combined company.
- We have a history of operating losses, and we expect to continue to incur losses and may never be profitable.
- We have a limited operating history, and the biotechnology industry in which we operate, makes it difficult to evaluate our business plan and prospects.

Risks Related to Our Business and Industry Regulation

- We may develop product candidates in combination with other therapies, which exposes us to additional risks.
- It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.
- Our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We have limited experience 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 Practice ("GCP") regulations, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.
- Our clinical trials may not be initiated or completed when we expect, and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.

- We use Immuno-Oncology Clinic, Inc., a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or required to contract with other clinical trial sites, and our clinical development plans will be significantly delayed, and we will incur additional costs.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.
- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- 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.
- A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.
- We have never commercialized a product candidate before, and we may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

Risks Related to Government Regulation

- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- Results for any patient who receives compassionate use access to our product candidates should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial, and cannot be used to establish safety or efficacy for regulatory approval.
- The clinical and commercial utility of our product candidates are uncertain and may never be realized.
- We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- Our GMP-in-a-Box will be regulated by the FDA as a medical device, and regulatory compliance for medical devices is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

Risks Related to Intellectual Property

- If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our product candidates and technologies, we may not be able to compete effectively or operate profitably.
- If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.
- We may be involved in lawsuits to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, which could be expensive, time-consuming and unsuccessful.
- Issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

- The use of our technology and product candidates could potentially conflict with the rights of others, and third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product candidates and technologies.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Risks Related to Our Common Stock

- Dr. Patrick Soon-Shiong, our Executive Chairman and our principal stockholder, has significant interests in other companies which may conflict with our interests.
- Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.
- The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.
- 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.

Risks Related to Our Financial Condition and Capital Requirements

We will need additional financing to fund our operations and complete the development and commercialization of our various product candidates, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Our operations have consumed substantial amounts of cash since inception. We have incurred net losses in each year since our inception and, as of March 31, 2021, we had an accumulated deficit of $1.7 billion. In addition, research and development and operating costs have also been substantial and are expected to increase. A significant portion of our funding had been in the form of promissory notes representing $297.5 million in indebtedness, including interest thereon, as of March 31, 2021 held by entities affiliated with Dr. Soon-Shiong with a maturity date of September 30, 2025.

As of March 31, 2021, we held cash, cash equivalents and marketable securities totaling $84.3 million. In order to complete the development of our current product candidates, and in order to implement our business plan, we anticipate that we will have to spend more than the funds currently available to us. Furthermore, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Moreover, our fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- progress, timing, scope and costs of our clinical trials, including the ability to timely initiate clinical sites, enroll subjects and manufacture Anktiva and other therapies for the treatment of patients in our ongoing, planned and potential future clinical trials;
- time and cost necessary to obtain regulatory approvals that may be required by regulatory authorities to execute clinical trials;
- our ability to successfully commercialize any product candidates, if approved;
- our ability to have clinical and commercial product successfully manufactured consistent with FDA and European Medicines Agency regulations;

- amount of sales and other revenues from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- sales and marketing costs associated with commercializing any product candidates, if approved, including the cost and timing of building our marketing and sales capabilities;
- cost of building, staffing and validating our own manufacturing facilities in the United States;
- terms and timing of our current and any potential future collaborations, contingent value rights ("CVRs"), milestones, royalties, licensing or other arrangements that we have established or may establish;
- cash requirements of any future acquisitions or the development of other product candidates;
- time and cost necessary to respond to technological, regulatory, political and market developments;
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights; and
- costs associated with any potential business or product acquisitions, strategic collaborations, licensing agreements or other arrangements that we may establish.

Unless and until we can generate a sufficient amount of revenues, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. We expect to issue additional shares in connection with one or more future capital raising transactions. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all, including but not limited to the offering, issuance and sale by us of up to a maximum aggregate offering of $500.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement with Jefferies LLC, or the ATM. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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

Our debt could adversely affect our cash flows and limit our flexibility to raise additional capital.

We have a significant amount of debt and may need to incur additional debt to support our growth. As of March 31, 2021, our indebtedness was $297.5 million, consisting of related-party promissory notes and interest thereon, all held by entities affiliated with Dr. Soon-Shiong, with a maturity date of September 30, 2025.

Our substantial amount of debt could have important consequences and could:

- require us to dedicate a substantial portion of our cash and cash equivalents to make interest and principal payments on our debt, reducing the availability of our cash and cash equivalents and cash flow from operations to fund future capital expenditures, working capital, execution of our strategy and other general corporate requirements;
- increase our cost of borrowing and even limit our ability to access additional debt to fund future growth;
- increase our vulnerability to general adverse economic and industry conditions and adverse changes in governmental regulations;
- limit our flexibility in planning for, or reacting to, changes in our business and industry, which may place us at a disadvantage compared with our competitors; and
- limit our ability to borrow additional funds, even when necessary to maintain adequate liquidity, which would also limit our ability to further expand our business.

The occurrence of any of the foregoing factors could have a material adverse effect on our business, results of operations and financial condition.

We may also need to refinance a portion of our outstanding debt as it matures. We may not be able to refinance existing debt or the terms of any refinancing may not be as favorable as the terms of our existing debt. Furthermore, if prevailing interest rates or other factors at the time of refinancing result in higher interest rates upon refinancing, then the interest expense relating to that refinanced indebtedness would increase. These risks could materially adversely affect our financial condition, cash flows and results of operations.

The synergies and benefits expected from the integration of our operations may not be realized within the expected time frame.

The ability of the company, now renamed ImmunityBio, Inc. and formerly known as NantKwest, Inc., to realize the anticipated benefits of the merger with ImmunityBio will depend, to a large extent, on our ability to integrate our businesses in a manner that facilitates growth opportunities and achieves the projected synergies identified by each company without adversely affecting current revenues and investments in future growth. Even if we are able to integrate the two companies successfully, the anticipated benefits of the merger, including the expected synergies, may not be realized fully or at all or may take longer to realize than expected.

Our businesses may not be integrated successfully, or such integration may be more difficult, time consuming or costly than expected. Operating costs, customer loss and business disruption, including difficulties in maintaining relationships with employees, customers, suppliers or vendors, may be greater than expected for the combined company. Revenues may be lower than expected for the combined company.

The combination of two businesses is complex, costly and time-consuming and may divert significant management attention and resources to combining our prior businesses. This process may disrupt our businesses. The failure to meet the challenges involved in combining the two businesses and to realize the anticipated benefits of the merger could cause an interruption of, or a loss of momentum in, the activities of the combined company and could adversely affect the results of operations of the combined company. The overall combination of our businesses may also result in material unanticipated problems, expenses, liabilities, competitive responses, and loss of customer and other business relationships. The difficulties of combining the operations of the companies include, among others:

- the diversion of management attention to integration matters;
- difficulties in integrating operations and systems, including intellectual property and communications systems, administrative and information technology infrastructure and financial reporting and internal control systems;
- challenges in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;
- difficulties in integrating employees and attracting and retaining key personnel, including talent;
- challenges in retaining existing, and obtaining suppliers and employees;
- difficulties in achieving anticipated cost savings, synergies, accretion targets, business opportunities, financing plans and growth prospects from the combination;
- difficulties in managing the expanded operations of a significantly larger and more complex company;
- contingent liabilities that are larger than expected; and
- potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the merger.

Many of these factors are outside of our control, and any one of them could result in lower revenues, higher costs and diversion of management time and energy, which could materially impact the business, financial condition and results of operations of the combined company. In addition, even if the operations of our businesses are integrated successfully, the full benefits of the merger may not be realized, including, among others, the synergies or growth opportunities that are expected. These benefits may not be achieved within the anticipated time frame or at all. Further, additional unanticipated costs may be incurred in the integration of our businesses. All of these factors could negatively impact the company's operations and/or the price of the company's common stock. As a result, it cannot be assured that the combination of our businesses will result in the realization of the full benefits expected from the merger within the anticipated time frames or at all. Accordingly, holders of the combined company's common stock may experience a loss as a result of a decline in the market price of such common stock. In addition, a decline in the market price of the combined company's common stock could adversely affect the company's ability to issue additional securities and to obtain additional financing in the future.

We have a history of operating losses, and we expect to continue to incur losses and may never be profitable.

We are a biopharmaceutical company, and now that the merger with ImmunityBio has been completed, we have a much broader portfolio of product candidates at various stages of development. None of our products have been approved for commercial sale or for which marketing approval has been sought, although we have generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables and grant programs.

We expect to incur significant expenses as we seek to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals and, upon successful receipt of FDA approval, commercializing our products. We will also 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 ongoing and future clinical trials and, upon potential receipt of FDA approval, for our initial commercialization activities. Moreover, we do not expect to have significant product sales or revenue for the next 12 to 24 months. These losses have had an adverse impact on our stockholders' equity and working capital and, as these operating losses continue to increase significantly in the future due to such 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 the company may become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to achieve profitability in the future is dependent upon obtaining regulatory approvals for our product candidates and successfully commercializing our product candidates alone or with third parties. However, our operations may not be profitable even if one or more of our product candidates under development are successfully developed and produced and thereafter commercialized.

We have a limited operating history, and the biotechnology industry in which we operate, makes it difficult to evaluate our business plan and prospects.

We have only a limited operating history on which a decision to invest in us can be based and against which we can test the plans and assumptions in our business plan. Our future is dependent upon our ability to implement our business plan, as that business plan may be modified from time to time by our new management and board of directors. Investors therefore cannot evaluate the likelihood of our success.

We face the problems, expenses, difficulties, complications and delays normally associated with a pre-commercial biotechnology company, many of which are beyond our control. Accordingly, our prospects should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a new business developing technologies in an industry that is characterized by a number of market entrants and intense competition. Because of our size and limited resources, we may not possess the ability to successfully overcome many of the risks and uncertainties frequently encountered by pre-commercial companies involved in the rapidly evolving field of immunotherapy. If our research and development efforts are successful, we may also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. There can be no assurance that we will be successful in developing our business.

We will be substantially dependent on the success of our product candidates and cannot guarantee that these product candidates will successfully complete development, receive regulatory approval or be successfully commercialized.

Other than our proprietary GMP-in-a-Box bioreactors for which we have received nominal revenue to date, we currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our main product candidates, Anktiva, aldoxorubicin and human adenovirus serotype 5 ("hAd5") vaccine candidates, some or all of which are used in combination with our natural killer cells. We expect to invest heavily in these product candidates as well as in our existing product candidates and in any future product candidates that the company may develop. Our business depends entirely on the successful development, regulatory approval and commercialization of such product candidates, each of which may never occur. Our ability to generate revenues in the future is substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize, our product candidates. We currently generate no meaningful revenues from the sale of any product candidates, and we may never be able to develop or commercialize a product.

Our product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenues from product sales. We cannot assure you that we will meet our timelines for current or future clinical trials, which may be delayed or not completed for a number of reasons, including the negative impact of the COVID-19 pandemic.

We will not be permitted to market or promote any of our product candidates without receiving regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow successful commercialization, and then successfully commercialize our product candidates, we will not be able to generate revenues from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

We have not previously submitted a Biologics License Application ("BLA") for any biologics product candidates, or a New Drug Application ("NDA") for any small molecule product candidates or similar marketing application to the FDA or comparable foreign authorities, for any product candidate, and we cannot be certain that any of our current product candidates or any future product candidates will be successful in clinical trials or receive regulatory approval. Furthermore, although we do not expect to submit a BLA and/or NDA with comparisons to existing or more established therapies, and we do not expect the FDA to base its determination with respect to product approval on such comparisons, the FDA may factor these comparisons into its decision whether to approve Anktiva or any of our product candidates. The FDA may also consider approvals of competing products, which may alter the treatment landscape concurrently with their review of our BLA and/or NDA filings, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate withdrawal of our BLA and/or NDA filings.

Our product candidates will be susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our product candidates will depend on our ability to:

- price our product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our product;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;
- manufacture product candidates through contract manufacturing organizations ("CMOs") or in our own, or our affiliates', manufacturing facilities in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our product candidates;
- successfully commercialize any of our product candidates that receive regulatory approval;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement for our product candidates;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;
- effectively compete with other therapies or competitors; and
- following launch, assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Additionally, our ability to generate revenues from our combination therapy products will also depend on the availability of the other therapies with which our products are intended to be used. For example, we have in the past experienced, and may in the future experience, challenges obtaining sufficient quantities of bacillus Calmette-Guérin ("BCG") for some of our clinical trials involving Anktiva due to global shortages. There can be no assurance that we will be able to source adequate supplies of BCG to continue these clinical trials in a timely fashion or at all, and in the future, there may be other supply-related challenges that delay or prevent patient enrollment and continued progress on our clinical trials. For more information, see "*—Our clinical trials may not be initiated or completed when we expect, and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.*"

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 to preserve liquidity.

Risks Related to Our Business and Industry

We may develop product candidates in combination with other therapies, which exposes us to additional risks.

We may develop product candidates in combination with one or more other therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delays in clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.

We have projected the date for the commencement of future trials, and continuation and completion of our ongoing clinical trials. However, a number of factors, including scheduling conflicts with participating clinicians and clinical institutions, and difficulties in identifying and enrolling patients who meet trial eligibility criteria, may cause significant delays. Our clinical trials may also experience delays related to the COVID-19 pandemic; for more information, see "*—Our business could be adversely affected by the effects of health epidemics, pandemics or contagious diseases, including the recent pandemic of the disease caused by the novel coronavirus SARS-CoV-2, or COVID-19, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.*" We may not commence or complete clinical trials involving any of our product candidates as projected or may not conduct them successfully.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Our ability to enroll or treat patients in our other studies, or the duration or costs of those studies, could be affected by multiple factors, including, preliminary clinical results, which may include efficacy and safety results from our ongoing Phase II trials, but may not be reflected in the final analyses of these trials. Although preliminary data from our Phase I trials were generally positive, that data may not necessarily be representative of interim or final results, as new patients are cycled through the applicable treatment regimes. As the trials continue, investigators may prioritize patients with more progressed forms of cancer than the initial patient population, based on the success or perceived success of that initial population. Patients with more progressed forms of cancer may be less responsive to treatment, and accordingly, interim efficacy data may show a decline in patient response rate or other assessment metrics. As the trials continue, investigators may shift their approach to the patient population, which may ultimately result in a decline in both interim and final efficacy data from the preliminary data, or conversely, an increase in final efficacy data following a decline in the interim efficacy data, as patients with more progressed forms of cancer are cycled out of the trials and replaced by patients with less advanced forms of cancer. This opportunity for investigator selection bias in our trials as a result of open-label design may not be adequately handled and may cause a decline in or distortion of clinical trial data from our preliminary results. Depending on the outcome of our studies, we may need to conduct one or more follow-up or supporting studies in order to successfully develop our product candidates for FDA approval. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we cannot be certain that we will not face such setbacks.

Furthermore, the timely completion of clinical trials in accordance with their protocols will depend, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion, including the ability of us or our collaborators to conduct clinical trials under the constraints of the COVID-19 pandemic. In addition, we expect that our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Accordingly, we cannot guarantee that our trials will progress as planned or as scheduled. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We expect to rely on medical institutions, academic institutions or contract research organizations ("CROs") to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. See "*—We have limited experience 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 Practice ("GCP") regulations, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.*" If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

We currently anticipate that we will have to rely on our CMOs or partners to manufacture our product candidates for some of our clinical trials. If they fail to commence or complete, or experience delays in, manufacturing our product candidates, our planned clinical trials will be delayed, which will adversely affect our stock price and our ability to conduct our business as currently planned.

Our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.

Because our product candidates include, and we expect our future product candidates to include, candidates based on advanced therapy technologies, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and clinical trial sites outside of the United States may not reimburse for costs typically covered by third-party payors in the United States, and as a result we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates as well as the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective, or safe, pure and potent, for use in each target indication. Because most of our product candidates will be subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. For small molecule product candidates, we will need to demonstrate that they are safe and effective for their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Regulatory authorities may ultimately disagree with our chosen endpoints or may find that our studies or study results do not support product approval. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates with small patient populations may not be predictive of the results of later-stage clinical trials or the results once the applicable clinical trials are completed. Additionally, early clinical trials may not produce data that support further development of our product candidates and regulatory authorities may not allow continued clinical development of our product candidates. Preliminary, single cohort or top-line results from clinical trials may not be representative of the final study results. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another and the results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Our current and our future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial or cross-site variation that are not properly addressed, it may not become apparent until the clinical trial is well advanced or until data from different sites become available. For example, our current clinical trials are, and we expect our clinical trials to be, conducted at multiple sites in different geographies, with different levels of experience and expertise by medical professionals, and these professionals may make mistakes or introduce site-specific variation that could have an impact on clinical trials by disqualifying patients or impacting patient ability to continue in a study or on the clinical data. Further, because we currently plan to test our product candidates for use with other oncology products, the design, implementation and interpretation of the clinical trials necessary for marketing approval may be more complex than if we were developing our product candidates alone.

In addition, even if such 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.

We have reported preliminary results for clinical trials of our product candidates, including Anktiva. These preliminary results, which include assessments of efficacy, are subject to substantial risk of change due to small sample sizes and may change as patients are evaluated or as additional patients are enrolled in these clinical trials. These outcomes may be unfavorable, deviate from our earlier reports, and/or delay or prevent regulatory approval or commercialization of our product candidates, including candidates for which we have reported preliminary efficacy results.

Further, certain of our hypotheses regarding the potential benefits of our product candidates compared to alternative therapies and treatments are based on cross-trial comparisons of results that were not derived from head-to-head clinical trials. Such clinical trial data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, these cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of our product candidates compared to other product candidates that may have been approved previously.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We have limited experience 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 Practice ("GCP") regulations, and in a timely manner, may delay or prevent our ability to seek or obtain regulatory approval for or commercialization of our product candidates.

We expect to be heavily reliant on third and related parties to conduct our clinical trials. We have a limited history of conducting clinical trials and have no experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity, and potency, or efficacy, for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, CMOs, if used, partners or consultants. Relying on third-party clinical investigators, CROs or CMOs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from patients treated with products from these different facilities, in our product registrations. Further, if we use CMOs, they may not be able to manufacture Anktiva or our other product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with Good Laboratory Practice ("GLP") regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA or NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CMOs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations.

Our clinical trials will need to be conducted with product candidates that were produced under current Good Manufacturing Practices ("cGMP") regulations. Our failure to comply or our CMOs' failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity.

We rely on third parties to manufacture, package, label and ship some of our product candidates for the clinical trials that we conduct. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential product revenues.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. Immuno-Oncology Clinic, Inc. (the "Clinic") has conducted, and is currently conducting, and in the future may conduct clinical trials involving our product candidates. NantWorks is a collection of healthcare and technology companies that is controlled, and a majority of which is owned, by our Executive Chairman, Dr. Patrick Soon-Shiong, and provides certain administrative services (and has loaned money) to the Clinic. We are conducting ongoing clinical trials and single patient investigational new drug ("spIND") applications that may include the use of Anktiva, aldoxorubicin or product candidates enabled by our adenovirus, or Ad, technologies. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators that are determined to have conflicts of interest.

Our CROs, clinical trial sites and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our trial protocols, regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

Our reliance on third and related parties can also present intellectual property-related risks. For example, collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or technology or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. Collaborators may also own or co-own intellectual property covering our product candidates or technology that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or technology. Collaborators may also gain access to our trade secrets or formulations and impact our ability to commercialize proprietary technology. We may also need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us.

If any of our relationships with these third or related parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

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 agreements 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 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, GCP 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 intend to rely for conducting our clinical trials are required to comply with GCP. GCP 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 fails to comply or failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under GMP and/or Good Tissue Practice ("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 Anktiva will involve further investigator-initiated clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy, 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 from investigator-initiated clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our business 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, the Clinic has conducted, is currently conducting, and in the future may conduct, clinical trials involving our product candidates, and in the future the Clinic may conduct, clinical trials involving our product candidates. NantWorks, which is controlled by, and a majority of which is owned by, our Executive Chairman, Dr. Soon-Shiong, provides certain administrative services (and has loaned money) to the Clinic. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us, 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.

Our clinical trials may not be initiated or completed when we expect, and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that any of our product candidates will receive regulatory approval. We previously initiated clinical trials in patients with bladder cancer and in other indications, sometimes in collaboration with third parties. We plan to initiate trials in new indications, and new cohorts in existing trials. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our BLA and/or NDA filing timelines or permit competitors to obtain approvals that may alter our BLA and/or NDA filing strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful.

Events that may prevent successful or timely initiation or completion of clinical development or product approval include:

- regulators or Institutional Review Boards ("IRBs") may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- delays in reaching a consensus or inability to obtain agreement with the FDA or comparable foreign regulatory authorities on trial design or eligibility criteria for patient enrollment;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications, trial design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from trials with clinical trial sites in foreign countries;
- the FDA may not allow us to use the clinical trial data from a research institution to support an investigational new drug ("IND") if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical trials;
- delays in or failure to reach an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- imposition of a temporary or permanent clinical hold, such as the clinical hold on the Phase II/III clinical trial for our hAd5 COVID-19 vaccine candidate pending modifications to the protocol and FDA's review of additional information, including of immunogenicity and safety data from the Phase I portion of the study, or the temporary hold previously experienced in our 2014 clinical study relating to aldoxorubicin; although this temporary clinical hold involved a single death of a compassionate use patient, since that time, aldoxorubicin has been administered in multiple Phase II clinical trials and a Phase III clinical trial with no further clinical holds;
- suspensions or terminations by regulatory agencies, IRBs, or us for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically or mechanistically similar therapeutic or therapeutic candidate;
- delays in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a trial;
- failure by our CROs, clinical trial sites or patients, or other third parties, or us to adhere to clinical trial requirements, including regulatory, contractual or protocol requirements;
- failure to perform in accordance with the GCP requirements, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols to regulatory authorities and IRBs, and which may cause delays in our development programs, or changes to regulatory review times;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical trials of our product candidates being greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a BLA or NDA;
- clinical trials of our product candidates producing negative or inconclusive results may fail to provide sufficient data and information to support product approval, or our trials may fail to reach the necessary level of statistical or clinical significance, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials, or preclinical studies, or abandon product development programs;
- interruption of, or delays in receiving, supplies of our product candidates or other drugs or components of our therapies due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- early results from our clinical trials of our product candidates may be negatively affected by changes in efficacy measures such as overall response rate and duration of response as more patients are enrolled in our clinical trials or as new cohorts of our clinical trials are tested, and overall response rate and duration of response may be negatively affected by the inclusion of unconfirmed responses in preliminary results that we report if such responses are not later confirmed;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- there may be changes to the therapeutics or their regulatory status which we are administering in combination with our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the FDA or comparable regulatory authorities may take longer than we anticipate when making a decision on our product candidates;
- transfer of our manufacturing processes to our CMOs or other larger-scale facilities operated by a CMO or by us and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- our use of different manufacturing processes within our clinical trials, and any effects that may result from the use of different processes on the clinical data that we have reported and will report in the future;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing, including as a result of any quality issues associated with the contract manufacturer;
- delays and additional costs associated with business disruptions, new regulatory requirements, social distancing and other restrictions imposed by governmental or regulatory agencies and clinical trial sites due to the COVID-19 pandemic, which may include enrollment delays or failures to follow trial protocols; and
- obtaining sufficient supply of therapies that may be used in combination with our molecular agents or as comparative agents in clinical trials.

We are conducting our Phase II trial of Anktiva in combination with BCG in BCG unresponsive patients with non-muscle invasive bladder cancer, (“NMIBC”) in both carcinoma in situ (“CIS”) and papillary forms. Due to BCG shortages, delays were encountered in patient enrollment. As of December 2020, we completed our planned enrollment in the BCG unresponsive CIS cohort. We have enrolled patients who have received a lower dosage of BCG therapy before enrollment in its trial as a result of BCG shortages. During the period of shortages, we have also enrolled patients who have received a lower dosage of BCG therapy before enrollment in the trial due to the global shortage of BCG; for example, some patients received the recommended number of doses, but the amount per dose was one-third of recommended strength. All patients, without exception, received the number of BCG doses consistent with FDA guidance, and no less than approximately 90% of patients enrolled in the trial as of December 2020 have received the amount of BCG recommended by the American Urological Association before enrolling in the trial.

The FDA agreed with our modification of the study design to allow enrollment of patients who have received a reduced dose of BCG as first line therapy. These patients received the full dose of BCG + Anktiva during the trial; however, such patients should not be considered BCG unresponsive. The disposition of such patients in the assessment of our trial results to support approval of Anktiva in BCG unresponsive CIS NMIBC patients will be determined by the FDA during their review. We may consider enrolling additional patients before BLA submission, and the labeling will reflect the enrolled patient population and will also be determined by the FDA during their review.

We also may conduct clinical and preclinical research in collaboration with other academic, pharmaceutical, biotechnology and biologics entities in which we combine our technologies with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing and clinical trials will require additional FDA regulatory approval and will increase our future costs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues. In addition, if we make manufacturing changes to our product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified product candidates to earlier versions. These changes may require FDA approval or notification and may not have their desired effect. The FDA may also not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. We may find that this change has unintended consequences that necessitates additional development and manufacturing work, additional clinical and preclinical studies, or that results in refusal to file or non-approval of a BLA and/or NDA.

Clinical trial delays could shorten any periods during which our product candidates have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other research. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also vary depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that any product candidates we may seek to develop in the future will never obtain the appropriate regulatory approvals necessary for us or any future collaborators to commence product sales. Any delay in completing development or obtaining, or failing to obtain, required approvals could also materially adversely affect our ability or that of any of our collaborators to generate revenues from any such product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

We use Immuno-Oncology Clinic, Inc., a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or required to contract with other clinical trial sites, and our clinical development plans will be significantly delayed, and we will incur additional costs.

Many of our Phase I and II clinical trials for our haNK, PD-L1.t-haNK and other t-haNK products as well as Anktiva have been conducted by Immuno-Oncology Clinic, Inc., which is a related party. Relying on a related party clinical site to develop data that is used as the basis to support regulatory approval can expose us to significant regulatory risks. For example, a study used to support regulatory approval that is conducted at a related party site can be rejected by the FDA if there are data integrity issues, or if there are significant GCP violations at the site. If any data integrity, or regulatory non-compliance issues occur during the study, we may not be able to use the data for our regulatory approval. Furthermore, if the operations of the clinical site are disrupted or if the site experiences disruptions in its clinical supplies or resources, such as potential disruptions due to COVID-19, then we may be required to suspend or terminate the study at this site, and we may need to contract with other clinical sites for the study, which will delay our clinical development and regulatory approval for the product candidate. Failure of this site to comply with the regulations or to recruit a sufficient number of patients may require us to delay submission for regulatory approval or repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if the site violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.

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

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the patient eligibility criteria defined in the protocol;

- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials and the effectiveness of recruiting publicity;
- the patient referral practices of physicians;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or enrollment in these clinical trials may be slower than we anticipate, potentially affecting our timelines for approval of our product candidates;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop such patients from the study or clinical trial, increase the needed enrollment size for the study or clinical trial or extend the study's or clinical trial's duration;
- competing clinical trials for similar therapies or other new therapeutics not involving cell-based immunotherapy;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product 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;
- clinical investigators enrolling patients who do not meet the enrollment criteria, requiring the inclusion of additional patients in the clinical trial;
- approval of new indications for existing therapies or approval of new therapies in general;
- our ability to obtain and maintain patient consents;
- the impact of the current COVID-19 pandemic or other material adverse events, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial, return for post-treatment follow-up, or follow the required study procedures. For instance, patients, including patients in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition. Withdrawal of patients from our clinical trials may compromise the quality of our data.

In addition, we expect that our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may need to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer and/or viral disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies, rather than enroll patients in any future clinical trial.

Amendments to our clinical protocols may affect enrollment in, or results of, our trials, including amendments we have made to further define the patient population to be studied.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment or small population size may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us, IRBs, Drug Safety Monitoring Boards ("DSMBs") or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a Risk Evaluation and Mitigation Strategy ("REMS") to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates.

If unacceptable toxicities or side effects arise in the development of our product candidates, we, an IRB, DSMB or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, order our clinical trials to be placed on clinical hold, or deny approval of our product candidates for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical, or preclinical studies should unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. Toxicities associated with our trials and product candidates may also negatively impact our ability to conduct clinical trials using tumor-infiltrating lymphocyte ("TIL") therapy in larger patient populations, such as in patients that have not yet been treated with other therapies or have not yet progressed on other therapies.

Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our trials or result in potential product liability claims. We have observed that certain events associated with our product candidates may include, for example, injection site pain and reaction, fatigue, nausea, vomiting, diarrhea, mucositis, abdominal pain, anorexia, chills, pyrexia, arthralgia, limb edema, myelosuppression (neutropenia, thrombocytopenia, and anemia) and hypoalbuminemia. Combination immunotherapy that includes our current product candidates may be associated with more frequent adverse events or additional adverse events, such as esophagitis, stomatitis, epistaxis, weight loss, headache, alopecia, night sweats, peripheral neuropathy, and death. In addition, these serious adverse effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidate are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may materially harm our business, financial condition and prospects.

The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our current product candidates include predominately biologics, vectors, small molecules and decentralized, advanced cell therapies. The manufacture of these product candidates involves complex processes, especially for our biologics, vectors and cell therapy product candidates, which are complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics, vectors and cell therapies is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, environmental or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Currently, our product candidates are manufactured using processes developed or modified by us, our affiliates or by our third-party research institution collaborators that we may not include for more advanced clinical trials or commercialization. As a result of these challenges, we may experience delays in our clinical development and/or commercialization plans. We may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

Currently we manufacture our product candidates or use CMOs. We may use third-party CMOs or some of our related parties to manufacture our product candidates. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

The manufacture of cell therapy products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel and compliance with strictly enforced federal, state, local and foreign regulations.

Moreover, any problems or delays we or our CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if we or our commercial manufacturers fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues.

In addition, the manufacturing process and facilities for any products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. The cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including our BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary chemistry, manufacturing and quality control documentation in support of a BLA or NDA on a timely basis. There is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenues.

Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

To the extent we use CMOs, we are ultimately responsible for the manufacture of our products, if approved, and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the federal civil False Claims Act ("FCA") corporate integrity agreements, consent decrees, or withdrawal of product approval.

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

Cell-based therapies and biologics rely on the availability of reagents, specialized equipment and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products, if approved.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing. For some of these reagents, equipment and materials, we rely, and we may in the future rely, on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we seek to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform both ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

We will be unable to commercialize our product candidates if our trials are not successful.

Our research and development programs are each at an early stage. We must demonstrate our product candidates' safety and efficacy in humans through extensive clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of our product candidates, including but not limited to the following:

- safety and efficacy results in various human clinical trials reported in scientific and medical literature may not be indicative of results we obtain in our clinical trials;
- after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising;
- we, our collaborators or regulators may suspend or terminate clinical trials if the participating subjects or patients are being exposed to unacceptable health risks;
- the standard of care may change as the result of new technology or therapies in our target clinical indications, precluding regulatory approval or limited commercial use if approved;
- the effects our potential products have may not be the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved;
- manufacturers may not meet the necessary standards for the production of the product candidates or may not be able to supply the product candidates in a sufficient quantity; and
- regulatory authorities may find that our clinical trial design or conduct does not meet the applicable approval requirements.

Clinical testing is very expensive, can take many years and the outcome is uncertain. It could take as much as 12 months or more before we learn the results from any clinical trial using Anktiva, aldoxorubicin, Ad and yeast technologies or other therapy. The data collected from our clinical trials may not be sufficient to support approval by the FDA of our Anktiva product candidate for the treatment of bladder cancer or of other therapies, including our hAd5 COVID-19 vaccine candidate. The clinical trials for our product candidates under development may not be completed on schedule and the FDA may not ultimately approve any of our product candidates for commercial sale. If we fail to adequately demonstrate the safety and efficacy of any product candidate under development, we may not receive regulatory approval for those product candidates, which would prevent us from generating revenues or achieving profitability.

Even if one of our leading product candidates, Anktiva, is approved and commercialized, we may not become profitable.

One of our leading product candidates, Anktiva, is initially targeting a small population of patients that suffer from bladder cancer, lung cancer and metastatic pancreatic cancer, when used as a combination therapy. Even if the FDA approves this candidate for these indications, and even if we obtain significant market share for it, because the potential target population may be small, we may never achieve profitability without obtaining regulatory approval for additional indications. The FDA often approves new therapies initially only for use in patients with relapsed or refractory metastatic disease, which may limit our patient population.

Additionally, in connection with the merger with ImmunityBio, we assumed the obligation to issue CVRs to the former stockholders of Altor BioScience Corporation (succeeded by Altor BioScience LLC) ("Altor") in connection with the acquisition of Altor. These CVRs become payable upon the attainment of certain regulatory and sales milestones related to Anktiva. The former Altor stockholders have the ability to choose to receive these payments either in cash, in an equivalent value of our common stock or in a combination of both cash and stock at the time such payments are due, except that Dr. Soon-Shiong and his related party, as prior stockholders of Altor, have irrevocably elected to receive all payments in respect of their CVRs in the form of our common stock. Such CVR payments to Dr. Soon-Shiong and his related party aggregate to approximately $279.5 million. We may, however, still be required to pay the other prior Altor stockholders up to $164.2 million for the CVRs relating to the regulatory milestone and up to $164.2 million for the CVRs relating to the sales milestone should they choose to have these CVRs paid in cash instead of common stock. If this were to occur, we may need to seek additional sources of capital, and we may not be able to achieve profitability or positive cash flow. We plan to collaborate with governmental, academic and corporate partners, including affiliates, to improve and develop Anktiva, hAd5 and other therapies for new indications for use in combination with other therapies and to improve and develop other product candidates, which may expose us to additional risks, or we may not realize the benefits of such collaborations.

Because some of our collaborations are conducted at outside laboratories, and we do not have complete control over how the studies are conducted or reported or over the manufacturing methods used to manufacture our Anktiva product candidate, the results of such studies, which we may use as the basis for our conclusions, projections or decisions with respect to our current or future product candidates, may be incorrect or unreliable, or may have a negative impact on us if the results of such studies are imputed to our product candidates or proposed indications, even if such imputation is improper. Additionally, we may use third-party data to analyze, reach conclusions or make predictions or decisions with respect to our product candidates that may be incomplete, inaccurate or otherwise unreliable.

Further, collaborations involving our product candidates will be subject to numerous risks, which may include the following:

- collaborators, including their related or affiliated companies, may be entitled to receive exclusive rights for or involving our products;
- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources (see "*—If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies*.");
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- if an agreement with any collaborator terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely; and
- collaborators may own or co-own intellectual property covering our product candidates or technology that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our product candidates, 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, which could delay our timelines or otherwise adversely affect our business. Additionally, exclusive rights that we may grant in connection with collaboration agreements may limit our ability to enter into new or additional collaboration agreements or strategic partnerships if we experience issues with existing collaborations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new collaborations or 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 efforts to develop, manufacture and market COVID-19 therapeutics will require additional personnel who will require training, which may cause some of our employees to reallocate their time from other duties which could in turn cause delays in clinical supply of our other product candidates or trials.

We have been planning for the development of COVID-19-related product candidates. We have repurposed some of our personnel overseeing quality, clinical operations and manufacturing of their oncology product candidates to support our COVID-19 efforts and we plan to hire additional staff to support the COVID-19 efforts, which will increase our expenses. If our personnel fail to remain focused on our oncology or other infectious disease drug candidates or, if the services of employees that may have shifted to the COVID-19 efforts are not adequately covered by other employees, or if new personnel that we plan to hire to support the COVID-19 efforts require extensive training, our current oncology operations may be adversely impacted.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our existing academic collaborators and strategic partners are conducting multiple product development efforts. Such collaborators or strategic partners may develop, either alone or with others, products that are competitive with the product candidates that are the subject of these collaborations. Competing product candidates, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborator's or partner's support for our product candidates.

Some of our future collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of our product candidates. For example, in May 2019, Sorrento Therapeutics, Inc. ("Sorrento") with which we jointly established a new entity called Immunotherapy NANTibody, LLC ("NANTibody") as a stand-alone biotechnology company, commenced litigation against us and certain of our officers and directors, alleging that we improperly caused NANTibody to acquire IgDraSol, Inc. ("IgDraSol") and in January 2020 and April 2020, Sorrento sent letters purporting to terminate an exclusive license agreement with us and an exclusive license agreement with NANTibody. Additionally, in July 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Shenzhen Beike Biotechnology Co. Ltd. ("Beike") asserting breach of contract under our subsidiary Altor's license agreement with them. For more information regarding these disputes, see Note 8, *Commitments and Contingencies—Contingencies*, of the "Notes to Unaudited Condensed Combined Consolidated Financial Statements" that appear in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q. Any of these developments could harm our product development efforts.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations

In general, under Sections 382 and 383 of the Internal Revenue Code, or Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have not conducted a complete study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If we have experienced a change of control, as defined by Section 382, at any time since inception (including as a result of the merger), utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. In addition, our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

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 allows post-2017 unused NOLs to be carried forward indefinitely. Similar rules may apply under state tax laws.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us and our stockholders. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the TCJA was enacted in 2017 and significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses to 80% of current year taxable income and an elimination of net operating loss carrybacks (though any net operating losses generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. Additionally, on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act was enacted, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our transfer pricing policies may be subject to challenge by the IRS or other taxing authorities.

Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant taxing authorities may disagree with our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. We believe that our financial statements reflect adequate reserves to cover such a contingency, but there can be no assurances in that regard.

We may become subject to examinations of our tax returns by the IRS and other domestic and foreign tax authorities. An adverse outcome of any such audit or examination by the IRS or other tax authority could have a material adverse effect on our operating results and financial condition.

We may become subject to regular review and audit by the IRS and other tax authorities in various domestic and foreign jurisdictions. As a result, we may in the future receive assessments in multiple jurisdictions on various tax-related assertions. Taxing authorities may in the future challenge our tax positions and methodologies on various matters, including our positions regarding the collection of sales and use taxes, the determination and payment of value added taxes and the jurisdictions in which we are subject to taxes, which could expose us to additional taxes. We regularly assess the likelihood of adverse outcomes resulting from future tax examinations to determine the adequacy of our provision for income taxes. These assessments can require considerable estimates and judgments. The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a variety of jurisdictions. There can be no assurance that our tax positions and methodologies or calculation of our tax liabilities are accurate or that the outcomes from ongoing and future tax examinations will not have an adverse effect on our operating results and financial condition.

We will be subject to extensive regulation, which can be costly, time consuming and can subject us to unanticipated delays; even if we obtain regulatory approval for some of our product candidates, those products may still face regulatory difficulties.

Our potential products, cell processing and manufacturing activities will be subject to comprehensive regulation by the FDA in the United States and by comparable authorities in other countries. The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive and often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

No fusion protein or cell therapy using Anktiva has been approved for marketing by the FDA. Consequently, there is no precedent for the successful commercialization of products based our technologies. In addition, we have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely FDA approvals, if at all. We have not yet sought FDA approval for any adaptive cell therapy product. We will not be able to commercialize any of our potential products until we obtain FDA approval, and so any delay in obtaining, or inability to obtain, FDA approval would harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements, including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and adverse publicity, among other adverse consequences. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates. We may also be required to undertake post-marketing trials. In addition, if we or others identify side effects after any of our therapies are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn, and reformulation of our product candidates may be required.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products, if approved, may be smaller than we estimate.

We do not have verifiable internal marketing data regarding the potential size of the commercial market for our product candidates, nor have we obtained current independent marketing surveys to verify the potential size of the commercial markets for our current product candidates or any future product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. Our projections of both the number of people who have the cancers or viral diseases we are targeting, as well as the subset of people with these diseases who are in a position to receive second- or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, and may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. For instance, we expect Anktiva to initially target a small patient population that suffers from bladder cancer. Even if we obtain significant market share for our product candidates, because the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Because our current product candidates represent, and our other potential product candidates will represent novel approaches to the treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and the commercial potential of our product candidates.

Human immunotherapy products are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. The FDA may take longer than usual to come to a decision on any BLA and/or NDA that we submit and may ultimately determine that there is not enough data, information, or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect, do not work with other combination therapies or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects.

We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers who have the capability of producing our product candidates. Should any of our CMOs no longer produce our product candidates, it may take us significant time to find a replacement, if we are able to find a replacement at all.

There is no assurance that the approaches offered by our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for our proposed product candidates. The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we can reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our potential products, we will not become profitable, which would materially and adversely affect the value of our common stock. Our Anktiva therapies and our other therapies may be provided to patients in combination with other agents provided by third parties or our affiliates. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

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

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

- decreased demand for our products, if approved;
- injury to our reputation;
- withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulators, refusal to approve marketing applications or supplements, and withdrawal or limitation of product approvals;
- costs to defend litigation;
- a diversion of management’s time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- significant negative media attention;
- decrease in the price of our stock and overall value of our company;
- exhaustion of our available insurance coverage and our capital resources; or
- the inability to commercialize our product candidates.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we may develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to product liability claims for which we have no coverage. While we have obtained clinical trial insurance for our clinical trials, we may have to pay 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize among many different opportunities. Moreover, we may expend our limited resources on programs that do not yield successful product candidates as opposed to indications that may be more profitable or for which there is a greater likelihood of success.

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 product candidates. 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 and indications to pursue and how much of our resources to allocate to each. Our management must also evaluate the benefits of developing in-licensed or jointly owned technologies, which in some circumstances we may be contractually obligated to pursue, relative to developing other product candidates, indications or programs. 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.

We will face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer and viral infectious disease therapy is intense and is accentuated by the rapid pace of technological development. Research and discoveries by others may result in breakthroughs which may render our product candidates obsolete even before they generate any revenues. There are products that are approved and currently under development by others that could compete with the product candidates that we are developing. Many of our potential competitors have substantially greater research and development capabilities and approval, manufacturing, marketing, financial and managerial resources and experience than we do. Our competitors may:

- develop safer, more convenient or more effective immunotherapies and other therapeutic products;
- develop therapies that are less expensive or have better reimbursement from private or public payors;
- reach the market more rapidly, reducing the potential sales of our product candidates; or
- establish superior proprietary positions.

We will focus our efforts on oncological and infectious disease indications that are difficult to treat and with large unmet needs, and we believe our platforms will be broadly applicable across multiple tumor types and infections. Based on the breadth and depth of our platforms, we believe our competitors will range from large pharmaceutical companies to emerging novel biotechnology companies.

From an oncology perspective, we have different competitors based on modality. In the NK and T cells activation modality, we primarily compete with large pharmaceutical companies marketing checkpoint inhibitors including AstraZeneca PLC, or AstraZeneca, Bristol-Myers Squibb Company, or BMS, GlaxoSmithKline plc, or GSK, Merck & Co., Inc., or Merck, Pfizer Inc., or Pfizer, and Roche Holding AG, or Roche. The potential exists for some of these large pharmaceutical companies to seek collaboration for combination of Anktiva with their marketed checkpoint inhibitors. Also, in the NK and T cell activation modality, we will compete with immunotherapy fusion protein companies developing similar approaches including Nektar Therapeutics, Neoleukin Therapeutics, Inc. Novartis International AG, Roche, Sanofi S.A., and in the context of NMIBC, FerGene, Inc., Merck and Sesen Bio, Inc.

In the tumoricidal macrophage activation modality, we will compete with various chemotherapeutic agents, including Abraxane, doxorubicin and paclitaxel/Taxol, as well as an antibody drug conjugate produced by Immunomedics, Inc., or Immunomedics.

In the T cell memory modality, we also compete with cell therapy and chimeric antigen receptor T cell, or CAR-T cell, based companies including Allogene Therapeutics Inc., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Gilead Sciences, Inc., or Gilead, Intellia Therapeutics, Inc., Iovance Biotherapeutics, Inc. and Legend Biotech Corporation.

From an infectious disease perspective, we will compete with Abbott Laboratories Inc., or Abbott Laboratories, BMS, Gilead, and GSK, in the field of human immunodeficiency virus, or HIV.

Competitor companies focused on COVID-19 cell therapy currently include Altimmune, Inc., AstraZeneca, Athersys, Inc./Healios K.K., CanSioBio Biologics Inc., Capricor Therapeutics, Inc., CAR-T (Shanghai) Biotechnology, Cellavita Pesquisa Científica Ltda, Cellenkos, Inc., Cellular Biomedicine Group, Inc., Celularity, Inc., Sorrento Therapeutics, Inc., Chinese Academy of Sciences, Chongqing Sidemu Biotechnology Technology/ImmunCyte Life Science, Inc., Enlivex Therapeutics Ltd, Green Cross LabCell Corp., Hope Biosciences, Johnson & Johnson, Merck, Mesoblast Limited, Moderna, Inc., Novavax, Inc., Orbsen Therapeutics Limited, Pfizer/BioNTech SE, Pluristem Therapeutics, Inc., Rigshospitalet, Tianhe Stem Cell Biotechnologies Inc., University of Minnesota/Fate Therapeutics, Inc., Vaxart, Inc., Xinjiang Medical University, and many other new competitors that are emerging frequently.

A large number of companies, government agencies and academic centers around the world are developing COVID-19 vaccines, and many of these entities are in more advanced stages of development than we are, including some that have started Phase II and/or III clinical trials or have already obtained emergency regulatory approval in the United States and internationally. Even if our COVID-19 vaccine candidate is ultimately approved for marketing, the value of our opportunity will be adversely impacted by other COVID-19 vaccines that have obtained emergency regulatory approval, obtain full regulatory approval, or demonstrate better efficacy or safety than our COVID-19 vaccine candidate.

Many of these companies and our other current and potential competitors have substantially greater research and development capabilities and financial, scientific, regulatory, manufacturing, marketing, sales, human resources, and experience than we do. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the United States and internationally. Our competitors may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the market.

Universities and public and private research institutions in the United States and Europe are also potential competitors. While these universities and public and private research institutions primarily have educational objectives, they may develop proprietary technologies that lead to other FDA approved therapies or that secure patent protection that we may need for the development of our technologies and product candidates and that can be licensed or sold to other parties, including our competitors.

One of our product candidates, Anktiva, is a potential therapy for the treatment of bladder cancer and (1) when used in combination with checkpoint inhibitors, lung cancer, and (2) when used in combination with natural killer cells, metastatic pancreatic cancer and triple negative breast cancer, or TNBC. Currently, there are numerous companies that are developing various alternate treatments for bladder, pancreatic and breast cancer, including patients that have progressed after prior treatment with checkpoint inhibitors and chemotherapy. For example, Nektar Therapeutics is currently developing an immunotherapy treatment for muscle-invasive bladder cancer using an IL-2 agonist and is in Phase III clinical trials. Accordingly, Anktiva faces significant competition in the bladder, lung, pancreatic and breast cancer treatment space from multiple companies. Even if we obtain regulatory approval for Anktiva, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our therapies. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our product candidates for use in limited circumstances.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents or other intellectual property relating to our competitors' products, and our competitors may allege that our product candidates infringe, misappropriate or otherwise violate their intellectual property. See "*Risks Related to Intellectual Property.*"

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties 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.

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

We use relatively novel technologies involving the Anktiva, aldoxorubicin, hAd5 and yeast technologies and cell-based therapies and our natural killer cell platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals. Public perception may be influenced by claims, such as claims that our technologies are 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 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.

Development of a product candidate intended for use in combination with an already approved product may present more or different challenges than development of a product candidate for use as a single agent.

We are currently developing Anktiva for use along with our natural killer cell platform. We are also studying Anktiva therapy along with other product candidates, such as aldoxorubicin and hAd5 product candidates. The development of product candidates for use in combination with another product may present challenges. For example, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement. Moreover, developments related to the already approved products may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the approved product's safety of efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

A Fast Track designation, Breakthrough Therapy designation or other designation to facilitate product candidate development may not lead to faster development or a faster regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We have received, and may seek in the future, Fast Track or Breakthrough Therapy designation for current or future product candidates. Receipt of a designation to facilitate product candidate development is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions.

As a condition of approval, the FDA may require that we implement various post-marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects.

As a condition of biologic licensing, the FDA is authorized to require that sponsors of approved BLAs implement various post-market requirements, including REMS and Phase IV trials. For example, when the FDA approved Novartis' Kymriah in August 2017, a CAR-T cell therapy for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia ("ALL") that is refractory or in second or later relapse, the FDA required significant post-marketing commitments, including a Phase IV trial, revalidation of a test method, and a substantial REMS program that included, among other requirements, the certification of hospitals and their associated clinics that dispense Kymriah, which certification includes a number of requirements, the implementation of a Kymriah training program and limited distribution only to certified hospitals and their associated clinics. If we receive approval of our product candidates, the FDA may determine that similar or additional or more burdensome post-approval requirements are necessary to ensure that our product candidates are safe, pure and potent. To the extent that we are required to establish and implement any post-approval requirements, we will likely need to invest a significant amount of time, effort and money. Such post-approval requirements may also limit the commercial prospects of our product candidates.

We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties or related parties to market and sell our product candidates, if they are approved, and as a result, we may be unable to generate product revenues.

We currently do not have a commercial infrastructure for the marketing, sale and distribution of our products. If approved, in order to commercialize our product candidates, we must build our marketing, sales and distribution capabilities or arrange with third parties to perform these services, which will take time and require significant financial expenditures and we may not be successful in doing so. There are risks involved with establishing our own marketing and sales capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Even if we are able to effectively establish a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we would have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have little to no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. The establishment and development of commercial capabilities, including a comprehensive healthcare compliance program, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We, or our collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage and retain medical affairs, marketing, sales and commercial support personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Factors that may inhibit our efforts to commercialize our current or future product candidates and generate product revenues include:

- if the COVID-19 pandemic continues or reoccurs it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;

- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

We have not commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of our product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch from, existing therapies even when new and potentially more effective or safer treatments enter the market. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the continued safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with such product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration of such product candidates;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- the timing of market introduction of such product candidates, as well as competitive products;
- our ability to offer such product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the approval of other new products for the same indications;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenues from our product candidates, in which case we would not expect to become profitable.

Our product candidates may face competition sooner than anticipated.

The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, the FDA cannot make an approval of an application for a biosimilar product effective until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest or other related entity do not qualify for the 12-year exclusivity period.

Our product candidates may qualify for the BPCIA's 12-year period of exclusivity. However, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not block companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Changes may also be made to this exclusivity period as a result of future legislation as there have been ongoing efforts to reduce the period of exclusivity. Even if we receive a period of BPCIA exclusivity for our first licensed product, if subsequent products do not include a modification to the structure of the product that impacts safety, purity, or potency, we may not receive additional periods of exclusivity for those products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference product candidates in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Medicare Part B encourages use of biosimilars by paying the provider the same percentage of the reference product average sale price as a mark-up, regardless of which product is reimbursed. It is also possible that payors will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability.

For our small molecular product candidates, if qualified, the regulatory exclusivity period is less than for our biologic product candidates. The Federal Food, Drug, and Cosmetic Act ("FDCA") provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

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

Any name we intend to use for our product candidates in the United States will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe or otherwise violate 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 product name in a timely manner or at all, which would limit our ability to commercialize our product candidates.

We will be dependent on information technology, systems, infrastructure and data. Our internal computer systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may fail or suffer security breaches.

We will be dependent upon information technology systems, infrastructure and data. In the ordinary course of our business, we will directly or indirectly collect, store and transmit sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance and transmission of this information is critical to our operations. The multitude and complexity of our computer systems and those of our CROs, CMOs, clinical sites or other contractors or consultants make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Data privacy or security breaches by third parties, employees, contractors or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public. Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, clinical sites and other contractors and consultants are vulnerable to failure or damage from computer viruses and other malware, employee error, unauthorized and authorized access or other cybersecurity attacks, natural disasters, terrorism, war, fire and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Cyberattacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. While we and our shared services partner, NantWorks, have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants will prevent service interruptions, or identify breaches in our or their systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

If any such event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required. 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 personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Our business could be adversely affected by the effects of health epidemics, pandemics or contagious diseases, including the recent pandemic of the disease caused by the novel coronavirus SARS-CoV-2 or COVID-19, including its currently known and unknown variants, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.

Outbreaks of epidemic, pandemic or contagious diseases, such as the COVID-19 pandemic, may significantly disrupt our operations and adversely affect our business, financial condition and results of operations. In March 2020, the World Health Organization (“WHO”) declared the outbreak of the COVID-19 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. The COVID-19 pandemic, including currently known and unknown variants of COVID-19, could materially affect our operations, including at our headquarters and at our manufacturing facilities, which are currently subject to state executive orders and shelter-in-place orders, and at our clinical trial sites, as well as the business or operations of our other manufacturers, CROs, CMOs, clinical sites or other third parties with whom we conduct business.

Executive orders have been issued by state and local governments in California and elsewhere, and states of emergency have been declared at the state and local level in most jurisdictions throughout the United States. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the COVID-19 pandemic or other infectious diseases could impact our personnel or personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. We are monitoring a number of risks related to this pandemic, including the following:

- Financial: 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 during the year-ended December 31, 2021 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.
- Supply Chain: An extended duration of this pandemic could result in significant disruptions in our respective supply chains and distribution channels 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 have manufactured certain product candidates for clinical supply.
- Clinical Trials: This pandemic may 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, at least 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 Environment: The impact of the COVID-19 pandemic could result in a prolonged recession or depression in the United States 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 United States and global capital markets, which could result in a decline in stock price, 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 have been highly volatile as a result of the COVID-19 pandemic.
- Regulatory Reviews: The operations of the 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 IND applications, BLAs, and/or NDAs.

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 and related 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 have 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 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 acquire 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 manufacturing facilities may be negatively impacted by the ongoing COVID-19 pandemic.

The COVID-19 pandemic, including any actions we have taken in response, may disrupt our internal operations, including by heightening the risk that a significant portion of our workforce could suffer illness or otherwise not be permitted or be unable to work, and required that certain of our employees work remotely, which has heightened certain risks, including those related to cybersecurity and internal controls. Additionally the COVID-19 pandemic has impacted, and may continue to impact, our office and manufacturing locations, as well as our analytical, process development, and transitional research teams, including through the effects of facility closures, reductions in operating hours and other social distancing efforts. For example, if even a small number of our employees in our working clusters related to manufacturing, analytical, process development, or translational research, tested positive for COVID-19, it would require us to temporarily close a number of our offices or manufacturing facilities and temporarily suspend operations in order to conduct a deep clean of the facilities in order to ensure the safety of our employees. Additionally, we cannot predict whether these conditions and concerns will continue or whether we will experience more significant or frequent disruptions in the future, including the complete closure of one or more of our facilities.

Our failure to comply with state, national and/or international data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

There are numerous laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act (“HIPAA”) and associated regulations. For example, California recently enacted legislation—the California Consumer Privacy Act (“CCPA”)—which went into effect on January 1, 2020. The CCPA, among other things, creates new data privacy and security obligations for covered companies and provides new privacy rights to California consumers, including the right to opt out of certain disclosures of their information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. Additionally, a new privacy law, the California Privacy Rights Act (“CPRA”), was approved by California voters in November 2020. The CPRA significantly modified the CCPA, which may require us to modify our practices and policies and may further increase our compliance costs and potential liability. To the extent these state laws as well as other federal and state privacy laws, including new laws and changes in existing laws, apply to our business and operations, our compliance costs and potential liability with respect to personal information we collect could expose us to great liability and increase compliance costs.

There are also various laws and regulations in other jurisdictions relating to privacy and security. For example, European Union (“EU”) member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the EU Data Protection Directive, which formerly governed the collection, processing and other use of personal health or other data in the EU, was replaced with the EU General Data Protection Regulation (“GDPR”) in May 2018. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to such individuals, the security and confidentiality of the personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the United States, 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 entity, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information.

Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, could adversely affect our business, financial condition and results of operations, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The recent implementation of the CCPA and GDPR has increased 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 CCPA, GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, 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 United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will be heavily dependent on our senior management, particularly Dr. Soon-Shiong, our Executive Chairman, 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 our future development depend to a significant extent upon the performance and active participation of certain key individuals, particularly Dr. Soon-Shiong, our Executive Chairman. Although Dr. Soon-Shiong focuses heavily on our matters and is highly active in our management, he does devote a significant amount of his time to a number of different endeavors and companies, including NantHealth, Inc., NantMedia Holdings, LLC (which operates the Los Angeles Times and the San Diego Union-Tribune) 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, his role in our company and his public reputation. We may also be dependent on additional funding from Dr. Soon-Shiong and his affiliates, which may not be available when needed and which he is under no obligation to provide. If we were to lose the services of Dr. Soon-Shiong for a short or an extended time, for any reason, including, for example, due to 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, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards 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. We do not have employment agreements with our key employees and all of our employees are hired on an "at-will" basis, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. 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.

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

Our operations will be dependent upon the services of our executives and our employees who are engaged in research and development. The loss of the services of our executive officers or senior research personnel could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business plan, we will have to hire additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. However, competition for qualified employees among companies in the biotechnology and biopharmaceutical industry is intense, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future we expect to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, compliance or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development, and commercialization goals on a timely basis, or at all.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company or product, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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 may become involved in securities litigation or stockholder derivative litigation in connection with the merger with ImmunityBio, and this could divert the attention of our management and harm our business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. We are involved in this type of litigation in connection with the merger with ImmunityBio, and we may become involved in this type of litigation in the future. Litigation often is expensive and diverts management’s attention and resources, which could adversely affect our business and the combined company.

We expect to rely on third parties to perform many essential services for any products that we commercialize, including services related to distribution, government price reporting, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We expect to retain third-party service providers to perform a variety of functions related to the sale of our current or future product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management, and cash collection. If we retain a service provider, we would substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage in the future with third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, we may contract in the future with a third party to calculate and report pricing information mandated by various government programs. If a third party fails to timely report or adjust prices as required or errs in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability, and potentially subject us to regulatory sanctions or FCA lawsuits.

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.

In order to market and sell our product candidates outside the United States, we or our third-party collaborators may be required to obtain separate marketing approvals and comply with numerous and varying regulatory requirements. 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. Approval policies and requirements may vary among jurisdictions. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates is also subject to approval. We or our collaborators may not be able to file for regulatory approval of our product candidates in international jurisdictions or obtain approvals from regulatory authorities outside the United States on a timely basis, if at all.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates 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.

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;

- 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 never commercialized a product candidate before, and we may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no therapeutic sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA or NDA to the FDA, or similar approval filings to comparable foreign authorities. BLAs and NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and efficacy for NDAs, or safety, purity and potency for BLAs, for each desired indication. Additionally, the patient population is defined per the discussion with the FDA as patients who have progressed following initial systemic therapy for recurrent or metastatic disease, which include many of the more advanced patients enrolled to date. Our current beliefs regarding the registration pathway for our Anktiva product candidate are based on our interpretation of our communications with the FDA to date and its efforts to address such communications, which may be incorrect. Further, enrollment in our trials may need to be further adjusted based on future feedback from the FDA or other regulatory agency input. The revised protocol which further defines the patient population to include more advanced patients in the study, may have an adverse effect on the results reported to date, changes to implement an independent review committee and assay validation and implementation, and the data within this study may not ultimately be supportive of product approval, all of which could result in significant delays to our currently anticipated timeline for development and approval of our product candidates or prevent their approval entirely.

We may also experience delays, including delays arising from the need to increase enrollment, in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB or central IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;

- manufacturing sufficient quantities of qualified materials under cGMP and applying them on a subject by subject basis for use in clinical trials; or
- timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted by the FDA or other regulatory authorities, or recommended for suspension or termination by DSMBs due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues.

Results for any patient who receives compassionate use access to our product candidates should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial, and cannot be used to establish safety or efficacy for regulatory approval.

We often receive requests for compassionate use access to our investigational drugs by patients that do not meet the entry criteria for enrollment into our clinical trials. Generally, patients requesting compassionate use have no other treatment alternatives for life threatening conditions. We evaluate each compassionate use request on an individual basis, and in some cases grant access to our investigational product candidates outside of our sponsored clinical trials if a physician certifies that the patient receiving treatment is critically ill and does not meet the entry criteria for one of our open clinical trials. Individual patient results from compassionate use access may not be used to support submission of a regulatory application, may not support approval of a product candidate and should not be considered to be indicative of results from any on-going or future well-controlled clinical trial. Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication we are seeking approval. The results of our compassionate use program may not be used to establish safety or efficacy or regulatory approval.

The clinical and commercial utility of our product candidates are uncertain and may never be realized.

Our current product candidates are in the early stages of development. We currently have ongoing clinical trials to evaluate our respective product candidates. 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 Anktiva or therapies that meet our minimum specifications. In addition, Anktiva and many of our other product candidates have 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 product candidates 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 our product candidate 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 our product candidates are safe. We do not have data on possible harmful long-term effects of our 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 product candidates is uncertain and is subject to significant risk.

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require post-approval Phase IV trials. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance, including requirements related to product design, testing, clinical trials and preclinical studies approval, manufacturing processes and quality, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, marketing, promotion, sale, import, export, submissions of safety and other post-marketing information and reports such as deviation reports, registration, product listing, annual user fees, and recordkeeping for our product candidates. We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. The cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, that the product is less effective than previously thought, problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing, distribution, or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- restrictions on the labeling of our product candidates, including required additional warnings, such as black box warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- changes to product labeling or the way the product is administered;
- liability for harm caused to patients or subjects;
- fines, restitution, disgorgement, warning letters, untitled letters, or holds on or termination of clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates;
- injunctions or the imposition of civil or criminal penalties, including imprisonment;
- FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the biologic;
- reputational harm; or
- the product becoming less competitive.

Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

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

Our GMP-in-a-Box will be regulated by the FDA as a medical device, and regulatory compliance for medical devices is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies.

FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- laboratory and preclinical studies and clinical trials;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Medical devices regulated by the FDA are subject to general controls which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMP under Quality Systems Regulations; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as 510(k)-exempt devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the general controls, some Class II medical devices are also subject to special controls, including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to pre-market approval, or PMA.

The FDA can also refuse to clear or approve pre-market applications for any medical device we develop. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition and results of operations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, for any medical device products we develop, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals for any medical device products, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. The FDA also regulates the advertising and promotion of medical devices to ensure that the claims are consistent with their regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Any medical device products we develop will be subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential medical device products and material modifications will be subject to extensive regulation and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution as well as after clearance or approval. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing, or labeling our medical device products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. If any of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

We will be 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 product candidates will be 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 product candidates and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our product candidates or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our product candidates and solutions in international markets, prevent customers from using our product candidates and solutions or, in some cases, prevent the export or import of our product candidates and solutions to certain countries, governments or persons altogether. Any limitations on our ability to export, provide, or sell our product candidates 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 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 use CROs abroad for clinical trials. In addition, we may engage third-party intermediaries to sell our product candidates 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 have adopted an anti-corruption policy, which 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. Non-compliance 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.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

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

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

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

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.

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, the Securities and Exchange Commission, or the 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. In response to the COVID-19 pandemic, in 2020, the FDA had announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. According to FDA's 2021 guidance on manufacturing, supply chain, and drug and biological product inspections during COVID-19 public health emergency, FDA indicated that it intends to continue using other tools and approaches where possible for pre-approval inspections, and that it will continue to conduct "mission-critical" inspections on a case-by-case basis, or, where possible to do so safely, resume prioritized domestic inspections, such as pre-approval and surveillance inspections. If a prolonged government shutdown occurs, or if the government experiences a protracted backlog of inspections and regulatory review, 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, delays, or prioritization policies could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If we fail to comply with federal and state healthcare and promotional laws, including fraud and abuse and information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a biopharmaceutical company, we are subject to many federal and state healthcare laws, including the federal Anti-Kickback Statute, or AKS, the FCA, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the federal Physician Payment Sunshine Act, the Veterans Health Care Act of 1992, HIPAA (as amended by the Health Information Technology for Economics and Clinical Health Act), the FCPA, the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act), or the ACA, and similar state laws. Even though we do not make referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we do not comply with all applicable fraud and abuse laws, we may be subject to healthcare fraud and abuse enforcement by both the federal government and the states in which we conduct our business.

Laws and regulations require calculation and reporting of complex pricing information for prescription drugs, and compliance will require us to invest in significant resources to develop a price reporting infrastructure, or depend on third parties to compute and report our drug pricing. Pricing reported to the Centers for Medicare and Medicaid Services, or CMS, must be certified. Non-compliant activities expose us to FCA risk if they result in overcharging agencies, underpaying rebates to agencies, or causing agencies to overpay providers.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote our product candidates for those indications and uses, referred to as off-label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our product candidates including claims comparing our product candidates to other companies' products and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These false claims statutes include the FCA, which allows any individual to bring a lawsuit against a biopharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These FCA lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our future collaborators do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenues from our product candidates.

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. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party 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 of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our product candidates. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA or BLA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our product candidates, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenues and profitability will suffer. Moreover, the recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals and other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

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 and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- 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.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. A particular challenge for our product candidates arises from the fact that they will primarily be used in an inpatient setting. Inpatient reimbursement generally relies on stringent packaging rules that may mean that there is no separate payment for our product candidates. Additionally, data used to set the payment rates for inpatient admissions is usually several years old and would not take into account all of the additional therapy costs associated with the administration of our product candidates. If special rules are not created for reimbursement for immunotherapy treatments such as our product candidates, hospitals might not receive enough reimbursement to cover their costs of treatment, which will have a negative effect on their adoption of our product candidates.

We are subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our product candidates, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

Since enactment of the ACA in 2010, in both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates profitably. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction including implementation of aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect until 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or ATRA, was approved which, among other things, reduced Medicare payments to several providers, with primary focus on the hospital outpatient setting and ancillary services, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since its enactment, various portions of the ACA have been subject to judicial and constitutional challenges. In particular, on December 14, 2018, the U.S. District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter. On December 18, 2019, the Fifth Circuit ruled that the ACA's individual mandate is unconstitutional given that the Tax Act eliminated the tax penalty associated with the individual mandate. In concluding that the individual mandate is unconstitutional, the question remains whether, or how much of, the rest of the ACA is severable from that constitutional defect. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. The Supreme Court of the United States held oral arguments on the Fifth Circuit Court case in November 2020 and is expected to issue a decision later in 2021. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among other directives. It is unclear how this Supreme Court decision, future litigation, and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Additional federal and state healthcare reform measures may be adopted in the future that may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased revenues from our biopharmaceutical product candidates, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In addition, there have been increasing legislative efforts and enforcement interest in the United States with respect to drug pricing practices, including Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives, some of which resulted in lawsuits against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the Biden administration on us and the pharmaceutical industry as a whole remains unclear. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

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

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, 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 coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, 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 laws in the United States and similar foreign fraudulent misconduct laws, 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 product candidates in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter misconduct or other improper activities by our employees or third parties that we engage for our business operations, including independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors, 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 comply 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, or our employees', consultants', collaborators', contractors', or vendors' business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, compliance agreements, withdrawal of product approvals, and curtailment of our operations, among other things, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our product candidates and technologies, we may not be able to compete effectively or operate profitably.

Our success is dependent in large part on our obtaining, maintaining, protecting and enforcing patents and other proprietary rights in the United States and other countries with respect to our product candidates and technology and on our ability to avoid infringing the intellectual property and other proprietary rights of others. Certain of our intellectual property rights are licensed from other entities, and as such the preparation and prosecution of any such patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date.

The issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be provided by our patents, including if they are challenged in court or in other proceedings, such as re-examinations or oppositions, which may be brought in the United States or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, it is possible that competitors may infringe our patents or successfully avoid the patented technology through design innovation. To stop these activities, we may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if we were successful in stopping the violation of our patent rights. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the grounds that its activities are not covered by, that is, do not infringe, our patents.

Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office ("USPTO") to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the United States, or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the first-inventor-to-file law in the United States. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may be required to cease using the technology or to license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding or derivation proceeding. A prevailing party in that case may not offer us a license on commercially acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in-licensed pending and future patent applications may not result in patents being issued which protect our Anktiva, hAd5, aldoxorubicin or other product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our Anktiva, hAd5 or other product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our Anktiva, hAd5 or other product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our Anktiva, hAd5 or other product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. In addition, certain of our licensors co-own the patents and patent applications we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors also may become involved in inventorship, priority or validity disputes. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our owed or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or other technologies, the defendant could counterclaim that the patent is invalid and/or unenforceable or that we infringe their patents. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or other applicable body, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of such litigation or other proceeding because they have substantially greater resources. Such proceedings could result in revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our product candidates or technologies. 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, our licensor, our or our licensor's patent counsel and the patent examiner were unaware during prosecution. If a third party 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, financial condition, results of operations and prospects.

The use of our technology and product candidates could potentially conflict with the rights of others, and third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product candidates and technologies.

Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biopharmaceutical industry. Our potential competitors or other parties may have, develop or acquire patent or other intellectual property rights that they could assert against us. If they do so, then we may be required to alter our product candidates, pay licensing fees or cease our development and commercialization activities with respect to the applicable product candidates or technologies. If our product candidates conflict with patent or other intellectual property rights of others, such parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing, use and marketing of the affected products.

Although we have conducted freedom-to-operate, or FTO, analyses of the patent landscape with respect to our lead product candidates and continue to undertake FTO analyses of our manufacturing processes, our Anktiva product candidate, and contemplated future processes and products, because patent applications do not publish for 18 months, and because the claims of patent applications can change over time, no FTO analysis can be considered exhaustive. We may not be aware of patents that have already been issued and that a competitor or other third party might assert are infringed by our current or future product candidates or technologies. It is also possible that we could be found to have infringed patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or technologies may infringe. Furthermore, patent and other intellectual property rights in biotechnology remains an evolving area with many risks and uncertainties. As such, we may not be able to ensure that we can market our product candidates without conflict with the rights of others.

If intellectual property-related legal actions asserted against us are successful, in addition to any potential liability for damages (including treble damages and attorneys' fees for willful infringement), we could be enjoined from, or required to obtain a license to continue, manufacturing, promoting the use of or marketing the affected products. We may not prevail in any legal action and a required license under the applicable patent or other intellectual property may not be available on acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be required to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. 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. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensors to pay these fees and take the necessary actions to comply with these requirements. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse impact on our business, financial condition, results of operations and prospects.

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

As is the case with other immunotherapy and biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our product candidates or other technologies or invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter parte*s review, and derivation proceedings. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. 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. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. While we do not believe that any of the patents owned or licensed by us will be found invalid based on the foregoing, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

Our rights to develop and commercialize our product candidates and technologies are subject, in part, to the terms and conditions of licenses granted to us by others.

We will rely on licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of aldoxorubicin and products enabled by our yeast, including Tarmogen, technologies. For example, in July 2017, we entered into an exclusive license agreement with CytRx Corporation, or CytRx, pursuant to which we received an exclusive license to certain of CytRx's intellectual property relating to aldoxorubicin. In January 2020 we entered into an exclusive license agreement with GlobeImmune, Inc., or GlobeImmune, pursuant to which we obtained an exclusive license to certain of GlobeImmune's intellectual property relating to their Tarmogen platform to complement our proprietary yeast technology. In August 2020, we entered into an exclusive license agreement with iosBio Ltd., formerly named Stabilitech Biopharma Ltd., or iosBio, pursuant to which iosBio granted us an exclusive license to certain of iosBio's intellectual property rights relating to the SARS-CoV-2 and successor vaccine candidates (and, in connection with such license, we granted iosBio a non-exclusive license relating to its adenovirus constructs for the prevention and treatment of shingles and other infectious disease targets to be mutually agreed by the parties in good faith).

License agreements may not provide exclusive rights to use certain licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that also utilizes technology that we have in-licensed.

In addition, subject to the terms of any such license agreements, we do not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed or out-licensed patents and patent applications that are controlled by our licensors or licensees will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors or licensees fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize Anktiva and any of our product candidates that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, certain of our in-licensed intellectual property was funded in part by the U.S. government. As a result, the U.S. government may have certain rights to such intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States in certain circumstances if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and growth prospects.

If we fail to comply with our obligations in 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.

We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or continue to utilize our existing technology, which could harm our business, financial condition, results of operations and growth prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In addition, each of our license agreements, and we expect our future agreements, will impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates or of Anktiva. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

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

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

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed trade secrets or other confidential information of third parties or claims asserting ownership of what we regard as our own intellectual property.

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

In addition, while it is our policy to require our employees, consultants and independent contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

An element of our intellectual property strategy is to license intellectual property rights and technologies from third parties and/or our affiliates. Other parties, including our competitors or our affiliates, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. In addition, with respect to any patents we co-own with other parties, including our affiliates, we may require licenses to such co-owners' interest to such patents. The licensing or acquisition of intellectual property rights is a competitive area, and other more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties and/or our affiliates. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future additional product candidates and could increase the cost, and extend the timelines associated with our development, of such other products, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and growth prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our Anktiva product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our Anktiva product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

In addition to seeking patents for Anktiva, hAd5 and yeast technologies and other product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

One of our issued U.S. patents is subject to a claim challenging the inventorship.

On September 10, 2020, a legal complaint was filed in a California court where Institute for Cancer Research (d/b/a Fox Chase Cancer Center) argued that it has a co-ownership interest in U.S. Patent No. 10,456,420 and its underlying U.S. Patent Application No. 15/529,848, as well as in certain related patent applications or issued patents that include claimed subject matter allegedly invented by one of the claimant's employees. On September 30, 2020, we filed motion with the court asking that the complaint be dismissed. We disagree that this claim for co-ownership has merit and intends to vigorously defend our position. All of the existing named inventors have assigned their rights in this patent to us. We will continue to have an undivided interest in the entire patent even if claimant succeeds in this suit. However, litigating this matter could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Common Stock

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

Our Executive Chairman, Dr. Soon-Shiong, is the founder of NantWorks, LLC ("NantWorks"). The various NantWorks companies are currently exploring opportunities in the immunotherapy, oncology, 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 their efforts to develop their product pipelines. 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 their clinical trials. If Dr. Soon-Shiong were to cease his affiliation with us or 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 revenues that is at least proportional to the costs that we will incur in commercializing the product candidate.

We have entered into shared services agreements with NantWorks, pursuant to which NantWorks and its affiliates provide corporate, general and administrative and other support services to us. 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. In addition, the loss of the services of NantWorks might significantly delay or prevent the development of our product candidates 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.

Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.

Dr. Soon-Shiong, through his direct and indirect ownership of the company's common stock, has voting control of the company. As of March 31, 2021, Dr. Soon-Shiong and certain of his affiliates beneficially own approximately 81.8% of the company's common stock outstanding. Additionally, an affiliate of Dr. Soon-Shiong holds a warrant to purchase an additional 1,638,000 shares of the company's common stock that will become exercisable if certain performance conditions are satisfied. Dr. Soon-Shiong and his related party also hold approximately $279.5 million in the aggregate of contingent value rights ("CVRs") issued to the former stockholders of Altor BioScience Corporation (succeeded by Altor BioScience LLC) ("Altor") in connection with NantCell's acquisition of Altor. If the underlying conditions for payment are met, the CVRs become payable in cash or shares of the company's common stock or any combination as the holder elects. Dr. Soon-Shiong and his related party have irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs.

Dr. Soon-Shiong is in a position to control the outcome of corporate actions that require, or may be accomplished by, stockholder approval, including amending the bylaws of the company, the election or removal of directors and transactions involving a change of control. Dr. Soon-Shiong's controlling ownership could limit the ability of the remaining stockholders of the company to influence corporate matters, and the interests of Dr. Soon-Shiong may not coincide with the company's interests or the interests of its remaining stockholders. In addition, entities affiliated with Dr. Soon-Shiong hold promissory representing $297.5 million in indebtedness, including interest thereon, of the company as of March 31, 2021.

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 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 common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.

Although our common stock is listed on The Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The 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 liquidity position and the amount and nature of any debt we may incur;
- 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;
- 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;
- general economic slowdowns;
- coordinated actions by independent third-party actors to affect the price of certain stocks, coordinated via the Internet and otherwise; and
- 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, our Executive Chairman, Dr. Soon-Shiong, and his affiliates currently beneficially own approximately 81.8% of our outstanding shares of common stock. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

Certain holders 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 an 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 as a public company. To raise capital, we may sell common stock, including as part of the offering, issuance and sale by us of up to a maximum aggregate offering of $500.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement with Jefferies LLC, or the ATM, 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, including through the ATM, convertible securities or other equity securities, investors may be materially diluted 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 no longer qualify as a "smaller reporting company," we have incurred and will continue to incur significant additional legal, accounting and other expenses as a result of operating as a public company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the 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 will 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 may be 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. 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. In addition, we are required to disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we no longer qualify as a "smaller reporting company," we will be required to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. To date, we have not engaged our independent registered public accounting firm to perform an audit of, and give an opinion on, our internal control over financial reporting. 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 if or when our auditor conducts such audit and delivers an opinion.

In the normal course of business our controls and procedures 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 investors could lose 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.

Operating as a public company makes it more expensive for us to obtain directors' and officers' 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 stockholders' 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 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 Executive Chairman, 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. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements. However, our board of directors is currently comprised of a majority of independent directors.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.

Although we no longer qualify as an emerging growth company, we qualify as a "smaller reporting company" during fiscal year 2021, which allows 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. 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; and
- reduced disclosure obligations regarding executive compensation.

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.

We could be subject to additional income tax liabilities.

We are a U.S.-based company subject to tax in the U.S. and certain foreign tax jurisdictions. 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.

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.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, which was approved by Congress on December 20, 2017 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. We have generally accounted for such changes in accordance with our understanding of the TCJA and guidance available as of the date of this filing as described in more detail in our financial statements. The CARES Act, which was signed into law on March 27, 2020, further modified the TCJA and we will continue to monitor and assess the impact of the federal legislation on our business and the extent to which various states conform to the newly enacted federal tax law. In addition, adverse changes in the financial outlook of our operations or further changes in tax laws or regulations 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.

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 Executive Chairman (who, with members of his immediate family and entities affiliated with him, currently beneficially own, in the aggregate, approximately 81.8% of our common stock as of March 31, 2021) 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.

Form 8-K/Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(e) Richard Adcock, our Chief Executive Officer, President and member of our Board of Directors, had previously received an award of restricted stock units, or RSUs, in NantCell (formerly known as ImmunityBio, Inc., a private company). On March 9, 2021, in connection with the closing of the Merger, these RSUs in NantCell were assumed by the Company and converted (using the Exchange Ratio of 0.8190) into RSUs, on the same terms and conditions immediately prior to the Merger, to purchase 172,420 shares of the Company's common stock. The RSUs subject to Mr. Adcock's award shall vest as follows: five percent (5%) will vest on September 9, 2021; five percent (5%) will vest on the earlier of (A) December 31, 2022 and (B) the 60th day following approval by the FDA of a biologics license application or equivalent application for approval of Anktiva for use in the treatment of non-muscle invasive bladder cancer; twenty percent (20%) will vest on December 31, 2023; twenty percent (20%) will vest on December 31, 2024; twenty percent (20%) will vest on December 31, 2025; and the remaining thirty percent (30%) will vest on December 31, 2026.

(f) On May 12, 2021, the Compensation Committee of the Company's Board of Directors approved the payment of cash bonuses to the Company's named executive officers for the 2020 fiscal year in the following amounts:

- Richard Adcock, Chief Executive Officer and President of the Company (served as Chief Executive Officer during 2020 from hire date of October 26, 2020), 100% of target bonus, prorated from date of hire, equivalent to $67,808;
- David Sachs, Chief Financial Officer of the Company (served as Chief Financial Officer of privately held NantCell during 2020), 100% of target bonus, equivalent to $193,500;
- Barry Simon, M.D., Chief Corporate Affairs Officer of the Company (served as President and Chief Administrative Officer during 2020), 75% of target bonus, equivalent to $152,786; and
- Sonja Nelson, Senior Vice President, Finance of the Company (served as Chief Financial Officer during 2020), 100% of target bonus, equivalent to $147,000

As previously disclosed, Dr. Patrick Soon-Shiong is no longer compensated as an executive of the Company and therefore did not receive a cash bonus for 2020.

The bonus payments are consistent with the previously disclosed terms of the employment agreements or offer letters of each executive offer listed above, and the cash bonus awards were based on the Compensation Committee's consideration of achievement of operational and financial goals plus a discretionary component.

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 of Exhibit
2.1	Agreement and Plan of Merger, dated as of December 21, 2020, by and among ImmunityBio, Inc. (f/k/a NantKwest, Inc.), NantCell, Inc. (f/k/a ImmunityBio, Inc.) and Nectarine Merger Sub, Inc. (filed as Exhibit 2.1 to the company's Current Report on Form 8-K filed with the SEC on December 22, 2020).
3.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. (f/k/a NantKwest, Inc.) dated March 9, 2021 (filed as Exhibit 3.1 to the company's Form 8-K filed with the SEC on March 10, 2021).
10.2#^	Offer Letter, dated August 3, 2020, by and among ImmunityBio, Inc. and David Sachs (filed as Exhibit 10.31 to the company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021).
99.2	Combined Consolidated Financial Statements of ImmunityBio, Inc. as of December 31, 2020 and December 31, 2019 (including NantCell, Inc.) (filed as Exhibit 99.2 to the company's Current Report on Form 8-K/A filed with the SEC on April 22, 2021).
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	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* 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 ImmunityBio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

# Indicates management contract or compensatory plan.

^ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(a)(6).

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.

IMMUNITYBIO, INC.

Date: May 14, 2021

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer
(Principal Executive Officer)

Date: May 14, 2021

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Richard Adcock, certify that:

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

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

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

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

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 14, 2021

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer and President
(*Principal Executive Officer*)

Exhibit 31.2

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

I, David C. Sachs, certify that:

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

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

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

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

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 14, 2021

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

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, Richard Adcock, the chief executive officer of ImmunityBio, 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, 2021 (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 14, 2021

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer and President
(*Principal Executive Officer*)

Exhibit 32.2

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

I, David C. Sachs, the chief financial officer of ImmunityBio, 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, 2021 (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 14, 2021

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial and Accounting Officer)