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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 June 30, 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 August 10, 2021 was 391,156,513 (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 Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,958	$ 34,915
Marketable securities	19,970	61,146
Due from related parties	2,047	2,003
Prepaid expenses and other current assets (including amounts with related parties)	7,756	13,649
Total current assets	113,731	111,713
Marketable securities, noncurrent	822	950
Property, plant and equipment, net	89,023	72,541
Non-marketable equity investment	—	7,849
Intangible asset, net	1,445	1,463
Convertible note receivable	6,253	6,129
Operating lease right-of-use assets, net (including amounts with related parties)	28,230	18,138
Other assets (including amounts with related parties)	6,797	2,598
Total assets	$ 246,301	$ 221,381
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 19,153	$ 11,510
Accrued expenses and other liabilities	36,134	36,771
Due to related parties	16,711	14,838
Operating lease liabilities (including amounts with related parties)	2,430	5,015
Total current liabilities	74,428	68,134
Related-party notes payable	300,252	254,353
Operating lease liabilities, less current portion (including amounts with related parties)	29,116	16,179
Deferred income tax liability	170	170
Other liabilities	920	1,035
Total liabilities	404,886	339,871
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 390,347,740 and 382,243,142 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; excluding treasury stock, 163,800 shares outstanding as of June 30, 2021 and December 31, 2020, respectively	39	38
Additional paid-in capital	1,625,018	1,495,163
Accumulated deficit	(1,783,033)	(1,615,131)
Accumulated other comprehensive income	37	122
Total ImmunityBio stockholders' deficit	(157,939)	(119,808)
Noncontrolling interests	(646)	1,318
Total stockholders' deficit	(158,585)	(118,490)
Total liabilities and stockholders' deficit	$ 246,301	$ 221,381

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 339	$ 436	$ 478	$ 601
Operating expenses:				
Research and development (including amounts with related parties)	53,800	33,005	94,928	60,379
Selling, general and administrative (including amounts with related parties)	32,445	18,347	77,720	27,840
Total operating expenses	86,245	51,352	172,648	88,219
Loss from operations	(85,906)	(50,916)	(172,170)	(87,618)
Other (expense) income:				
Interest and investment (loss) income, net	(177)	986	8,767	1,064
Interest expense (including amounts with related parties)	(3,577)	(2,123)	(6,745)	(4,012)
Other income, net (including amounts with related parties)	277	81	290	1,185
Total other (expense) income	(3,477)	(1,056)	2,312	(1,763)
Loss before income taxes and noncontrolling interests	(89,383)	(51,972)	(169,858)	(89,381)
Income tax expense	(2)	(45)	(8)	(63)
Net loss	(89,385)	(52,017)	(169,866)	(89,444)
Net loss attributable to noncontrolling interests, net of tax	(1,097)	(578)	(1,964)	(967)
Net loss attributable to ImmunityBio common stockholders	$ (88,288)	$ (51,439)	$ (167,902)	$ (88,477)
Net loss per ImmunityBio common share – basic and diluted	$ (0.23)	$ (0.14)	$ (0.44)	$ (0.24)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	384,820,486	372,286,278	383,939,031	372,137,752

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (89,385)	$ (52,017)	$ (169,866)	$ (89,444)
Other comprehensive income (loss), net of income taxes:				
Net unrealized gains on available-for-sale securities	18	29	17	5
Foreign currency translation adjustments	60	(63)	(102)	7
Reclassification of net realized gains on available-for-sale securities included in net loss	(3)	(1)	—	—
Total other comprehensive income (loss)	75	(35)	(85)	12
Comprehensive loss	(89,310)	(52,052)	(169,951)	(89,432)
Less: Comprehensive loss attributable to noncontrolling interests	(1,097)	(578)	(1,964)	(967)
Comprehensive loss attributable to ImmunityBio common stockholders	$ (88,213)	$ (51,474)	$ (167,987)	$ (88,465)

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

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

Three Months Ended June 30, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
Balance as of March 31, 2021	383,067,321	$ 38	$ 1,508,958	$ (1,694,745)	$ (38)	$ (185,787)	$ 451	$ (185,336)
Issuance of common stock under "at-the market" offering net of commissions and offering costs of $3,077	6,420,441	1	94,886	—	—	94,887	—	94,887
Stock-based compensation expense	—	—	17,863	—	—	17,863	—	17,863
Exercise of stock options	759,639	—	3,311	—	—	3,311	—	3,311
Vesting of restricted stock units (RSUs)	100,359	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(20)	—	—	—	—	—	—	—
Other comprehensive income, net of tax	—	—	—	—	75	75	—	75
Net loss	—	—	—	(88,288)	—	(88,288)	(1,097)	(89,385)
Balance as of June 30, 2021	390,347,740	$ 39	$ 1,625,018	$ (1,783,033)	$ 37	$ (157,939)	$ (646)	$ (158,585)

Six Months Ended June 30, 2021	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	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)
Issuance of common stock under "at-the market" offering net of commissions and offering costs of $3,077	6,420,441	1	94,886	—	—	94,887	—	94,887
Stock-based compensation expense	—	—	33,161	—	—	33,161	—	33,161
Exercise of stock options	1,450,104	—	4,432	—	—	4,432	—	4,432
Vesting of RSUs	336,084	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(102,031)	—	(2,624)	—	—	(2,624)	—	(2,624)
Other comprehensive loss, net of tax	—	—	—	—	(85)	(85)	—	(85)
Net loss	—	—	—	(167,902)	—	(167,902)	(1,964)	(169,866)
Balance as of June 30, 2021	390,347,740	$ 39	$ 1,625,018	$ (1,783,033)	$ 37	$ (157,939)	$ (646)	$ (158,585)

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

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

Three Months Ended June 30, 2020	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total ImmunityBio Stockholders' (Deficit) Equity	Noncontrolling Interests	Total Stockholders' (Deficit) Equity
Balance as of March 31, 2020	372,015,023	$ 37	$ 1,406,359	$ (1,430,318)	$ (40)	$ (23,962)	$ 3,265	$ (20,697)
Issuance of common stock, net of offering costs of $4,392	8,521,500	1	86,281	—	—	86,282	—	86,282
Stock-based compensation expense	—	—	322	—	—	322	—	322
Exercise of stock options	259,017	—	564	—	—	564	—	564
Vesting of RSUs	495,226	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(10,017)	—	(40)	—	—	(40)	—	(40)
Other comprehensive loss, net of tax	—	—	—	—	(35)	(35)	—	(35)
Net loss	—	—	—	(51,439)	—	(51,439)	(578)	(52,017)
Balance as of June 30, 2020	381,280,749	$ 38	$ 1,493,486	$ (1,481,757)	$ (75)	$ 11,692	$ 2,687	$ 14,379

Six Months Ended June 30, 2020	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total ImmunityBio Stockholders' Equity	Noncontrolling Interests	Total Stockholders' Equity
Balance as of December 31, 2019	371,976,995	$ 37	$ 1,406,002	$ (1,393,280)	$ (87)	$ 12,672	$ 3,654	$ 16,326
Issuance of common stock, net of offering costs of $4,392	8,521,500	1	86,281	—	—	86,282	—	86,282
Stock-based compensation expense	—	—	802	—	—	802	—	802
Exercise of stock options	259,017	—	564	—	—	564	—	564
Vesting of RSUs	558,976	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(35,739)	—	(163)	—	—	(163)	—	(163)
Other comprehensive income, net of tax	—	—	—	—	12	12	—	12
Net loss	—	—	—	(88,477)	—	(88,477)	(967)	(89,444)
Balance as of June 30, 2020	381,280,749	$ 38	$ 1,493,486	$ (1,481,757)	$ (75)	$ 11,692	$ 2,687	$ 14,379

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

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

	Six Months Ended June 30,	
	2021	2020
Operating activities:		
Net loss	$ (169,866)	$ (89,444)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	33,161	802
Unrealized gains on equity securities	(8,391)	(494)
Depreciation and amortization	6,956	6,959
Non-cash interest items, net (including amounts with related parties)	6,248	3,988
Non-cash lease expense related to operating lease right-of-use assets	2,269	2,034
Realized gains on sales of equity securities	(173)	—
Amortization of net premiums and discounts on marketable debt securities	248	93
Change in fair value of contingent consideration obligations	(118)	(457)
Deferred tax	—	(1,029)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,420	(5,635)
Other assets	(4,199)	114
Accounts payable	2,600	2,287
Accrued expenses and other liabilities	(3,821)	10,216
Related parties	2,579	(4,740)
Operating lease liabilities	(2,977)	(1,823)
Net cash used in operating activities	(130,064)	(77,129)
Investing activities:		
Purchases of property, plant and equipment	(15,128)	(324)
Purchases of marketable debt securities, available-for-sale	(266)	(14,828)
Maturities of marketable debt securities, available for sale	44,159	42,920
Proceeds from sales of marketable debt and equity securities	13,569	1,500
Net cash provided by investing activities	42,334	29,268
Financing activities:		
Proceeds from equity offering, net of issuance costs paid	95,026	86,816
Proceeds from issuance of related-party promissory notes	40,000	—
Proceeds from exercises of stock options	4,432	564
Net share settlement for RSUs vesting	(2,624)	(163)
Net cash provided by financing activities	136,834	87,217
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(61)	5
Net change in cash, cash equivalents, and restricted cash	49,043	39,361
Cash, cash equivalents, and restricted cash, beginning of period	35,094	75,980
Cash, cash equivalents, and restricted cash, end of period	$ 84,137	$ 115,341

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

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

	Six Months Ended June 30,	
	2021	2020
Reconciliation of cash, cash equivalents, and restricted cash, end of period:		
Cash and cash equivalents	$ 83,958	$ 115,162
Restricted cash (Note 3)	179	179
Cash, cash equivalents, and restricted cash, end of period	$ 84,137	$ 115,341
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 842	$ 10
Income taxes	10	6
Supplemental disclosure of non-cash activities:		
Property and equipment purchases included in accounts payable, accrued expenses and due to related parties	$ 8,347	$ 2,368
Unpaid offering costs included in accounts payable and accrued expenses	140	534
Right-of-use assets obtained in exchange for operating lease liabilities	12,361	—
Unrealized gains on marketable debt securities	17	5

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

ImmunityBio, Inc. and Subsidiaries
Notes to Unaudited Condensed 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 and 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) ("NantCell"), and we changed our name to ImmunityBio, Inc. Our principal executive offices are located in San Diego, California. In these notes to the unaudited condensed 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 next-generation immunotherapies and 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 ("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 NK 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 (M-ceNK), 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 ("U.S.") Food and Drug Administration ("FDA") granted Breakthrough Therapy designation to Anktiva for bacillus Calmette-Guérin ("BCG") unresponsive carcinoma in situ non-muscle invasive bladder cancer. Based on patient readout data that was submitted with our application to obtain our Breakthrough Therapy designation, Anktiva achieved its primary endpoint of complete response rate at any time in the ongoing registrational Phase II / III trial. 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 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 owned, 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 were listed on the Nasdaq Global Select Market under the symbol "IBRX."

We incurred costs totaling $23.3 million in connection with the Merger, consisting of financial advisory, legal and other professional fees, of which $13.0 million was recorded during the six months ended June 30, 2021. Merger-related costs are reported in *selling, general and administrative expense*, on the condensed consolidated statements of operations.

Accounting Treatment of the Merger

The Merger represents a business combination pursuant to Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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 both 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 tables provide the impact of the change in reporting entity on our unaudited condensed consolidated statements of operations for the three months ended March 31, 2021 and the three and six months ended June 30, 2020, respectively (in thousands):

	Three Months Ended March 31, 2021 (Unaudited)			
	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 June 30, 2020 (Unaudited)			
	NantCell	NantKwest	Intercompany Eliminations	ImmunityBio, Inc.
Revenue	$ 1,525	$ 1	$ (1,090)	$ 436
Operating expenses:				
Research and development (including amounts with related parties)	19,384	13,709	(88)	33,005
Selling, general and administrative (including amounts with related parties)	11,828	6,519	—	18,347
Loss from operations	(29,687)	(20,227)	(1,002)	(50,916)
Other (expense) income, net (including amounts with related parties)	(1,195)	139	—	(1,056)
Income tax expense	(41)	(4)		(45)
Net loss	$ (30,923)	$ (20,092)	$ (1,002)	$ (52,017)

	Six Months Ended June 30, 2020 (Unaudited)			
	NantCell	NantKwest	Intercompany Eliminations	ImmunityBio, Inc.
Revenue	$ 1,693	$ 22	$ (1,114)	$ 601
Operating expenses:				
Research and development (including amounts with related parties)	33,636	26,943	(200)	60,379
Selling, general and administrative (including amounts with related parties)	15,948	11,892	—	27,840
Loss from operations	(47,891)	(38,813)	(914)	(87,618)
Other (expense) income, net (including amounts with related parties)	(2,105)	342	—	(1,763)
Income tax expense	(59)	(4)	—	(63)
Net loss	$ (50,055)	$ (38,475)	$ (914)	$ (89,444)

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 ("SEC") on April 22, 2021.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the SEC. The unaudited condensed 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 consolidated financial statements do not include all information and notes required by U.S. GAAP for annual reports.

As of June 30, 2021, the company had an accumulated deficit of $1.8 billion. We also had negative cash flows from operations of $130.1 million for the six months ended June 30, 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 consolidated financial statements are derived from NantKwest'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 consolidated financial statements assume that the Merger took place at the beginning of the earliest period for which the condensed consolidated financial statements are presented. Accordingly, these financial statements should be read in conjunction with the audited Combined Consolidated Financial Statements and Notes thereto 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 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 (the "ATM")), and our potential ability to borrow from affiliated entities, will be sufficient to fund our 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 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 on the condensed 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 ("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 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* ("ASC 820"), we will apply the measurement alternative under ASC Topic 321, *Investments—Equity Securities* ("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 consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to 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* ("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 June 30,	
	2021	2020
	(Unaudited)	
Outstanding stock options	4,330,318	6,104,799
Outstanding RSUs	7,443,504	565,802
Outstanding related-party warrants	1,638,000	1,638,000
Total	13,411,822	8,308,601

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 June 30, 2021, were outstanding immediately prior to the Effective Time of the Merger and in the case of June 30, 2020 have been adjusted to include the combined NC 2015 Plan and NantCell warrants then outstanding (in both cases adjusted using the Exchange Ratio of 0.8190). See Note 10, *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 ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("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.

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 June 30, 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 June 30, 2021 and December 31, 2020, prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2021 (Unaudited)	December 31, 2020
Prepaid preclinical and clinical trial services – with related party (Note 8)	$ 1,760	$ 4,626
Prepaid license fees	1,579	801
Prepaid services	1,356	1,294
Prepaid insurance	1,191	1,365
Prepaid rent	659	589
Insurance premium financing asset	627	1,421
Prepaid equipment maintenance	198	243
Prepaid supplies – with related party (Note 8)	103	143
Insurance claims receivable	—	2,518
Equipment deposits	—	66
Interest receivable – marketable debt securities	—	473
Other	283	110
Prepaid expenses and other current assets	$ 7,756	$ 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 December 31, 2020 were 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 consolidated statements of operations.

Property, plant and equipment, net

As of June 30, 2021 and December 31, 2020, property, plant and equipment, net, consist of the following (in thousands):

	June 30, 2021 (Unaudited)	December 31, 2020
Leasehold improvements	$ 62,445	$ 52,251
Equipment	45,443	34,738
Buildings	22,690	22,690
Construction in progress	4,030	1,333
Software	1,449	2,376
Furniture & fixtures	1,046	1,015
Gross property, plant and equipment	137,103	114,403
Less: Accumulated depreciation and amortization	48,080	41,862
Property, plant and equipment, net	$ 89,023	$ 72,541

Construction in progress at June 30, 2021 is related primarily to expansion of our pharmaceutical development and manufacturing facilities, including construction of a new filling suite at our leased facilities in El Segundo, California. For the three months ended June 30, 2021, costs totaling $8.2 million were transferred from construction in progress to leasehold improvements as the construction was complete and the asset was ready for its intended use.

Depreciation and amortization expense related to property, plant and equipment totaled $7.0 million and $7.0 million for the six months ended June 30, 2021 and 2020, respectively.

Other assets

As of June 30, 2021 and December 31, 2020, other assets consist of the following (in thousands):

	June 30, 2021 (Unaudited)	December 31, 2020
Prepaid insurance	$ 3,220	$ —
Prepaid preclinical and clinical trial services – with related party (Note 8)	911	92
Value-added tax (VAT) receivable	877	864
ERP system implementation costs	585	—
Security deposits	486	634
Restricted cash	179	179
Prepaid software license fees	110	455
Due from related party	55	51
Other	374	323
Other assets	$ 6,797	$ 2,598

Prepaid insurance consists of policies required by and associated with the Merger. 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 June 30, 2021 and December 31, 2020, accrued expenses and other liabilities consist of the following (in thousands):

	June 30, 2021 (Unaudited)	December 31, 2020
Accrued dissenting shares (Note 7)	$ 6,941	$ 6,769
Accrued professional and service fees	6,575	7,668
Accrued preclinical and clinical trial costs	4,866	4,339
Accrued compensation	4,719	3,891
Accrued research and development costs	3,528	4,002
Accrued bonus	3,377	5,288
Accrued construction costs	2,894	—
Accrued contingent consideration payable	831	856
Accrued laboratory equipment, supplies and related services	779	641
Financing obligation – current portion	627	1,421
Deferred revenue	217	270
Accrued franchise, sales, use and property taxes	211	103
Accrued capital expenditures	—	337
Other	569	1,186
Accrued expenses and other liabilities	$ 36,134	$ 36,771

Interest and investment (loss) income, net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Unrealized (losses) gains from equity securities	$ (442)	$ 692	$ 8,391	$ 494
Interest income	112	341	451	663
Investment amortization expense, net	(23)	(48)	(248)	(93)
Realized gains on investments	176	1	173	—
Interest and investment (loss) income, net	$ (177)	$ 986	$ 8,767	$ 1,064

Interest income includes interest from marketable securities, convertible notes receivable, other assets, and interest from bank deposits.

4. Financial Instruments

Investments in Marketable Debt Securities

As of June 30, 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):

	June 30, 2021 (Unaudited)				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Foreign bonds	0.7	$ 244	$ —	$ —	$ 244
Mutual funds		35	3	—	38
Current portion		279	3	—	282
Noncurrent:					
Foreign bonds	5.4	761	61	—	822
Noncurrent portion		761	61	—	822
Total		$ 1,040	$ 64	$ —	$ 1,104

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

We do not have debt securities classified as available-for-sale that were in an unrealized loss position as of June 30, 2021. Accumulated unrealized losses on debt securities that have been in a continuous loss position for less than 12 months and more than 12 months as of December 31, 2020 were as follows (in thousands):

	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)	$ —	$ —

We evaluated our securities for other-than-temporary impairment, and we did not recognize any other-than-temporary impairment losses for the six months ended June 30, 2021 and 2020.

Realized gains and losses on sales of available-for-sale debt securities were not significant for the six months ended June 30, 2021 and 2020.

Marketable Equity Securities

We held investments in marketable equity securities with readily determinable fair values of $19.7 million and $6.3 million as of June 30, 2021 and December 31, 2020, respectively. Unrealized gains recorded on these securities totaled $8.4 million and $0.5 million in *interest and investment (loss) income, net*, on the condensed consolidated statements of operations for the six months ended June 30, 2021 and 2020, respectively. We recorded a realized gain totaling $0.2 million from sales of equity securities in *interest and investment (loss) income, net*, on the condensed consolidated statements of operations for the six months ended June 30, 2021.

5. 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 June 30, 2021 and December 31, 2020 (in thousands):

	Fair Value Measurements at June 30, 2021 (Unaudited)			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$ 83,958	$ 83,958	$ —	$ —
Equity securities	19,688 (1)	19,688	—	—
Foreign bonds	244	244	—	—
Mutual funds	38	38	—	—
Noncurrent:				
Foreign bonds	822	822	—	—
Total assets measured at fair value	$ 104,750	$ 104,750	$ —	$ —
Liabilities:				
Contingent consideration obligations	$ (854) (2)	$ —	$ —	$ (854)

	Fair Value Measurements at 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	$ (972) (2)	$ —	$ —	$ (972)

(1) Our equity securities include a $17.7 million investment in Viracta Therapeutics, Inc. (“Viracta”), a clinical stage drug development company with whom we have an exclusive worldwide license to develop and commercialize one of their proprietary drug candidates. In February 2021, Viracta merged with Sunesis Pharmaceuticals, Inc. (“Sunesis”), 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. Prior to the acquisition by Sunesis, we accounted for our investment in Viracta by applying the measurement alternative under ASC 321. 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.

(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 7, *Commitments and Contingencies*, for additional information.

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

	Six Months Ended June 30,	
	2021	2020
	(Unaudited)	
Fair value, beginning of period	$ (972)	$ (1,725)
Net change in fair value	118	457
Fair value, end of period	$ (854)	$ (1,268)

Non-recurring Valuations

Non-financial assets and liabilities are recognized at fair value subsequent to initial recognition when they are deemed to be other-than-temporarily impaired. There were no material non-financial assets and liabilities deemed to be other-than-temporarily impaired and measured at fair value on a non-recurring basis for the six months ended June 30, 2021 and 2020.

6. Collaboration and License Agreements

Collaboration Agreements

National Cancer Institute

In May 2015, Etubics Corporation (“Etubics”) entered into a Cooperative Research and Development Agreement (“CRADA”) with the U.S. Department of Health and Human Services as represented by the National Cancer Institute (“NCI”) of the National Institutes of Health (“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, the 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 payments of $0.6 million in each of the six months ended June 30, 2021 and 2020, respectively, and recorded $0.3 million in *research and development expense*, on the condensed consolidated statements of operations for the six months ended June 30, 2021 and 2020. The CRADA expires in May 2023.

In February 2018, we entered into an amendment to a CRADA with the NIH that was originally executed between the NIH and Amgen, Inc. ("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 on 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 the 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 $0.5 million and $0.6 million as of June 30, 2021 and December 31, 2020, respectively.

In February 2021, we entered into a CRADA with the NIH to conduct collaborative analysis of human clinical trial samples from clinical trials utilizing our proprietary recombinant NK cells and/or monoclonal antibodies ("mAbs") for preclinical development in monotherapy and in combination immunotherapies. The CRADA has a two-year term commencing on 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 the NIH for support of the research activities. We made a payment of $0.1 million during the six months ended June 30, 2021.

All CRADA agreements may be terminated at any time upon the mutual written consent of the company and the 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.

License Agreements

Infectious Disease Research Institute

In May 2021, we entered into license agreements with the Infectious Disease Research Institute ("IDRI"), pursuant to which we received licenses to certain of their platforms and formulations relevant to our product portfolio. Under the licenses, we were obligated to pay one-time, non-creditable, non-refundable upfront cash payments totaling $2.0 million that we recorded in *research and development expense*, on the condensed consolidated statements of operations for the six months ended June 30, 2021. In addition, we will owe IDRI milestone payments based on the achievement of certain development and regulatory milestones and royalties on net sales of licensed products. No milestone fees were incurred for the six months ended June 30, 2021. In connection with the license agreements, we also entered into a Sponsored Research Agreement ("SRA") with IDRI pursuant to which we will fund continued research of at least $2 million per year, payable in four equal quarterly installments each year until May 2024, or such year of earlier termination. For the six months ended June 30, 2021, we recorded $0.2 million in *research and development expense*, on the condensed consolidated statements of operations related to the SRA.

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 iosBio and its affiliates a non-exclusive, worldwide license for 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 June 30, 2021 and December 31, 2020, we accrued $0.2 million and $0.5 million payable, respectively, to iosBio for costs of supplies and reimbursable costs related to the clinical trial activities initiated by iosBio.

7. Commitments and Contingencies

Contingent Consideration Related to Business Combinations

VivaBioCell, S.p.A.

On April 10, 2015, NantWorks, LLC ("NantWorks"), a related party, acquired a 100% interest in VivaBioCell, S.p.A. ("VivaBioCell") through its wholly-owned subsidiary, VBC Holdings, LLC, ("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 six months ended June 30, 2021 to $0.8 million.

Altor BioScience Corporation

In connection with our July 2017 acquisition of Altor BioScience Corporation ("Altor"), we issued contingent value rights ("CVRs") under which we agreed to pay the prior stockholders of Altor approximately $304.0 million upon successful approval of the Biologics License Application ("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.

Litigation

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.

Altor BioScience, LLC Litigation

In 2017, NantCell announced it had entered into a definitive merger agreement to acquire Altor BioScience Corporation. An action captioned Gray v. Soon-Shiong, et al. was filed in Delaware Chancery Court by plaintiffs Clayland Boyden Gray ("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 and permitted the merger to close.

Subsequent to the close of the merger, in 2017 the plaintiffs (joined by two additional minority stockholders, Barbara Sturm Waldman and Douglas E. Henderson ("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. The 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 (the "Waldmans") agreed not to bring the lawsuit.

In a second action, Dyad Pharmaceutical Corporation, or Dyad, filed a petition in Delaware Chancery Court for appraisal in connection with the merger. Respondent moved to dismiss the appraisal petition in 2018, arguing in part that the petition was barred by the same "standstill" agreement. In 2018, the court heard oral arguments on the motions to dismiss in both consolidated cases and converted the motions to dismiss into motions for summary judgment with regard to the "standstill" agreement argument, or the Converted Motions.

The court issued an oral ruling in 2019 that dismissed certain claims and 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.

In 2019, the court issued a written order implementing its ruling on the Converted Motions (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. Gray and the Waldmans filed answers denying the counterclaims and asserting defenses. The plaintiffs moved for leave to file a third amended complaint to add two former Altor stockholders as plaintiffs and a fiduciary duty claim on behalf of a purported class of former Altor stockholders, which the defendants opposed.

In 2020, the court granted the plaintiffs' motion, and the plaintiffs filed a third amended complaint. In 2020, the defendants answered the third amended complaint and asserted counter claims against the plaintiffs. The defendants are seeking damages for attorneys' fees and costs incurred as a result of these breaches. The plaintiffs filed an answer denying the counterclaims and asserting defenses. The trial has been set to commence in October 2021, but trial is likely to be continued until the second half of 2022.

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 or 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 June 30, 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 stockholder dispute along with any accrued statutory interest. We cannot reasonably estimate a range of loss or likelihood of loss beyond the amounts recorded for dissenting shares as of June 30, 2021, 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. Discovery is ongoing, and class certification motions relating to the putative class have not yet been filed or decided. 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. ("Sorrento"), derivatively on behalf of NANTibody, LLC ("NANTibody"), filed an action in the Superior Court of California, Los Angeles County (the "Superior Court") against the company, Dr. Soon-Shiong and Charles Kim. The action alleged that the defendants improperly caused NANTibody to acquire IgDraSol, Inc. from our affiliate NantPharma, LLC ("NantPharma") and sought to have the transaction undone and the purchase amount returned to NANTibody. In 2019, we filed a demurrer to several causes of action alleged in the Superior Court action, and Sorrento filed an amended complaint, eliminating Mr. Kim as a defendant and dropping the causes of action we had challenged in our demurrer.

Sorrento filed a related arbitration proceeding, the Cynviloq arbitration, against Dr. Soon-Shiong and NantPharma; the company is not named in the Cynviloq arbitration. In 2020, the Superior Court 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, and at Sorrento's request, the arbitrator entered an order dismissing Sorrento's claims against Dr. Soon-Shiong in the Cynviloq arbitration. The hearing in the Cynviloq arbitration commenced in June 2021, and is scheduled to continue with breaks until at least September 2021.

Also in 2019, the company 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. Our claims 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. The Superior Court ruled that the company's claims should be pursued in arbitration and that Dr. Soon-Shiong's claims could be pursued in Superior Court.

In 2019, the company, along with NANTibody, filed an arbitration against Sorrento and Dr. Ji asserting our claims relating to the exclusive license agreement. In 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 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. Sorrento filed counterclaims against the company and NANTibody in the arbitration and requested leave to file a dispositive motion. The hearings in the antibody arbitration commenced in April 2021 and concluded in early August 2021. Post-hearing briefing will be followed by concluding arguments on November 10, 2021.

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.

Shenzhen Beike Biotechnology Corporation Litigation

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Shenzhen Beike Biotechnology Corporation ("Beike"). The arbitration relates to a license, development, and commercialization agreement that Altor Bioscience Corporation (succeeded by our wholly-owned subsidiary Altor BioScience, LLC ("Altor")) entered into with Beike in 2014, which agreement was amended and restated in 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 August 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 the Court to find that we have not breached material obligations 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. On June 4, 2021, the federal court separated the parties' claims, and returned ImmunityBio's declaratory judgment claims back to the San Diego County court while retaining the patent inventorship challenge. While the litigation is in the early stage, its outcome cannot be predicted. We do not consider the 2004 License or the patent inventorship challenge 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 were both voluntarily dismissed on May 18, 2021. The Hargett Complaint and the Gross Complaint also brought 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 8, *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:

	June 30, 2021	December 31, 2020
	(Unaudited)	
Weighted average remaining lease term	6.2 years	3.9 years
Weighted average discount rate	9%	9%

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Operating lease costs	$ 1,717	$ 1,624	$ 3,864	$ 3,406
Variable lease costs	517	726	1,183	1,574
Total lease costs	$ 2,234	$ 2,350	$ 5,047	$ 4,980

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

	Six Months Ended June 30,	
	2021	2020
	(Unaudited)	
Operating cash flows for operating leases	$ 4,004	$ 2,785

Future minimum lease payments as of June 30, 2021, including $12.6 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 six months ended June 30, 2021)	$ 834
2022	8,952
2023	7,288
2024	5,840
2025	5,467
Thereafter	15,729
Total future minimum lease payments	44,110
Less: Interest	12,564
Present value of operating lease liabilities	$ 31,546

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, LLC, a related party, for a facility primarily used for pharmaceutical development and manufacturing purposes. In May 2021, but effective on April 1, 2021, we entered into an amendment to our lease agreement with 605 Nash, LLC. See Note 8, *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 SEC on April 22, 2021.

Commitments

We did not enter into any significant contracts during the six months ended June 30, 2021, other than those disclosed in these condensed 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 SEC on April 22, 2021.

8. 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):

	June 30, 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	162	118
Total due from related parties	$ 2,047	$ 2,003
Due to related party–NantWorks	$ 12,925	$ 10,650
Due to related party–Duley Road	2,427	2,787
Due to related party–NantBio	943	943
Due to related party–Immuno-Oncology Clinic	229	271
Due to related party–Various	187	187
Total due to related parties	$ 16,711	$ 14,838

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, a related party, 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. For the three months ended June 30, 2021 and 2020, we recorded $1.2 million and $2.4 million, respectively, in *selling, general and administrative expense*, and $0.1 million and $0.2 million, respectively, of expense reimbursements under this arrangement in *research and development expense*, on the condensed consolidated statements of operations. For the six months ended June 30, 2021 and 2020, we recorded $3.0 million and $3.9 million, respectively, in *selling, general and administrative expense*, and $0.4 million and $1.2 million, respectively, of expense reimbursements under this arrangement in *research and development expense*, on the condensed consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third-party vendors directly for our benefit, which have been reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

As of June 30, 2021 and December 31, 2020, we owed NantWorks a net amount of $12.9 million and $10.7 million, respectively, for all agreements between the two affiliates, which is included in *due to related parties*, on the condensed consolidated balance sheets. We also recorded $1.2 million and $1.1 million of prepaid expenses for services that have been passed through to the company from NantWorks as of June 30, 2021 and December 31, 2020, respectively, which are included in *prepaid expenses and other current assets*, on the condensed consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks 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 current Good Manufacturing Practice ("cGMP") manufacturing facility. The initial license was effective from May 2015 through December 2020. The base rent for the initial lease term was $47,000 per month, 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 base rent increased by 3% to approximately $54,500 per month. 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 base rent will increase by 3% annually commencing on January 1 of each year. On the date of amendment, we recorded an increase of $1.2 million in both *operating lease right-of-use assets* and *operating lease liabilities*, on the condensed 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 $0.3 million and $0.3 million for the six months ended June 30, 2021 and 2020, respectively, was recorded in *research and development expense*, on the condensed consolidated statements of operations.

Immuno-Oncology Clinic, Inc.

Beginning in 2017, we entered into multiple agreements with Immuno-Oncology Clinic, Inc. (the "Clinic") to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an 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 a nominal 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 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.

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 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.

In April 2021, ImmunityBio executed two work orders under an existing master agreement with the Clinic. 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.

Based on a review of our updated clinical trial programs post-Merger, we updated our estimates of the investigator fees for the clinical trials currently underway or planned at the Clinic. As certain programs costs are excluded from and certain services are subject to credit adjustments under the Clinic Agreement, we determined the expected future fees for services to be performed are less than the carrying value of the prepaid asset on the condensed consolidated balance sheets. As a result, we partially wrote down the value of our prepayments under the Clinic Agreement and recorded approximately $1.9 million in *research and development expense*, on the condensed consolidated statements of operations for the three months ended June 30, 2021. In addition, we reclassified $0.9 million of prepaid assets from *prepaid expenses and other current assets* to *other assets*, on the condensed consolidated balance sheets as of June 30, 2021 based on the additional time expected for them to be realized than initially estimated.

For the three months ended June 30, 2021 and 2020, we incurred $0.5 million and $0.1 million in *research and development expense*, on the condensed consolidated statements of operations related to the Clinic Agreement. For the six months ended June 30, 2021 and 2020, we incurred $0.8 million and $0.2 million in *research and development expense*, on the condensed consolidated statements of operations related to the Clinic Agreement. As of June 30, 2021 and December 31, 2020, we owed the Clinic $0.2 million and $0.3 million, respectively, for services excluded from the Clinic Agreement. As of June 30, 2021 and December 31, 2020, we had prepaid balances related to the Clinic Agreement of $2.7 million and $4.7 million, respectively.

NantBio, Inc.

In March 2016, NantBio, Inc. (“NantBio”) and 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 recognize expense related to this agreement ratably over a 12-month period for each funding year. We accrued $0.2 million in *research and development expense*, on the condensed consolidated statements of operations related to this agreement for the six months ended June 30, 2021 and 2020. As of December 31, 2020, we recorded $0.1 million in *prepaid expenses and other current assets*, on the condensed consolidated balance sheets related to this agreement.

In August 2018, we entered into a supply agreement with NantCancerStemCell, LLC (“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. We recognized revenue of $0.3 million for the six months ended June 30, 2021. We recorded $0.1 million and $0.3 million of deferred revenue for bioreactors that were delivered but not installed as of June 30, 2021 and December 31, 2020, respectively. As of June 30, 2021 and December 31, 2020, we recorded $0.9 million in *due to related parties*, on the condensed 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 June 30, 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 2019, we made a strategic decision and transferred certain employees from NantOmics, LLC ("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 June 30, 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 base rent is approximately $72,385 per month, with annual increases of 3% that began in July 2017. Lease expense of $0.4 million for this facility for the six months ended June 30, 2021 and 2020, respectively, was recorded in *research and development expense*, on the condensed consolidated statements of operations. The prepaid rent for this lease was $0.1 million, which was included in *prepaid expenses and other current assets*, and the security deposit for this lease was $0.1 million, which was included in *other assets*, on the condensed consolidated balance sheets as of June 30, 2021.

Duley Road, LLC

In February 2017, Altor BioScience Corporation (succeeded by our wholly-owned subsidiary Altor BioScience, LLC), through its wholly-owned subsidiary, entered into a lease agreement with Duley Road, LLC ("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 base rent is approximately $40,700 per month, with annual increases of 3% that began in November 2018. As of June 30, 2021 and December 31, 2020, we recorded rent payable to Duley Road of $1.1 million and $1.0 million, respectively. For the six months ended June 30, 2021 and 2020, we recorded rent expense of $0.3 million and $0.3 million, respectively, which is reflected in *research and development expense*, on the condensed 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 base rent for the two leases is approximately $35,800 per month that increases at a rate of 3% per year.

As of June 30, 2021 and December 31, 2020, we recorded $0.9 million and $0.7 million of leasehold improvement payables, respectively, and $0.4 million and $1.1 million of lease-related payables to Duley Road, which were included in *due to related parties*, on the condensed consolidated balance sheets. For the six months ended June 30, 2021 and 2020, we recorded $0.2 million and $0.1 million of rent expense for the two leases, respectively, which was included in *research and development expense*, on the condensed consolidated statements of operations. The security deposits for the leases totaled $0.1 million as of June 30, 2021, which were included in *other assets*, on the condensed 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 (the "Initial Premises") in a two story mixed use building containing approximately 64,643 rentable square feet on 605-607 Nash Street in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease term commenced in January 2021 and expires in December 2027, and includes an option to extend the lease for an additional three-year term through December 2030. The base rent 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 will receive a rent abatement for the first seven months, and a tenant improvement incentive of $0.3 million from the landlord for costs and expenses associated with the construction of tenant improvements for the Initial Premises.

During the three months ended June 30, 2021, we completed the build out of certain facility space in connection with this lease and transferred costs totaling $8.2 million from construction in progress to leasehold improvements. For the three and six months ended June 30, 2021, we recorded rent expense of $0.1 million, which is reflected in *research and development expense*, on the condensed consolidated statements of operations.

In May 2021, but effective on April 1, 2021, we entered into an amendment to our Initial Premises lease with 605 Nash, LLC. The amendment expanded the leased square feet by approximately 57,760 rentable square feet (the "Expansion Premises"). The lease term of the Expansion Premises commenced in April 2021 and expires in March 2028, whereby the company has the option to extend the initial term for three years. Per the terms of the amendment, the term of the Initial Premises lease was extended for an additional three months and now expires on March 31, 2028. Base rent for the Expansion Premises is approximately $170,400 per month with annual increases of 3% on April 1 of each year. We are responsible for the build out of the facility space and associated costs. The amended lease provides for a rent abatement for the first seven months, and for a tenant improvement allowance of approximately $2.6 million for costs and expenses related to improvements made by us to the Expansion Premises. During the three and six months ended June 30, 2021, we incurred $0.5 million of rent expense related to the Expansion Premises lease agreement. The security deposits for the leases total $0.2 million as of June 30, 2021, which are included in *other assets*, on the condensed consolidated balance sheets.

Related-Party Notes Payable

As of June 30, 2021 and December 31, 2020, related-party notes payable consist of the following (in thousands):

				Total Notes and Interest Payable	
Related-Party Notes Payable	Note Year	Outstanding Advances	Interest Rate	June 30, 2021 (Unaudited)	December 31, 2020
Nant Capital (1)	2015	$ 55,226	5.0%	$ 59,908 (2)	$ 58,482 (2)
Nant Capital (1)	2020	50,000	6.0%	52,252 (3)	50,764 (3)
Nant Capital (4)	2021	40,000	6.0%	40,000 (4)	—
NantMobile (1)	2019	55,000	3.0%	57,502 (5)	56,660 (5)
NantWorks (1)	2017	43,418	5.0%	52,791 (6)	51,546 (6)
NCSC (1)	2018	33,000	5.0%	37,799 (7)	36,901 (7)
Total related-party notes payable		$ 276,644		$ 300,252	$ 254,353

(1) All outstanding advances and accrued and unpaid interest is due and payable on September 30, 2025. Interest on related-party notes payable is compounded annually. We may prepay the outstanding principal at any time without premium, penalty or the prior consent of the issuer. All outstanding amounts under the notes become due and payable upon certain bankruptcy and insolvency-related events. There are no equity or equity-linked convertible rights related to these promissory notes.

(2) Accrued and unpaid interest on this note totaled $4.7 million and $3.3 million as of June 30, 2021 and December 31, 2020, respectively.

(3) Accrued and unpaid interest on this note totaled $2.3 million and $0.8 million as of June 30, 2021 and December 31, 2020, respectively.

(4) The outstanding principal is due and payable on September 30, 2025. Interest on this related-party note is compounded annually and payable quarterly commencing on June 30, 2021. We paid $0.8 million in interest on this loan during the three months ended June 30, 2021. All outstanding amounts under the note become due and payable upon certain bankruptcy and insolvency-related events. There are no equity or equity-linked convertible rights related to this promissory note.

(5) Accrued and unpaid interest on this note totaled $2.5 million and $1.7 million as of June 30, 2021 and December 31, 2020, respectively.

(6) Accrued and unpaid interest on this note totaled $9.4 million and $8.1 million as of June 30, 2021 and December 31, 2020, respectively.

(7) Accrued and unpaid interest on this note totaled $4.8 million and $3.9 million as of June 30, 2021 and December 31, 2020, respectively.

9. 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 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

No shares of our common stock were repurchased during the six months ended June 30, 2021 and 2020 under the company's 2015 Share Repurchase Program. As of June 30, 2021, $18.3 million remained authorized for repurchase under the program.

Common Stock Reserved for Future Issuance

As of June 30, 2021, a total of approximately 11.8 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 Exchange Ratio of 0.8190), on the same terms and conditions as immediately prior to the Effective Time. As of June 30, 2021, there were approximately 6.8 million RSUs and 0.7 million stock options outstanding under the NC 2015 Plan, and there were no additional shares available for future grant.

Open Market Sale Agreement

On April 30, 2021, we entered into an Open Market Sale Agreement (the "Sale Agreement") with respect to an 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 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.

During the three months ended June 30, 2021, we received net proceeds totaling $94.9 million from the issuance of 6,420,441 shares under the ATM, which we expect to use for general corporate purposes, including to progress our clinical development programs, fund other research and development activities, for capital expenditures and to fund working capital. We may also use a portion of the net proceeds to license intellectual property or to make acquisitions or investments. As of June 30, 2021, we had $402.0 million available for future stock issuances under the ATM.

We are not obligated to sell any shares 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.

10. 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. Pursuant to the Merger, we assumed 7,121,110 RSUs (adjusted for the Exchange Ratio of 0.8190) issued under NantCell's equity incentive plan. As of June 30, 2021, the 2015 Plan is the only equity plan available for grant of equity awards to employees, directors and consultants of the company. As of June 30, 2021, a total of approximately 5.9 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 consolidated statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Stock-based compensation expense:				
Stock options	$ 1,610	$ 198	$ 7,965	$ 328
RSUs	16,253	124	25,196	474
	$ 17,863	$ 322	$ 33,161	$ 802
Stock-based compensation expense in operating expenses:				
Research and development	$ 8,545	$ (53)	$ 11,433	$ 108
Selling, general and administrative	9,318	375	21,728	694
	$ 17,863	$ 322	$ 33,161	$ 802

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 the effective date of Post-Effective Amendment No. 1 on Form S-3 to our Form S-4 Registration Statement. We recorded 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 independent directors, the Board of Directors approved the acceleration of vesting of 83,333 shares of unvested stock options 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 recorded 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 recorded in *selling, general and administrative expense*, on the condensed consolidated statements of operations during the six months ended June 30, 2021.

Stock Options

The following table summarizes stock option activity and related information for the six months ended June 30, 2021:

	Number of Options	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
Granted	1,069,940	$ 21.38		
Exercised	(1,661,912)	$ 3.86		
Expired/forfeited	(73,994)	$ 5.22		
Outstanding at June 30, 2021	4,330,318	$ 15.25	$ 19,012	5.7
Vested and exercisable at June 30, 2021	3,143,710	$ 13.61	$ 17,705	4.3

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.

On May 3, 2021, the compensation committee of the board of directors of the company granted each of our newly-appointed independent directors a non-qualified stock option award to purchase 21,873 shares of our common stock pursuant to the 2015 Plan at an exercise price of $17.24 per share, the closing price as reported on the Nasdaq on the date of grant. The shares subject to the award will vest in three (3) equal installments on each of the first, second and third anniversary date of their appointment to the board of directors, such that the award will be fully vested on the third anniversary date in 2024, subject to the director continuing to be a service provider as defined in the 2015 Plan through the applicable vesting dates.

On June 10, 2021, the compensation committee of the board of directors of the company granted our Chairman and each of the independent members of our board of directors a non-qualified stock option award to purchase 26,064 shares of our common stock pursuant to the 2015 Plan at an exercise price of $14.91 per share, the closing price as reported on the Nasdaq on the date of grant. The shares subject to the award will vest 100% on the earlier to occur of June 10, 2022 or the date immediately preceding the 2022 annual meeting of stockholders, subject to the recipient continuing to be a service provider as defined in the 2015 Plan through the applicable vesting date. These grants were made in connection with the re-election of our Executive Chairman and independent directors to the company's board of directors at the 2021 annual meeting of stockholders.

As of June 30, 2021, the unrecognized compensation cost related to outstanding stock options was $16.2 million, which is expected to be recognized over a remaining weighted-average period of 2.4 years.

The total intrinsic value of stock options exercised during the six months ended June 30, 2021 was $20.6 million. Cash proceeds received from stock option exercises during the six months ended June 30, 2021 was $4.4 million.

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

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

	Six Months Ended June 30, 2021 (Unaudited)
Expected term (in years)	5.9
Risk-free interest rate	0.7%
Expected volatility	101.0%
Dividend yield	0.0%
Weighted-average grant date fair value	$ 16.80

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.

Restricted Stock Units

The following table summarizes RSU activity during the six months ended June 30, 2021:

	Number of Units	Weighted-Average Grant Date Fair Value
Nonvested balance at December 31, 2020	466,842	$ 2.52
Granted	7,643,955	$ 25.23
Vested	(336,084)	$ 11.78
Forfeited/canceled	(331,209)	$ 23.91
Nonvested balance at June 30, 2021	7,443,504	$ 24.47

As of June 30, 2021, there was $159.9 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 8, *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 six months ended June 30, 2021, we recorded approximately $21.1 million of stock-based compensation expense related to these awards, of which approximately $11.3 million was recorded in *research and development expense* and approximately $9.8 million was recorded in *selling, general and administrative expense*, on the condensed 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 8, *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 recorded $0.5 million of deemed dividends for the six months ended June 30, 2021 in *additional paid-in capital*, on the condensed 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 were outstanding as of June 30, 2021. The fair value of $18.0 million assigned to the warrants will be recognized in equity upon achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for one of our product candidates.

11. 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, and is considered a nontaxable transaction for U.S. income tax purposes, as 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.

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

Forward-Looking Statements

The following discussion and analysis should be read together with our condensed consolidated financial statements and the notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. 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 ("Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended ("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 M-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 ("IND"); Biologics License Application ("BLA"); or New Drug Application ("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 ("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 M-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 M-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 (“CVRs”) held by former Altor BioScience Corporation (“Altor”) stockholders become due and payable in accordance with their terms; and
- regulatory developments in the United States (“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.

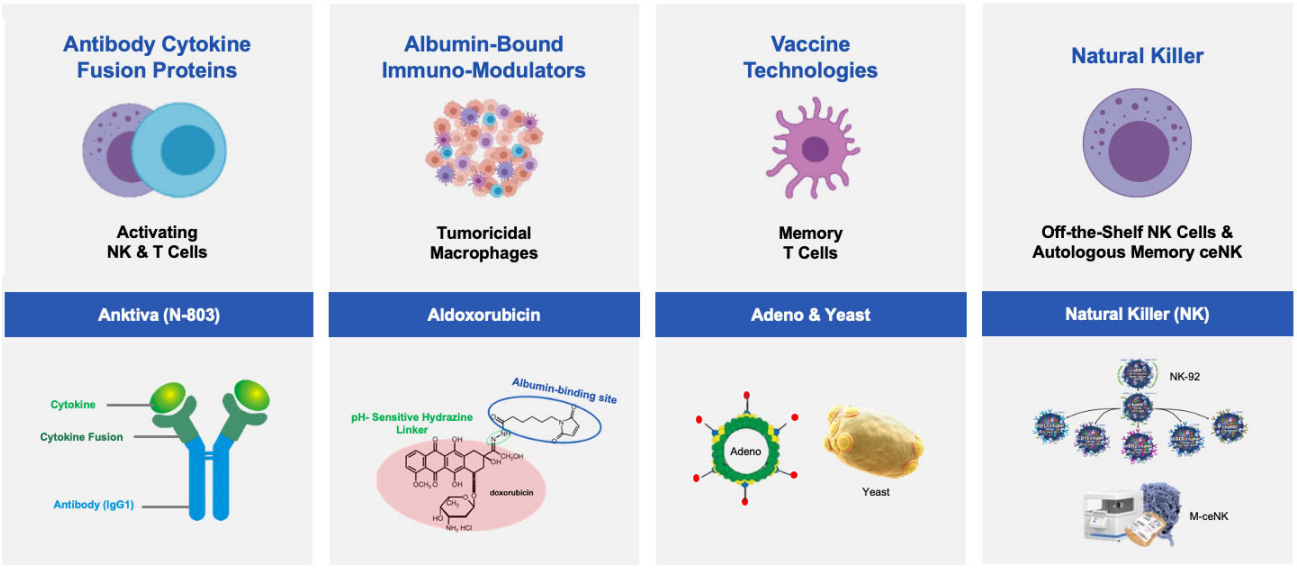
Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Quarterly 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 next-generation immunotherapies and 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 ("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 ("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 NK cells ("M-ceNK"), 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 ("FDA") granted Breakthrough Therapy designation to Anktiva for bacillus Calmette-Guérin ("BCG") unresponsive carcinoma in situ non-muscle invasive bladder cancer. Based on patient readout data that was submitted with our application to obtain our Breakthrough Therapy designation, Anktiva achieved its primary endpoint of complete response rate at any time in the ongoing registrational Phase II / III trial. 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 owned, 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 were listed on the Nasdaq Global Select Market under the symbol "IBRX."

We incurred costs totaling $23.3 million in connection with the Merger, consisting of financial advisory, legal and other professional fees, of which $13.0 million was recorded during the six months ended June 30, 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 both 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 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 ("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 ("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 June 30, 2021, we had an accumulated deficit of $1.8 billion. Our net losses attributable to ImmunityBio common stockholders were $167.9 million and $88.5 million for the six months ended June 30, 2021 and 2020, 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 June 30, 2021, we had 511 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 8, *Related-Party Agreements*, of the "Notes to Unaudited Condensed 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 6, *Collaboration and License Agreements*, of the "Notes to Unaudited Condensed 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 June 30, 2021, we have outstanding promissory notes with certain entities affiliated with Dr. Soon-Shiong in an aggregate amount of $300.3 million, including accrued interest. The notes bear interest at a per annum rate ranging from 3.0% to 6.0%. As of June 30, 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.

In May 2021, but effective on April 1, 2021, we entered into an amendment to our existing lease with 605 Nash, LLC. The amendment expanded the leased square feet by approximately 57,760 rentable square feet (the “Expansion Premises”). The lease term of the Expansion Premises commenced in April 2021 and expires in March 2028, whereby the company has the option to extend the initial term for three years. Per the terms of the amendment, the term of the lease that commenced in January 2021 was extended for an additional three months and now expires on March 31, 2028. Base rent for the Expansion Premises is approximately $170,400 per month with annual increases of 3% on April 1 of each year. We are responsible for the build out of the facility space and associated costs. The amended lease provides for a rent abatement for the first seven months, and for a tenant improvement allowance of approximately $2.6 million for costs and expenses related to improvements made by us to the Expansion Premises.

We entered into multiple agreements with Immuno-Oncology Clinic, Inc. (the “Clinic”) to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an officer of the company and NantWorks manages the administrative operations of the Clinic. Based on a review of our updated clinical trial programs post-Merger, we updated our estimates of the investigator fees for the clinical trials currently underway or planned at the Clinic. As certain programs costs are excluded from and certain services are subject to credit adjustments under the Clinic Agreement, we determined the expected future fees for services to be performed are less than the carrying value of the prepaid asset on the condensed consolidated balance sheets. As a result, we partially wrote down the value of our prepayments under the Clinic Agreement and recorded approximately $1.9 million in *research and development expense*, on the condensed consolidated statements of operations for the three months ended June 30, 2021. In addition, we reclassified $0.9 million of prepaid assets from *prepaid expenses and other current assets* to *other current assets*, on the condensed consolidated balance sheets as of June 30, 2021 based on the additional time expected for them to be realized than initially estimated.

See Note 8, *Related-Party Agreements*, of the “Notes to Unaudited Condensed 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 the foreseeable future, 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 June 30, 2021 and 2020

	Three Months Ended June 30,			
	2021	2020	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue	$ 339	$ 436	$ (97)	(22%)
Operating expenses:				
Research and development (including amounts with related parties)	53,800	33,005	20,795	63%
Selling, general and administrative (including amounts with related parties)	32,445	18,347	14,098	77%
Total operating expenses	86,245	51,352	34,893	68%
Loss from operations	(85,906)	(50,916)	(34,990)	69%
Other expense:				
Interest and investment (expense) income, net	(177)	986	(1,163)	(118%)
Interest expense (including amounts with related parties)	(3,577)	(2,123)	(1,454)	68%
Other income, net (including amounts with related parties)	277	81	196	242%
Total other expense	(3,477)	(1,056)	(2,421)	229%
Loss before income taxes and noncontrolling interests	(89,383)	(51,972)	(37,411)	72%
Income tax expense	(2)	(45)	43	(96%)
Net loss	$ (89,385)	$ (52,017)	$ (37,368)	72%

Research and Development Expense

Research and development expense increased $20.8 million during the three months ended June 30, 2021, as compared to the three months ended June 30, 2020. The increase in research and development expense was primarily driven by an $11.2 million increase in compensation expense, including an $8.6 million increase in stock compensation expense due to new grants issued and a $2.6 million increase in personnel costs due to higher headcount to support our continued research and development efforts, a $3.4 million increase in clinical trial and regulatory expenses related to our Anktiva and COVID-19 programs, including a $1.9 million expense associated with the write down of a prepaid asset with the Clinic, a $2.5 million increase in license and research agreement costs, primarily driven by new license agreements entered into in the second quarter of 2021, a $1.9 million increase in facilities expense, primarily related to the expansion of our manufacturing facility in El Segundo, California during 2021, and a $1.8 million increase in laboratory supply expenses and other research and development costs, primarily driven by higher expenses related to our 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 $14.1 million during the three months ended June 30, 2021, as compared to the three months ended June 30, 2020. The increase in selling, general and administrative expense was primarily attributable to $9.8 million increase in compensation expense, including an $8.9 million increase in stock compensation expense driven by new grants and option modifications resulting in incremental stock-based compensation expense in 2021 and a $0.9 million increase personnel-related expenses, and a $6.2 million increase in legal expense, primarily due to ongoing litigation. These increases were partially offset by a $1.2 million decrease in shared services and travel costs, and a $0.7 million decrease in general liability insurance costs.

Other Expense

Other expense increased $2.4 million during the three months ended June 30, 2021, as compared to the three months ended June 30, 2020. The increase in other expense was mainly due to a $1.4 million increase in interest expense driven higher related-party borrowings and a reduction in net unrealized gains of $1.2 million related to our equity securities, which were partially offset by a $0.2 million increase in other income.

Comparison of the six months ended June 30, 2021 and 2020

	Six Months Ended June 30,			
	2021	2020	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue	$ 478	$ 601	$ (123)	(20%)
Operating expenses:				
Research and development (including amounts with related parties)	94,928	60,379	34,549	57%
Selling, general and administrative (including amounts with related parties)	77,720	27,840	49,880	179%
Total operating expenses	172,648	88,219	84,429	96%
Loss from operations	(172,170)	(87,618)	(84,552)	97%
Other income (expense):				
Interest and investment income, net	8,767	1,064	7,703	724%
Interest expense (including amounts with related parties)	(6,745)	(4,012)	(2,733)	68%
Other income, net (including amounts with related parties)	290	1,185	(895)	(76%)
Total other income (expense)	2,312	(1,763)	4,075	(231%)
Loss before income taxes and noncontrolling interests	(169,858)	(89,381)	(80,477)	90%
Income tax expense	(8)	(63)	55	(87%)
Net loss	$ (169,866)	$ (89,444)	$ (80,422)	90%

Research and Development Expense

Research and development expense increased $34.5 million during the six months ended June 30, 2021, as compared to the six months ended June 30, 2020. The increase in research and development expense was primarily driven by a $15.3 million increase in compensation expense, including an $11.3 million increase in stock compensation expense due to new grants issued and a $4.0 million increase in the personnel costs due to higher headcount in support of our continued research and development efforts, a $5.1 million increase in clinical trial expenses and regulatory costs related to our Anktiva and COVID-19 programs, including a $1.9 million expense associated with the write down of a prepaid asset with the Clinic, a $4.7 million increase in laboratory supply expenses and other preclinical research and development costs, a $4.5 million increase in manufacturing costs for contract manufacturing of clinical materials, a $2.8 million increase in facilities expense, primarily related to the expansion of our manufacturing facility in El Segundo, California during 2021, and a $2.1 million increase in license and collaboration costs, primarily driven by new license agreements entered in the second quarter of 2021.

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 $49.9 million during the six months ended June 30, 2021, as compared to the six months ended June 30, 2020. The increase in selling, general and administrative expense was primarily attributable to a $22.4 million increase in compensation expense, including a $21.0 million increase in stock compensation expense driven by new grants issued and option modifications resulting in incremental stock-based compensation expense in 2021 and a $1.4 million increase in personnel-related expenses due to higher headcount needed to support our business activities, a $24.3 million increase in financial advisory, legal, public company and other professional fees (including fees related to our Merger, which was announced in December 2020 and closed in March 2021), as well as higher costs associated with ongoing litigation, patent-related legal fees and other matters, and a $3.2 million increase in insurance costs, primarily due to higher directors' and officers' insurance renewal rates and increased insurance coverage.

Other Income and Expense

Other income increased $4.1 million during the six months ended June 30, 2021, as compared to the six months ended June 30, 2020. The increase was mainly due a $7.7 million increase in unrealized gains from our equity investments, which were partially offset by a $2.7 million increase in interest expense driven primarily by higher related-party borrowings and a $0.9 million decrease in other income.

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 June 30, 2021, we had cash and cash equivalents, and marketable securities of $104.8 million compared to $97.0 million as of December 31, 2020. On April 30, 2021, we entered into an Open Market Sale Agreement (the "Sale Agreement") with respect to an at-the-market (the "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. For the three months ended June 30, 2021, we received net proceeds totaling $94.9 million from the issuance of 6,420,441 shares under the ATM, which we expect to use for general corporate purposes, including to progress our clinical development programs, fund other research and development activities, for capital expenditures and to fund working capital. We may also use a portion of the net proceeds to license intellectual property or to make acquisitions or investments. As of June 30, 2021, we had $402.0 million available for future stock issuances under the ATM.

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 June 30, 2021, we had related-party notes payable together with accrued interest thereon of $300.3 million compared to $254.4 million as of December 31, 2020. During the six months ended June 30, 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:

	Six Months Ended June 30,	
	2021	2020
	(Unaudited, in thousands)	
Cash provided by (used in):		
Operating activities	$ (130,064)	$ (77,129)
Investing activities	42,334	29,268
Financing activities	136,834	87,217
Effects of exchange rate changes on cash, cash equivalents, and restricted cash	(61)	5
Net change in cash, cash equivalents, and restricted cash	$ 49,043	$ 39,361

Operating Activities

For the six months ended June 30, 2021, net cash used in operating activities of $130.1 million consisted of a net loss of $169.9 million and $0.4 million of cash used in net working capital changes, partially offset by $40.2 million in adjustments for non-cash items. Adjustments for non-cash items primarily consisted of $33.2 million in stock compensation expense, $7.0 million in depreciation and amortization expense, $6.2 million in non-cash interest related primarily to related party loans, $2.3 million in 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 $8.4 million in unrealized gains on equity securities driven primarily by an increase in the value of our investments, $0.2 million in realized gains on sales of equity securities, and a $0.1 million change in the fair value of contingent consideration. The change in net working capital consisted primarily of increases of $5.4 million in prepaid and other current assets and $2.6 million in each of accounts payable and related parties. The increases in net working capital were partially offset by decreases of $4.2 million in other assets, $3.8 million in accrued expenses and other liabilities and $3.0 million in operating lease liabilities.

For the six months ended June 30, 2020, net cash used in operating activities of $77.1 million consisted of a net loss of $89.4 million, partially offset by $11.9 million in adjustments for non-cash items and $0.4 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of $7.0 million in depreciation and amortization, $4.0 million in non-cash interest items, $2.0 million in non-cash lease expense related to operating lease right-of-use assets, and $0.8 million in stock compensation expense, partially offset by a $1.0 million change in deferred tax liability, a $0.5 million unrealized gain on equity securities and a $0.4 million change in the fair value of contingent consideration obligation. The changes in net working capital consisted primarily of increases related to $10.2 million in accrued expenses and other liabilities and $2.3 million in accounts payable, partially offset by decreases related to $5.6 million in prepaid expenses and other current assets, $4.7 million in due to related parties and $1.8 million in operating lease liabilities.

Investing Activities

For the six months ended June 30, 2021, net cash provided by investing activities was $42.3 million, which included cash inflows of $57.7 million from maturities and sales of marketable securities, partially offset by $15.1 million of purchases of property, plant and equipment and $0.3 million of purchases of marketable debt securities. 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 six months ended June 30, 2020, net cash provided by investing activities was $29.3 million, which included cash inflows of $44.4 million from maturities and sales of marketable securities, partially offset by $14.8 million of purchases of marketable debt securities and $0.3 million of purchases of property, plant and equipment.

Financing Activities

For the six months ended June 30, 2021, net cash provided by financing activities was $136.8 million, which consisted of $95.0 million in net proceeds from the ATM offering, $40.0 million in proceeds from issuances of related party notes and $4.4 million in proceeds 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 payroll tax withholding.

For the six months ended June 30, 2020, net cash provided by financing activities was $87.2 million, which consisted primarily of $86.8 million in net proceeds from an equity offering.

Future Funding Requirements

To date, we have generated minimal revenue, and 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 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. However, we believe our existing cash, cash equivalents, and investments in marketable securities, together with capital to be raised through equity offerings (including the ATM) and our potential ability to borrow from affiliated entities, will be sufficient to fund our operations through at least the next 12 months following the issuance date of the condensed 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 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 numerous risks and uncertainties associated with the development and commercialization of our product candidates, we may need additional funds to meet our needs sooner than planned.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and 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.

Our future funding requirements will depend on many factors, including, but not limited to:

- progress, timing, number, scope and costs of researching and developing our product candidates and our ongoing, planned and potential clinical trials;
- time and cost of regulatory approvals;
- our ability to successfully commercialize any product candidates, if approved and the costs of such commercialization activities;
- revenue 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;
- cost of building, staffing and validating our own manufacturing facilities in the United States, including having a product candidate successfully manufactured consistent with FDA and European Medicines Agency regulations;
- terms, timing and costs of our current and any potential future collaborations, business or product acquisitions, CVRs, milestones, royalties, licensing or other arrangements that we have established or may establish;
- time and cost necessary to respond to technological, regulatory, political and market developments; and
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

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. 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 amount of $500.0 million of our common stock that may be issued and sold under the ATM. See Note 9, *Stockholders' Deficit*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appear in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q.

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. 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.

Contractual Obligations, Commitments and Contingencies

Contractual Obligations and Commitments

See Note 7, *Commitments and Contingencies – Lease Arrangements*, and Note 8, *Related-Party Agreements*, of the "Notes to Unaudited Condensed 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 consolidated financial statements conform in all material respects with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses for 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.

Stock-Based Compensation

We account for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation* ("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 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 ("CEO") and chief financial officer ("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 June 30, 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 June 30, 2021, our CEO and CFO have concluded that, as of June 30, 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 June 30, 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 7, *Commitments and Contingencies—Litigation*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" included in Part I, Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q 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 Limited Operating History, 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 when needed, or on acceptable terms, 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.
- 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 are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of operating losses, and we expect to continue to incur losses and may never be profitable, which together with our limited operating history, makes it difficult to assess our future viability.
- 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.

Risks Related to Our Business and Industry Regulation

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

- Our clinical trials may not be initiated or completed when we expect, or at all, they may take longer and cost more to complete than we project and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the United States ("U.S.") Food and Drug Administration ("FDA").
- We will be unable to commercialize our product candidates if our trials are not successful.
- Even if one of our product candidates is approved and commercialized, we may not become profitable.
- We use Immuno-Oncology Clinic, Inc. (the "Clinic"), 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 delays or difficulties enrolling and/or maintaining 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 adequate 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.
- 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.
- 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.
- Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.
- Changes in tax law could adversely affect our business and financial condition. Negative or unexpected tax consequences could adversely affect our results of operations.
- Our transfer pricing policies may be subject to challenge by the Internal Revenue Service ("IRS") or other taxing authorities.
- We could be subject to additional income tax liabilities and 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.
- 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.
- 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.
- 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 will face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.
- Public opinion and scrutiny of immunotherapy approaches may impact public perception of us and our product candidates, which may adversely affect our ability to conduct our business and implement our business plans.

- We may seek orphan drug status or Fast Track or Breakthrough Therapy designations or other designation for one or more of our product candidates, but even if any such designation or status is granted, it 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 and we may be unable to maintain any benefits associated with such designations or status, including market exclusivity.
- 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.
- 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 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 generate product revenues.
- 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.
- If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.
- 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.
- Our internal computer systems, or those used by our contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), clinical sites or other contractors or consultants, may fail or suffer security breaches.
- Our business could be adversely affected by the effects of health epidemics, pandemics or contagious diseases, including the recent COVID 19 pandemic, 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 have formed, and may in the future form or seek, strategic alliances or enter into collaborations with third parties or additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. If we fail to enter into such strategic alliances, collaborations or licensing arrangement, or such strategic alliances, collaborations or licensing arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates.
- 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.
- 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.
- We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.
- 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 become involved in securities litigation or stockholder derivative litigation in connection with our recent merger, 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.
- A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

Risks Related to Government Regulation

- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, be unable to commercialize our product candidates. We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.
- 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.
- If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.
- 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.
- 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.
- 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.
- 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.
- 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.
- If we, or any third party contract manufacturers or suppliers that we engage, 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.
- Disruptions at the FDA, the Securities and Exchange Commission (“SEC”) and other government agencies caused by funding shortages or global health concerns 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.
- 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.
- 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.
- We may face difficulties from changes to current regulations and future legislation.
- Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.
- Our employees, independent contractors, consultants, commercial partners, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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 and our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.
- 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. We or our licensors, collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our product candidates, or may put our patents and other proprietary rights at risk.
- 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.
- Changes in United States patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.
- 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.
- 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 may be required to pay damages and we could lose license rights that are important to our business.
- We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.
- 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 may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.
- If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be 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.
- Intellectual property rights do not necessarily address all potential threats.

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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- We are not subject to the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which could negatively affect your investment.
- 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.
- 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.

Risks Related to Our Limited Operating History, 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 when needed, or on acceptable terms, we may be unable to complete the development and commercialization of our product candidates.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. A significant portion of our funding had been in the form of promissory notes representing $300.3 million in indebtedness, including interest thereon, as of June 30, 2021 held by entities affiliated with Dr. Soon-Shiong with a maturity date of September 30, 2025.

As of June 30, 2021, we held cash, cash equivalents and marketable securities totaling $104.8 million.

We will need to obtain additional financing to fund our future operations, including completing the development and commercialization of our product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and 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.

Our future funding requirements will depend on many factors, including, but not limited to:

- progress, timing, number, scope and costs of researching and developing our product candidates and our ongoing, planned and potential clinical trials;
- time and cost of regulatory approvals;
- our ability to successfully commercialize any product candidates, if approved and the costs of such commercialization activities;
- revenue 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;
- cost of building, staffing and validating our own manufacturing facilities in the United States, including having a product candidate successfully manufactured consistent with FDA and European Medicines Agency regulations;
- terms, timing and costs of our current and any potential future collaborations, business or product acquisitions, contingent value rights (“CVRs”), milestones, royalties, licensing or other arrangements that we have established or may establish;
- time and cost necessary to respond to technological, regulatory, political and market developments; and
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

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. 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 amount of $500.0 million of our common stock that may be issued and sold under an “at-the-market” sales agreement with Jefferies LLC (the “ATM”).

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. 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.

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 June 30, 2021, our indebtedness was $300.3 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.

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. Our ability to realize the anticipated benefits of the merger 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. 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;
- 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 are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of operating losses, and we expect to continue to incur losses and may never be profitable, which together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects, and now that the merger 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 and we have not generated any revenue from product sales, 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. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry, including in connection with obtaining marketing approvals, manufacturing a commercial-scale product or arranging for a third party to do so on our behalf or conducting sales and marketing activities necessary for successful product commercialization. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all.

Since the commencement of our operations, we have incurred significant losses in each year and, as of June 30, 2021 we had an accumulated deficit of $1.8 billion. We expect to continue 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, increasing our manufacturing capabilities and, upon successful receipt of FDA approval, commercializing our products. Moreover, we do not expect to have significant product sales or revenue for the foreseeable future.

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. Our ability to achieve profitability 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. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. As a result, it may be more difficult for you to assess our future viability than it could be if we had a longer operating history.

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 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. 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 expect to invest heavily in these product candidates as well as in our other existing product candidates and in any future product candidates that we may develop. Our business and our ability to generate revenues in the future substantially depends on the successful development, regulatory approval and commercialization of such product candidates, each of which may never occur. 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. Furthermore, 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. 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. 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.

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. We are 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. 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. 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. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. 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 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. Following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. 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 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 in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. 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 or revoke their approval of these other therapies, or if safety, efficacy, quality, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or market such combination therapy.

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. 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.

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. 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. 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. Preclinical studies may reveal unfavorable product candidate characteristics, including safety concerns. 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.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through 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. 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.

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.

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, interim 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. 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. 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 interim, 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. 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.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available 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 and to manufacture products. Any failure by a third party, related party, or by us to conduct the clinical trials according to 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.

Large-scale clinical trials require significant financial and management resources. We expect to be heavily reliant on third and related parties, including medical institutions, academic institutions, clinical investigators or CROs to conduct, supervise or monitor some or all aspects of our clinical trials, and in some cases, CMOs to manufacture products. We have entered into agreements with the Clinic, a related party, to continue to conduct and oversee certain of our clinical trials. Our CROs, the Clinic and other third parties must communicate and coordinate with one another in order for our trials to be successful. 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. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. 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.

Relying on third-party clinical investigators, CROs or CMOs may force us to encounter delays and challenges that are outside of our control. 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 and the third parties upon which we intend to rely for conducting our clinical trials 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 Biologics License Application ("BLA") or New Drug Application ("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 have to be repeated, and our submission of marketing applications may be delayed or the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. 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 and materials that were produced under current Good Manufacturing Practices ("cGMP") and/or Good Tissue Practice regulations, which are enforced by regulatory authorities. 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 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. 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.

Our CROs, the Clinic, 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 conducting our clinical trials (i) do not successfully carry out their contractual duties, (ii) do not meet expected deadlines, (iii) experience work stoppages, (iv) do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, (v) need to be replaced, (vi) experience financial hardships or (vi) terminate their agreements with us or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP or other 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. Additionally, 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. 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. Furthermore, if any of the third parties conducting our clinical trials experience any financial hardships due to difficulties relating to the operation of their business, if could damage our business, financial condition, results of operations and prospects. 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 the 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. 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.

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.

Our clinical trials may not be initiated or completed when we expect, or at all, they may take longer and cost more to complete than we project 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 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. A failure of one or more clinical trials can occur at any stage of the clinical trial process, other events may cause us to temporarily or permanently stop a clinical trial, and our future clinical trials may not be successful. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- regulators or Institutional Review Boards ("IRBs") may (i) 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 (ii) require that we modify or amend our clinical trial protocols;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on trial design or eligibility criteria for patient enrollment;
- the FDA or comparable foreign regulatory authorities may (i) disagree with our intended indications, or our interpretation of data from preclinical studies and clinical trials, (ii) find that a product candidate's benefits do not outweigh its safety risks, (iii) not accept data from trials with clinical trial sites in foreign countries, (iv) fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies or (v) take longer than we anticipate when making a decision on our product candidates;
- the FDA may not allow us to use the clinical trial data from a research institution to support an investigational new drug ("IND") application 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;
- delays in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a trial, including scheduling conflicts with participating clinicians and clinical institutions;
- difficulties in identifying and enrolling patients who meet trial eligibility criteria and who remain in the study until its conclusion;
- 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 availability of financial resources to commence and complete the planned trials;
- ambiguous or negative interim results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials, or preclinical studies, or abandon product development programs;
- obtaining sufficient supply of therapies that may be used in combination with our molecular agents or as comparative agents in clinical trials or 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;
- 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 commence, make any necessary changes to or complete 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; and
- 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.

Collaborations with other entities 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, slow down our product development and approval process or impair our ability to commence product sales and 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. 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 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 and our current product candidates are in the early stages of development. We currently have ongoing clinical trials to evaluate our product candidates. We must demonstrate our product candidates' safety and efficacy in humans through extensive clinical testing. Success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. 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, adenovirus 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. 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. 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. 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. 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 product candidates is approved and commercialized, we may not become profitable.

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 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.

Even if the FDA approves Anktiva for certain 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, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates.

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.

We use the Clinic, 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.

The Clinic has conducted, is currently conducting, and in the future may conduct, clinical trials involving our product candidates. The Clinic is a related party as it is owned by an officer of the company and additionally, NantWorks, LLC ("NantWorks") manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for certain of the company's trials conducted at the Clinic. NantWorks, which is wholly 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. 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. 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 or comparable regulatory authorities 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. 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. 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.

If we encounter delays or difficulties enrolling and/or maintaining 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 and retention 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 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;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol or clinical investigators may enroll patients who do not meet the enrollment criteria, 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;
- 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;
- amendments to our clinical protocols, including amendments we have made to further define the patient population to be studied;
- 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.

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 that have established safety and efficacy profiles, rather than enroll patients in any future clinical trial.

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. Combination immunotherapy that includes our current product candidates may be associated with more frequent adverse events or additional adverse events. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us, IRBs, Drug Safety Monitoring Boards, the FDA or comparable foreign regulatory authorities to interrupt, delay or halt clinical trials or order our clinical trials to be placed on clinical hold, 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 for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical studies, 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 clinical trials and product candidates may also negatively impact our ability to conduct clinical trials using tumor-infiltrating lymphocyte 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. 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. In addition, these serious adverse effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates 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 adequate 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.

The manufacture of our 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. 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. 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. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. 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 utilize for more advanced clinical trials or commercialization.

Currently we manufacture our product candidates or 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. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing our product candidates 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 our agreements with them. If we were to need to find alternative manufacturing facilities it may take us significant time to find a replacement, if we are able to find a replacement at all and 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.

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 CMOs 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. 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.

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. Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and 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.

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 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 which could delay clinical trials and adversely harm our business. 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.

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.

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. For some of these reagents, equipment and materials used in the manufacture of our product candidates, we rely, and we may in the future rely, on sole source vendors or a limited number of vendors. 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. 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.

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 our 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.

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 ("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 ("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 ("TCJA"), as modified by the Coronavirus Aid, Relief, and Economic Security Act ("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. 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. 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 significantly reformed the Code. 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 condensed consolidated financial statements. Additionally, on March 27, 2020, the CARES 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. 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.

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 could be subject to additional income tax liabilities and 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 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. 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. While we believe our tax positions are consistent with the tax laws in the jurisdictions in which we conduct our business, 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.

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 data regarding 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 addressable patient populations that may 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. 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.

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 development, testing and manufacturing 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 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 a regulatory investigation of the safety and effectiveness of our products, our third-party manufacturer’s manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of approvals, decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price.

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.

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. Based on the breadth and depth of our platforms, we believe our competitors include large pharmaceutical and biotechnology companies, and specialized pharmaceutical and biotechnology firms acting either independently or together with other such companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research in the U.S. and Europe are also potential competitors and may seek patent protection or may establish collaborative arrangements for competitive products or programs. These competitors have developed, may develop and are developing product candidates and processes competitive with our product candidates. Research and discoveries by others may result in breakthroughs which may render our product candidates obsolete even before they generate any revenues. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing product candidates. 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. Many of our potential competitors have substantially greater research and development capabilities and scientific, regulatory, manufacturing, marketing, sales, financial, managerial, and human resources and experience than we do. Our competitors may be more successful than us in obtaining regulatory approval for their treatments and products, often more rapidly than we may obtain approval for ours, and achieving widespread market acceptance and a strong market position, rendering our treatments obsolete or non-competitive, possibly even before we are able to enter the market. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical 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. 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.

Even if we obtain regulatory approval for our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our therapies. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

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.

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. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise.

Public opinion and scrutiny of immunotherapy approaches may impact public perception of us and our product candidates, which may adversely affect our ability to conduct our business and implement 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 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 patients in 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.

We may seek orphan drug status or Fast Track or Breakthrough Therapy designations or other designation for one or more of our product candidates, but even if any such designation or status is granted, it 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 and we may be unable to maintain any benefits associated with such designations or status, including market 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 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.

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 the drug or biologic will be recovered from sales in the U.S. 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. 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.

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, in connection with FDA approval of another company’s drug, 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 dispensed the drug, including the implementation of a 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 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 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 have little to no prior experience in, and currently do not have a commercial infrastructure for, the marketing, sale and distribution of biopharmaceutical products. 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, if approved, in order to commercialize our product candidates, we must build our marketing, sales and distribution capabilities, including a comprehensive healthcare compliance program, or arrange with third parties to perform these services, which will take time and require significant financial expenditures and could delay any product launch and we may not be successful in doing so. There are significant risks involved with building and managing a commercial infrastructure. 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. Recruiting, training and retaining 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. 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. 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.

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.

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.

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. 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 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 or 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;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration of such product candidates;
- our ability to offer such product candidates for sale at competitive prices, including the 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;
- the timing of market introduction of such product candidates, as well as competitive products;
- 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;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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 drug where the FDA has not previously approved any other new drug containing the same active 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.

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 product 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 and commercialization 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.

Our business could be adversely affected by the effects of health epidemics, pandemics or contagious diseases, including the recent COVID-19 pandemic, 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 declared the outbreak of COVID-19 as a 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 and any actions we have taken in response, could materially affect our operations, including at our headquarters and at our manufacturing facilities, which have been and may in the future be 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 CROs, CMOs, clinical sites or other third parties with whom we conduct business. Any such epidemic or pandemic may heighten the risk that a significant portion of our workforce could suffer illness or otherwise not be permitted or be unable to work, and may require that certain of our employees work remotely, which heightens certain risks, including those related to cybersecurity and internal controls.

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. 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.
- Manufacturing: The pandemic has impacted, and may continue to impact, our manufacturing locations, 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.
- 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 collaborations with third parties or additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. If we fail to enter into such strategic alliances, collaborations or licensing arrangement, or such strategic alliances, collaborations or licensing arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates.

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 Therapeutics, Inc. ("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. 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;
- 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.

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 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 current or future collaborators or strategic partners could become our competitors in the future and 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. 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.

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. 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. asserting breach of contract under our subsidiary Altor's license agreement with them. For more information regarding these disputes, see Note 7, *Commitments and Contingencies—Litigation*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appear in Part 1. Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q. Any of these developments could harm our product development efforts.

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.

Our operations will be dependent upon the services of our executives and our employees who are engaged in research and development. If we lose the services of members of our senior management, particularly Dr. Soon-Shiong, for a short or an extended time, for any reason, we may not be able to find appropriate replacements on a timely basis, and our business, financial condition and results of operations could be materially 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.

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

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 their attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. 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 personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need, on acceptable terms or at all. 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.

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 on economically reasonable terms, or at all. 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.

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:

- 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 (including increased cash requirements). In addition, if we undertake acquisitions, we may issue dilutive equity securities, assume or incur additional debt obligations or contingent liabilities, 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 become involved in securities litigation or stockholder derivative litigation in connection with our recent merger, 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 our recent merger, 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.

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 ("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.

Risks Related to Government Regulation

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates. We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.

Our product candidates are subject to extensive governmental regulations relating to, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, lengthy, time-consuming, uncertain and subject to unanticipated delays and can vary substantially based upon the type, complexity and novelty of the products involved. 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. 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.

We have not previously submitted a BLA or NDA or similar marketing or drug approval application to the FDA or comparable foreign authorities, for any product candidate, which may impede our ability to obtain timely FDA approvals, if at all, 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. 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 and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

Any delay in completing development or obtaining, or failing to obtain, required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. 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.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, however 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, procedures and requirements may 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. 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. 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.

Obtaining foreign regulatory approvals and establishing and maintaining 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 fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

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.

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.

If the FDA or comparable foreign regulatory authorities become aware of new safety information or previously unknown problems after approval of any of our product candidates, including: (i) adverse events of unanticipated severity or frequency, (ii) that the product is less effective than previously thought, (iii) problems with our third-party manufacturers or manufacturing processes, or (iv) failure to comply with regulatory requirements, or 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 (including required additional warnings), provision of corrective information, imposition of post-market requirements, including the need for additional testing or costly post-approval studies or post-market surveillance, imposition of distribution, manufacturing or other restrictions under a REMS, imposition of restrictions on a product’s indicated uses, 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, issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, reputational harm and adverse publicity, among other adverse consequences. Any such restrictions could limit sales of the product. 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.

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.

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. 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. 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 (“PMA”).

The FDA can also refuse to clear or approve pre-market applications for any medical device we develop. 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.

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.

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. 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.

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.

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 of 2018 ("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. The collection and use of health data in the EU is governed by the EU General Data Protection Regulation ("GDPR"). 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 up to 4% of the total worldwide 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.

If we, or any third party contract manufacturers or suppliers that we engage, 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 and any of our third-party manufacturers or suppliers will be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, manufacture, storage, treatment and disposal of hazardous materials and wastes. Our operations and research and development activities involve the controlled use of medical and 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. Although we believe that our procedures for using, storing and disposing of these materials comply with legally prescribed standards, 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 or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. 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 comprehensive insurance coverage for liabilities arising from medical or hazardous materials, 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, which could harm our business, prospects, financial condition or results of operations. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, 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 employees and stop critical activities. In response to the COVID-19 pandemic, in 2020, the FDA announced that it would postpone domestic and foreign routine surveillance inspections. Based on updated guidance issued in May 2021, the FDA continues to conduct "mission-critical" inspections on a case-by-case basis, or, where possible to do so safely, has resumed prioritized domestic inspections, such as pre-approval and surveillance inspections. While the FDA indicated that it will consider alternative methods for inspections and exercise discretion on a case-by-case basis to approve products based on a desk review, 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 ("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) (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 ("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.

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. 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.

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. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. 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. 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. 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. 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. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. 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.

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. 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. 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. 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.

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. 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. 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.

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 a BLA or NDA, 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. 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.

Even if we obtain coverage for a given product, the resulting approved reimbursement payment rates might not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments or achieve or sustain profitability or may require co-payments that patients find unacceptably high. 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.

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 may face difficulties from changes to current regulations and future legislation.

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 federal and state healthcare reform measures that may be adopted in the future, 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, 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. These changes included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 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 (“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. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our financial operations.

Since its enactment, various portions of the ACA have been subject to judicial and constitutional challenges. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts to repeal or replace certain aspects of the ACA. It is unclear how judicial decisions, future litigation, and healthcare measures promulgated by the Biden administration will impact the ACA and our business, financial condition and results of operations. 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.

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, in 2020, 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 U.S Department of Health and Human Services 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, principal investigators, CROs, suppliers 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, principal investigators, CROs, suppliers 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. 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 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. 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs.

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 and our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

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 and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and has been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. As a result, the issuance, scope, validity, enforceability, or commercial value of our patent rights remain highly uncertain.

Any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing therapeutics and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, any of our issued or granted patents will not later be found to be invalid or unenforceable, or any issued or granted patents will include claims sufficiently broad to cover our product candidates and technology, or to provide meaningful protection from our competitors. 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 it is uncertain how much protection, if any, will be provided by our patents, including if they are challenged in the courts or patent offices 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, 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.

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. 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, or one of our licensors, may be required to participate in interference proceedings in the 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 also be required to participate 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. 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.

If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to cease using the technology or to obtain and maintain license rights from prevailing third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. 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. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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.

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, CMOs, 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.

We or our licensors, collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our product candidates, or may put our patents and other proprietary rights at risk .

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, even if we were successful in stopping the violation of our patent rights.

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).

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 cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources, including our scientists and management, from our business.

An adverse result in any litigation or defense proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and could put our patent applications at risk of not issuing. 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. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. In addition, in an infringement proceeding, there is a risk that a court may decide that one or more of our patents is not valid or is unenforceable 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. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, 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 better 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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.

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 ("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 (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.

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 may be required to pay damages and 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 (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 product candidates. 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, valuable intellectual property. 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.

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 intend 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.

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 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.

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. 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 June 30, 2021, Dr. Soon-Shiong and certain of his affiliates beneficially own approximately 80.3% 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 CVRs issued to the former stockholders of 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 notes representing $300.3 million in indebtedness, including interest thereon, of the company as of June 30, 2021.

In addition, pursuant to the Nominating Agreement between us and Cambridge Equities, LP ("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 80.3% of our outstanding shares of common stock as of June 30, 2021. 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 of 1933, as amended ("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 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 the Sarbanes-Oxley Act of 2002 ("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 are required, pursuant to Section 404 of Sarbanes-Oxley ("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, since we no longer qualify as a "smaller reporting company" as of fiscal year end 2021, we are required to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting in our Annual Report on Form 10-K. We have initiated the process of engaging and coordinating with our independent registered public accounting firm to perform an audit of, and give an opinion on, our internal control over financial reporting for the annual period ending December 31, 2021. 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 independent registered public accounting firm will agree with management's assessment of our internal control over financial reporting when they conduct such audit and deliver 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 and we currently have a nominating and corporate governance committee and the majority of the members of such committee are 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.

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 DGCL, 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 DGCL. 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 80.3% of our common stock as of June 30, 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 DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

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

(a) Recent Sales of Unregistered Securities

None.

(b) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

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

Exhibit Number	Description 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).
3.2*	Amended and Restated Bylaws of ImmunityBio, Inc., effective as of March 10, 2021.
10.1*	First Amendment to Lease made and entered into as of May 28, 2021, but made effective as of April 1, 2021, by and between 605 Nash, LLC and ImmunityBio, Inc.
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.
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).
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 on Form 10-Q 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.

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: August 12, 2021

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

Date: August 12, 2021

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

Exhibit 3.2

AMENDED AND RESTATED BYLAWS OF

IMMUNITYBIO, INC.

(As amended and restated on June 18, 2020. As further amended on March 10, 2021 to update the name of the company in connection with the merger with ImmunityBio, Inc.)

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AMENDED AND RESTATED BYLAWS OF IMMUNITYBIO, INC.

ARTICLE I — CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of ImmunityBio, Inc. shall be fixed in the corporation's certificate of incorporation. References in these bylaws to the certificate of incorporation shall mean the certificate of incorporation of the corporation, as amended from time to time, including the terms of any certificates of designation of any series of Preferred Stock.

1.2 OTHER OFFICES

The corporation may at any time establish other offices at any place or places.

ARTICLE II — MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. The board of directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the corporation's principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held on such date, at such time, and at such place (if any) within or without the State of Delaware as shall be designated from time to time by the board of directors and stated in the corporation's notice of the meeting. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted.

2.3 SPECIAL MEETING

(i) A special meeting of the stockholders, other than those required by statute, may be called at any time only by (A) the affirmative vote of a majority of the Whole Board, (B) the chairperson of the board of directors, (C) the chief executive officer or (D) the president. A special meeting of the stockholders may not be called by any other person or persons. The board of directors, by the affirmative vote of a majority of the Whole Board, may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders. For purposes of these bylaws, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies or unfilled directorships in previously authorized directorships.

(ii) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the board of directors, the chairperson of the board of directors, the chief executive officer or the president. Nothing contained in this Section 2.3(ii) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(i) *Advance Notice of Stockholder Business.* At an annual meeting of the stockholders, only such business shall be

conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be brought: (A) pursuant to the corporation's proxy materials with respect to such meeting, (B) by or at the direction of the board of directors, or (C) by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(i) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this Section 2.4(i). In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities and Exchange Act of 1934, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations, the "1934 Act"), clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of Section 2.4(i) above, a stockholder's notice must set forth all information required under this Section 2.4(i) and must be timely received by the secretary of the corporation. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the corporation not later than the 45th day nor earlier than the 75th day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; *provided*, *however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the tenth day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this Section 2.4(i)(a). "Public Announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

(b) To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the corporation's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class and number of shares of the corporation that are held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person as of the date of delivery of such notice, (4) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, (5) any material interest of the stockholder or a Stockholder Associated Person in such business, and (6) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the voting power of the corporation's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (1) through (6), a "Business Solicitation Statement"). In addition, to be in proper written form, a stockholder's notice to the secretary must be supplemented not later than ten days following the record date for notice of the meeting to disclose the information contained in clauses (3) and (4) above as of the record date for notice of the meeting. For purposes of this Section 2.4, a "Stockholder Associated Person" of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made, or (iii) any person controlling, controlled by or under common control with such person

referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this Section 2.4(i) and, if applicable, Section 2.4(ii). In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this Section 2.4(i), and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted.

(ii) *Advance Notice of Director Nominations at Annual Meetings.* Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this Section 2.4(ii) shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the board of directors of the corporation shall be made at an annual meeting of stockholders only (A) by or at the direction of the board of directors or (B) by a stockholder of the corporation who (1) was a stockholder of record at the time of the giving of the notice required by this Section 2.4(ii) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this Section 2.4(ii). In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the corporation.

(a) To comply with clause (B) of Section 2.4(ii) above, a nomination to be made by a stockholder must set forth all information required under this Section 2.4(ii) and must be received by the secretary of the corporation at the principal executive offices of the corporation at the time set forth in, and in accordance with, the final three sentences of Section 2.4(i)(a) above; provided additionally, however, that in the event the number of directors to be elected to the board of directors is increased and there is no Public Announcement naming all of the nominees for director or specifying the size of the increased board made by the corporation at least ten (10) days before the last day a stockholder may deliver notice of nomination pursuant to the foregoing provisions, a stockholder's notice required by this Section 2.4(ii) shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the secretary at the principal executive offices of the corporation not later than the close of business on the tenth day following the date on which such Public Announcement is first made by the corporation.

(b) To be in proper written form, such stockholder's notice to the secretary must set forth:

(1) as to each person (a "nominee") whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, gender (in accordance with Section 3.3(b) of these bylaws), business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class and number of shares of the corporation that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (D) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (E) a description of all arrangements or understandings between or among the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder or concerning the nominee's potential service on the board of directors, (F) a written statement executed by the nominee acknowledging that as a director of the corporation, the nominee will owe fiduciary duties under Delaware law with respect to the corporation and its stockholders, and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Regulation

14A under the 1934 Act (including without limitation the nominee's written consent to being named in the proxy statement, if any, as a nominee and to serving as a director if elected or re-elected, as the case may be); and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (5) of Section 2.4(i)(b) above, and the supplement referenced in the second sentence of Section 2.4(i)(b) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (B) a statement whether either such stockholder or Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of voting power of the corporation's voting shares reasonably believed by such stockholder or Stockholder Associated Person to be necessary to elect or re-elect such nominee(s) (such information provided and statements made as required by clauses (A) and (B) above, a "Nominee Solicitation Statement").

(c) At the request of the board of directors, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the corporation (1) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given, (2) such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the corporation under applicable law, securities exchange rule or regulation, or any publicly disclosed corporate governance guideline or committee charter of the corporation and (3) such other information that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee; in the absence of the furnishing of any such information of the kind specified in this Section 2.4(ii)(c) if requested, such stockholder's nomination shall not be considered in proper form pursuant to this Section 2.4(ii).

(d) Without exception, no person shall be eligible for election or re-election as a director of the corporation at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this Section 2.4(ii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded.

(iii) *Advance Notice of Director Nominations for Special Meetings.*

(a) If the board of directors has authorized in the specific case that stockholders may fill a vacancy or newly created directorship at a special meeting of stockholders, and a special meeting has been properly called for such purpose, nominations of persons for election or appointment to the board of directors at such special meeting shall be made only (1) by or at the direction of the board of directors or (2) by any stockholder of the corporation who (A) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(iii) and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the corporation that includes the information set forth in Sections 2.4(ii)(b) and (ii)(c) above. To be timely, such notice must be received by the secretary at the principal executive offices of the corporation not later than the close of business on the later of the 90th day prior to such special meeting or the tenth day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors to be elected or appointed at such meeting. A person shall not be eligible for election or appointment as a director at a special meeting unless the person is nominated (i) by or at the direction of the board of directors or (ii) by a stockholder in accordance with the notice procedures set forth in this Section 2.4(iii). In addition, a nominee shall not be eligible for election or appointment if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the

statements therein not misleading. Any person nominated in accordance with this Section 2.4(iii) is subject to, and must comply with, the provisions of Section 2.4(ii)(c).

(b) The chairperson of such special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

(iv) *Other Requirements and Rights.* In addition to the foregoing provisions of this Section 2.4, a stockholder must also comply with all applicable requirements of state law and of the 1934 Act with respect to the matters set forth in this Section 2.4. Nothing in this Section 2.4 shall be deemed to affect any rights of:

(a) a stockholder to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act; or

(b) the corporation to omit a proposal from the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act.

2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 QUORUM

The holders of a majority of the voting power of the stock issued, outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders, unless otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange. Where a separate vote by a class or series or classes or series is required, a majority of the voting power of the then-issued and outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange.

If a quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. The chairperson of the meeting shall have the authority to adjourn a meeting of the stockholders in all other events. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than

30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the board of directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business. The chairperson of any meeting of stockholders shall be designated by the board of directors; in the absence of such designation, the chairperson of the board, if any, the chief executive officer (in the absence of the chairperson) or the president (in the absence of the chairperson of the board and the chief executive officer), or in their absence any other executive officer of the corporation, shall serve as chairperson of the stockholder meeting.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange, directors who satisfy the qualifications for service on the board of directors, including as contemplated in Section 3.3(b) of these bylaws, shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the voting power of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise provided in the certificate of incorporation, any action required by statute to be taken at any annual or special of the stockholders, or any action which may be taken at an annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be (i) signed by the holders of record on the record date (established in the manner set forth in Section 2.11 and Article VIII of the corporation's certificate of incorporation) of outstanding shares of the corporation having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted; provided, however, that in the case of the election or removal of directors by written consent, such consent shall be effective only if signed by the holders of all outstanding shares entitled to vote for the election of directors, and (ii) delivered to the corporation in accordance with Section 228 of the DGCL.

2.11 RECORD DATES

In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date

upon which the resolution fixing the record date is adopted by the board of directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the board of directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the board of directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided*, *however*, that the board of directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy, in the manner and by the means contemplated by Section 212 of the DGCL, as it may be amended from time to time. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL, as it may be amended from time to time.

2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided*, *however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date. The stockholder list shall be arranged in alphabetical order and shall show the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the corporation's principal place of business. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. If the meeting is to be held at a place (as opposed to solely by means of remote communication), then a list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then a list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. The stock ledger of the corporation shall be the only evidence as to the identity of the stockholders entitled to examine the stock list and vote at the meeting and the number of shares held by each of them.

2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the corporation shall appoint an inspector or inspectors of election to act at the meeting or its adjournment and make a written report thereof. The number of inspectors shall be either one (1) or three (3), and the corporation may designate one (1) or more persons as alternate inspectors to replace any inspector who fails to act. If any person appointed as inspector or alternate inspector fails to appear or fails or refuses to act, then the chairperson of the meeting shall appoint a person to fill that vacancy.

Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability.

The inspector or inspectors so appointed and designated shall (i) ascertain the number of shares of capital stock of the corporation outstanding and the voting power of each share, (ii) determine the shares of capital stock of the corporation represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of capital stock of the corporation represented at the meeting and such inspector or inspectors' count of all votes and ballots.

At the meeting, the inspector or inspectors shall act in accordance with Section 231 of the DGCL, as it may be amended from time to time, including in accepting, counting and determining the validity of any ballots, proxies, and votes, and revocations thereof and changes thereto.

ARTICLE III — DIRECTORS

3.1 POWERS

The business and affairs of the corporation shall be managed by or under the direction of the board of directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time solely by resolution of the Whole Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

(a) Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy or newly created directorship, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

(b) During such time that the corporation is subject to Section 301.3 of the California Corporations Code, the following qualifications for directors shall apply:

(i) The board of directors shall consist of two (2) categories of directorships, which are "Category 1 Directorships" and "Category 2 Directorships". There shall be one (1) Category 2 Directorship until 11:59 p.m. Pacific time on December 31, 2021, at which time: (A) if the number of directors is six (6) or more, there shall be three (3) Category 2 Directorships; (B) if the number of directors is five (5), there shall be two (2) Category 2 Directorships; and (C) if the number of directors is four (4) or fewer, there shall be one (1) Category 2 Directorship; *provided*, that no decrease in the number of Category 1 Directorships shall have the effect of removing any director before that

director's term of office expires. All directorships that are not Category 2 Directorships, if any, are Category 1 Directorships, which shall be occupied by any individuals who are otherwise nominated and elected in accordance with these bylaws.

(ii) To qualify as a director to occupy a Category 2 Directorship, a person must be an individual who self-identifies her gender as a woman, without regard to the individual's designated sex at birth (referred to herein as "female"). A female nominee shall qualify as a director to occupy a Category 1 Directorship only if there is no unoccupied Category 2 Directorship. In the event that there is an unoccupied Category 2 Directorship, a female director then occupying a Category 1 Directorship, if any, beginning with the longest tenured such director (and, if more than one (1) such director has equal tenure, beginning with such director who received the most votes in favor of such director's election or re-election at the most recent annual meeting), shall automatically be deemed to occupy such Category 2 Directorship and not such Category 1 Directorship.

(iii) The board of directors shall have the power to construe and apply the provisions of this Section 3.3(b) and to make all determinations necessary or desirable to implement such provisions.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the corporation; *provided, however,* that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the director. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. Unless otherwise specified in the notice of resignation, acceptance of such resignation shall not be necessary to make it effective. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the board of directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws or if authorized by resolution of the board of directors, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class shall be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and not by the stockholders. A person so elected by the directors then in office to fill a vacancy or newly created directorship shall hold office until his or her successor shall have been duly elected and qualified, and, if the directors are divided into classes, a person so elected by the directors then in office to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board of directors (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least 10% of the voting power of the capital stock of the corporation at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the DGCL as far as applicable.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The board of directors and any committee of the board of directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors or

any committee of the board of directors may participate in a meeting of the board of directors or any committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairperson of the board of directors, the chief executive officer, the president, the secretary or a majority of the Whole Board, at such times and places as he or she or they shall designate.

Notice of the time and place of special meetings shall be:

(i) delivered personally by hand, by courier or by telephone;

(ii) sent by United States first-class mail, postage prepaid; or

(iii) given by means of electronic transmission as contemplated by Section 232 of the DGCL, as it may be amended from time to time, or any successor provisions thereto, directed to each director at the address, telephone number or form of electronic transmission for such director, as the case may be, as shown on the corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) or given by means of electronic transmission, it shall be delivered or given at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the corporation's principal executive office) nor the purpose of the meeting, to the fullest extent permitted by law.

3.8 QUORUM; VOTING

At all meetings of the board of directors, a majority of the total authorized number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

The affirmative vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation, these bylaws or statute, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a

meeting if all members of the board of directors or committee, as the case may be, consent thereto in writing or by electronic transmission. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this Section 3.9 at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation, these bylaws or statute, the board of directors shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS

A director may be removed from office by the stockholders of the corporation with or without cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE IV — COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The board of directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors or in these bylaws, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the corporation.

4.2 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(i) Section 3.5 (place of meetings and meetings by telephone);

(ii) Section 3.6 (regular meetings);

(iii) Section 3.7 (special meetings; notice);

(iv) Section 3.8 (quorum; voting);

(v) Section 3.9 (action without a meeting); and

(vi) Section 7.5 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members. *However*:

(i) the time of regular meetings of committees may be determined by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the committee; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors or a committee may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the board of directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V — OFFICERS

5.1 OFFICERS

The officers of the corporation shall be a president and a secretary. The corporation may also have, at the discretion of the board of directors, a chairperson of the board of directors, a vice chairperson of the board of directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The board of directors shall appoint the officers of the corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment. A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled in the manner prescribed in this Article V for the regular election to such office.

5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either

with or without cause, by the board of directors or by any officer upon whom such power of removal may be conferred by the board of directors, except that, unless specifically approved by the board, officers may not remove other officers chosen by the board of directors.

Any officer may resign at any time by giving written or electronic notice to the corporation; *provided, however*, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the officer. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the corporation shall be filled by the board of directors or as provided in Section 5.3.

5.6 REPRESENTATION OF SHARES OR INTERESTS OF OTHER CORPORATIONS OR ENTITIES

The chairperson of the board of directors, the president, any vice president, the treasurer, the secretary or any assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares or equity interests of any other corporation or corporations or entity or entities standing in the name of this corporation, including the right to act by written consent. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the board of directors.

ARTICLE VI — STOCK

6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the corporation by any two officers of the corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the corporation in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the corporation shall declare a dividend upon partly-paid shares of

the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the corporation shall send to the registered owner thereof a written notice or notice by electronic transmission containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 151, 156, 202(a) or 218(a) of the DGCL or with respect to this Section 6.2 a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

6.3 LOST, STOLEN OR DESTROYED CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 DIVIDENDS

The board of directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the corporation's capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock, subject to the provisions of the certificate of incorporation.

The board of directors may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer; *provided, however,* that such succession, assignment or authority to transfer is not prohibited by the certificate of incorporation, these bylaws, applicable law or contract.

6.6 STOCK TRANSFER AGREEMENTS

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any

one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.7 REGISTERED STOCKHOLDERS

The corporation:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(ii) shall be entitled (to the fullest extent permitted by law) to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII — MANNER OF GIVING NOTICE AND WAIVER

7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the corporation's records. An affidavit of the secretary or an assistant secretary of the corporation or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

7.2 NOTICE BY ELECTRONIC TRANSMISSION

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission permitted by applicable law.

Any notice given pursuant to the preceding paragraph shall be deemed given as contemplated by Section 232 of the DGCL, as it may be amended from time to time, or any successor provision thereto.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

7.3 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within 60 days of having been given written notice by the corporation of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.

7.4 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and

there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.5 WAIVER OF NOTICE

Whenever notice is required to be given to stockholders, directors or other persons under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, the board of directors or any committee designated by the board of directors, as the case may be, need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII — INDEMNIFICATION

8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding") (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director of the corporation or an officer of the corporation, or while a director of the corporation or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding 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 corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the corporation, or while a director or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit 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 corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and

only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

8.4 INDEMNIFICATION OF OTHERS; ADVANCE PAYMENT TO OTHERS

Subject to the other provisions of this Article VIII, the corporation shall have power to advance expenses to and indemnify its employees and its agents to the extent not prohibited by the DGCL or other applicable law. The board of directors shall have the power to delegate the determination of whether employees or agents shall be indemnified or receive an advancement of expenses to such person or persons as the board of directors determines.

8.5 ADVANCE PAYMENT OF EXPENSES

Expenses (including attorneys' fees) incurred by an officer or director of the corporation in defending any Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems reasonably appropriate and shall be subject to the corporation's expense guidelines. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in Section 8.6(ii) or 8.6(iii) prior to a determination that the person is not entitled to be indemnified by the corporation.

8.6 LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 and the DGCL, the corporation shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

(i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(iii) for any reimbursement of the corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the corporation, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(iv) initiated by such person against the corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its

initiation, (b) the corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the corporation under applicable law, (c) otherwise required to be made under Section 8.7 or (d) otherwise required by applicable law; or

(v) if prohibited by applicable law; *provided*, *however*, that if any provision or provisions of this Article VIII shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (1) the validity, legality and enforceability of the remaining provisions of this Article VIII (including, without limitation, each portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable, that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; and (2) to the fullest extent possible, the provisions of this Article VIII (including, without limitation, each such portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

8.7 DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the corporation of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The corporation shall indemnify such person against any and all expenses that are incurred by such person in connection with any action for indemnification or advancement of expenses from the corporation under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8 NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9 INSURANCE

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 EFFECT OF REPEAL OR MODIFICATION

Any amendment, alteration or repeal of this Article VIII shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to such amendment, alteration or repeal.

8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article VIII, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan (excluding any "parachute payments" within the meanings of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended); and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Article VIII.

ARTICLE IX — GENERAL MATTERS

9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the board of directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

9.3 SEAL

The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors. The corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both an entity and a natural person.

ARTICLE X — AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; *provided, however*, that

the affirmative vote of the holders of at least 66 2/3% of the total voting power of all outstanding shares of capital stock of the corporation entitled to vote thereon, voting together as a single class, shall be required for the stockholders of the corporation to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII and this Article X (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). The board of directors, acting by the affirmative vote of at least a majority of the Whole Board, shall also have the power to adopt, amend or repeal bylaws; *provided, however*, that a bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the board of directors.

ARTICLE XI — EXCLUSIVE FORUM

Unless the corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

FIRST AMENDMENT TO LEASE
(EXPANSION & EXTENSION)

This FIRST AMENDMENT TO LEASE ("Amendment") is made and entered into as of the 28th day of May, 2021, but made effective as of April 1, 2021, by and between 605 NASH, LLC, a California limited liability company ("Landlord"), and IMMUNITYBIO, INC., a Delaware corporation (formerly known as NantKwest, Inc., a Delaware corporation)("Tenant").

RECITALS:

A. Landlord and Tenant entered into that certain lease agreement dated as of February 11, 2021 (the "Lease"), whereby Landlord leased to Tenant and Tenant leased from Landlord certain space containing a total of approximately 6,883 rentable square feet (the "Existing Premises") located in the building commonly known as 605-607 Nash Street, El Segundo California (the "Building"). The building consists of approximately 64,643 rentable square feet.

B. By this Amendment, Tenant desires and Landlord has agreed to (i) to lease the entire Building by expanding the premises under the Lease by approximately 57,760 rentable square feet, (ii) extend the term of the Lease for three months, and (iii) otherwise modify the Lease as provided herein.

C. Unless otherwise defined herein, capitalized terms as used herein shall have the same meanings as given thereto in the Lease.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

AGREEMENT:

1. **Expansion Premises**. Effective, April 1, 2021 ("Expansion Commencement Date"), the Existing Premises shall be expanded by approximately 57,760 rentable square feet as depicted on Exhibit A attached hereto (the "Expansion Premises"). Accordingly, as of the Expansion Commencement Date, all references in the Lease to the term "*Premises*" shall hereinafter mean and include the Existing Premises and Expansion Premises (i.e., the entire Building) which will then consist of approximately 64,643 rentable square feet. Landlord and Tenant each acknowledge and agree that the aforesaid description of the size and square footage of the Premises and the Building are an approximation, which the parties agree is reasonable and payments made thereupon are not subject to dispute..

2. **Extended Lease Term**. The existing term of the Lease shall be extended an additional three (3) months and terminate on March 31, 2028 (as hereinafter extended the "Extended Term"), unless otherwise extended or renewed pursuant to Section 1.2 of the Lease. Upon the Expansion Commencement Date, all references in the Lease to the term "*Term*" shall hereinafter include the Extended Term.

3. **Base Rent for the Expansion Premises**. Effective from and after the Expansion Commencement Date through the end of the Term the initial monthly base rent for the Expansion Premises shall be $2.95 per rentable square foot of the Expansion Premises as set forth below ("Base Rent") (subject to abatement of rent pursuant to Section 4) and shall be increased by three percent (3%) annually

commencing on the Expansion Commencement Date and each year thereafter during the initial Term and, if applicable, during the Option Terms (the "Annual Increase"), all as set forth below:

Lease Period	Monthly Installment of Base Rent
Expansion Commencement Date –March 31, 2022	$170,392.00*
April 1, 2022 –March 31, 2023	$175,503.76
April 1, 2023 –March 31, 2024	$180,768.87
April 1, 2024 –March 31, 2025	$186,191.94
April 1, 2025 –March 31, 2026	$191,777.70
April 1, 2026 –March 31, 2027	$197,531.03
April 1, 2027 –March 31, 2028	$203,456.96

*The monthly Base Rent for the Expansion Premises shall be subject to rent abatement as set forth in Section 4.3 of this Lease.

4. **Rent Abatement.** As long as Tenant is not in default under the terms of the Lease, rent for the Expansion Premises shall be abated for the first seven (7) months following the Expansion Commencement Date.

5. **Security Deposit**. Tenant shall increase the total Security Deposit to $190,696.85, which shall be held subject to the terms of Article 5 of the Lease.

6. **Tenant Improvement Allowances.** Tenant hereby accepts the Expansion Premises on an "AS IS" basis, without any obligation of Landlord to construct any improvements in the Expansion Premises; provided, however, Landlord shall provide Tenant a tenant improvement allowance for the Expansion Premises in the amount of Two Million Six Hundred Twenty-Eight Thousand and Eighty Dollars ($2,628,080.00) (based on $6.50 per rentable square foot of the Expansion Premises per year of lease Term) ("Expansion Space Allowance") for costs and expenses associated with the construction of the initial tenant improvements in the Expansion Premises that are to be constructed by Tenant. The Improvements to be made to the Expansion Premises and the Expansion Space Allowance shall be subject to the terms and conditions set forth in the Work Letter attached to the Lease (except as modified by the terms of this Amendment).

7. **Parking.** From and after the Expansion Commencement Date, Tenant shall have the right to use all the parking spaces at the Project free of charge.

8. **Brokers**. Each party represents and warrants to the other that no broker, agent or finder negotiated or was instrumental in negotiating or consummating this Amendment. Each party further agrees to defend, indemnify and hold harmless the other party from and against any claim for commission or finder's fee by any entity who claims or alleges that they were retained or engaged by the first party or at the request of such party in connection with this Amendment.

9. **Miscellaneous.**

a. *Ratification*. Except as specifically amended or modified by this Amendment, the Lease shall remain in full force and effect and is hereby ratified and confirmed.

b. *Severability of Provisions*. If any provision of this Amendment is for any reason held to be invalid, illegal or unenforceable in any respect, such provision shall not affect the validity, legality or enforceability of any other provision of this Amendment.

c. *Entire Agreement; Amendments and Waivers*. This Amendment, together with any exhibits hereto and the agreements and documents contemplated herein to be executed by any of the parties hereto, constitutes the entire agreement between Tenant and the Landlord pertaining to the subject matter contained herein and supersedes any and all previous agreements between the parties hereto regarding the subject matter hereto. Any provision of this Amendment may be amended or waived if, but only if, such amendment or waiver is in writing and is signed by the party asserted to be bound thereby, and then such amendment or waiver shall be effective only in the specific instance and specific purpose for which given.

d. *Authority*. The individuals signing this Amendment on behalf of each party represent and warrant that such individual has the authority under the company's governing documents to execute and deliver this Amendment in the name of and on behalf of the company.

e. *Successors and Assigns*. The Lease, as amended hereby, shall apply to and bind Landlord and Tenant and their respective successors and assigns.

f. *Conflicts*. Notwithstanding anything to the contrary in the Lease, in the event of a conflict or inconsistency between the terms of the Lease and the terms and conditions of this Amendment, the terms and conditions set forth in this Amendment shall control and shall be deemed to supersede the printed terms of the Lease. Whether or not specifically amended by this Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Amendment.

g. *Counterparts*. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. In order to facilitate the agreements contemplated by this Amendment, signatures transmitted by facsimile or via e-mail in a "PDF" format may be used in place of original signatures. Each party intends to be bound by such party's facsimile or "PDF" format signature on this Amendment, is aware that the other parties are relying on such party's facsimile or "PDF" format signature, and hereby waives any defenses to the enforcement of this Amendment based upon the form of signature.

[*signature page follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the date first above written.

LANDLORD:

605 NASH, LLC,
a California limited liability company

By: /s/ CHARLES N. KENWORTHY
Name: Charles N. Kenworthy
Title: Manager

Address:
9922 Jefferson Blvd.
Culver City, CA 90232
Attention: Chuck Kenworthy

TENANT:

IMMUNITYBIO, INC.,
a Delaware corporation

By: /s/ DAVID SACHS
Name: David Sachs
Title: CFO

Address:
3530 Johns Hopkins Court
San Diego, CA 92121
Attention: Chief Financial 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: August 12, 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: August 12, 2021

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

Exhibit 32.1

CERTIFICATION 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 June 30, 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: August 12, 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 June 30, 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: August 12, 2021

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