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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

or

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

For the transition period from to

Commission File Number: 001-37507

IMMUNITYBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**43-1979754**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3530 John Hopkins Court San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

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

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of shares of the Registrant's common stock outstanding as of May 5, 2022 was 397,956,762 (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)

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,385	$ 181,101
Marketable securities	155,947	136,015
Due from related parties	3,893	1,333
Prepaid expenses and other current assets (including amounts with related parties)	16,116	15,898
Total current assets	212,341	334,347
Marketable securities, noncurrent	865	822
Property, plant and equipment, net	105,217	82,863
Intangible assets, net	22,349	1,420
Convertible note receivable	6,441	6,379
Operating lease right-of-use assets, net (including amounts with related parties)	35,897	36,304
Other assets (including amounts with related parties)	6,477	6,775
Total assets	$ 389,587	$ 468,910
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,832	$ 11,418
Accrued expenses and other liabilities	62,468	51,387
Related-party promissory notes, current portion	299,612	299,236
Due to related parties	5,595	3,943
Operating lease liabilities (including amounts with related parties)	3,507	3,011
Total current liabilities	381,014	368,995
Related-party promissory notes, less current portion	309,428	306,349
Operating lease liabilities, less current portion (including amounts with related parties)	36,251	37,068
Deferred income tax liability	162	162
Other liabilities	288	249
Total liabilities	727,143	712,823
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Common stock, $0.0001 par value; 900,000,000 shares authorized; 397,956,762 and 397,830,044 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively; excluding treasury stock, 163,800 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	40	40
Additional paid-in capital	1,729,430	1,719,704
Accumulated deficit	(2,064,747)	(1,961,921)
Accumulated other comprehensive (loss) income	(367)	4
Total ImmunityBio stockholders' deficit	(335,644)	(242,173)
Noncontrolling interests	(1,912)	(1,740)
Total stockholders' deficit	(337,556)	(243,913)
Total liabilities and stockholders' deficit	$ 389,587	$ 468,910

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 March 31,	
	2022	**2021**
Revenue	$ 14	$ 139
Operating expenses:		
Research and development (including amounts with related parties)	55,378	41,128
Selling, general and administrative (including amounts with related parties)	40,608	45,275
Total operating expenses	95,986	86,403
Loss from operations	(95,972)	(86,264)
Other (expense) income, net:		
Interest and investment income, net	1,666	8,944
Interest expense (including amounts with related parties)	(8,491)	(3,168)
Loss on equity method investment	(197)	—
Other (expense) income, net (including amounts with related parties)	(4)	13
Total other (expense) income, net	(7,026)	5,789
Loss before income taxes and noncontrolling interests	(102,998)	(80,475)
Income tax expense	—	(6)
Net loss	(102,998)	(80,481)
Net loss attributable to noncontrolling interests, net of tax	(172)	(867)
Net loss attributable to ImmunityBio common stockholders	$ (102,826)	$ (79,614)
Net loss per ImmunityBio common share – basic	$ (0.26)	$ (0.21)
Net loss per ImmunityBio common share – diluted	$ (0.26)	$ (0.21)
Weighted-average number of common shares used in computing net loss per share – basic and diluted	397,882,441	382,741,464

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 March 31,	
	2022	**2021**
Net loss	$ (102,998)	$ (80,481)
Other comprehensive loss, net of income taxes:		
Net unrealized losses on available-for-sale securities	(310)	(1)
Reclassification of net realized losses on available-for-sale securities included in net loss	—	3
Foreign currency translation adjustments	(61)	(162)
Total other comprehensive loss	(371)	(160)
Comprehensive loss	(103,369)	(80,641)
Less: Comprehensive loss attributable to noncontrolling interests	(172)	(867)
Comprehensive loss attributable to ImmunityBio common stockholders	$ (103,197)	$ (79,774)

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

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

Three Months Ended March 31, 2022	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
Balance as of December 31, 2021	397,830,044	$ 40	$1,719,704	$(1,961,921)	$ 4	$ (242,173)	$ (1,740)	$ (243,913)
Stock-based compensation expense	—	—	10,024	—	—	10,024	—	10,024
Exercise of stock options	14,767	—	74	—	—	74	—	74
Vesting of restricted stock units (RSUs)	177,783	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(65,832)	—	(372)	—	—	(372)	—	(372)
Other comprehensive loss, net of tax	—	—	—	—	(371)	(371)	—	(371)
Net loss	—	—	—	(102,826)	—	(102,826)	(172)	(102,998)
Balance as of March 31, 2022	397,956,762	$ 40	$1,729,430	$(2,064,747)	$ (367)	$ (335,644)	$ (1,912)	$ (337,556)

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

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

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

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)

	Three Months Ended March 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (102,998)	$ (80,481)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,024	15,298
Unrealized gains on equity securities	(1,419)	(8,834)
Depreciation and amortization	4,090	2,972
Non-cash interest items, net (including amounts with related parties)	3,398	3,435
Non-cash lease expense related to operating lease right-of-use assets	1,318	1,555
Loss on equity method investment	197	—
Other	848	100
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(218)	(934)
Other assets	101	693
Accounts payable	795	6,497
Accrued expenses and other liabilities	10,891	(1,893)
Related parties	(1,618)	2,597
Operating lease liabilities	(339)	(1,474)
Net cash used in operating activities	(74,930)	(60,469)
Investing activities:		
Purchases of property, plant and equipment	(27,347)	(7,083)
Purchase of intangible assets	(21,229)	—
Purchases of marketable debt securities, available-for-sale	(34,082)	(91)
Maturities of marketable debt securities, available for sale	14,345	31,925
Investment in joint venture – an equity method investment	(1,000)	—
Proceeds from sales of marketable debt and equity securities	—	7,094
Net cash (used in) provided by investing activities	(69,313)	31,845
Financing activities:		
Proceeds from issuance of related-party promissory notes, net of issuance costs paid	—	40,000
Proceeds from exercises of stock options	74	1,121
Net share settlement for RSUs vesting	(372)	(2,624)
Net cash (used in) provided by financing activities	(298)	38,497
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(175)	(109)
Net change in cash, cash equivalents, and restricted cash	(144,716)	9,764
Cash, cash equivalents, and restricted cash, beginning of period	181,280	35,094
Cash, cash equivalents, and restricted cash, end of period	$ 36,564	$ 44,858

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)

	Three Months Ended March 31,	
	2022	**2021**
Reconciliation of cash, cash equivalents, and restricted cash, end of period:		
Cash and cash equivalents	$ 36,385	$ 44,679
Restricted cash	179	179
Cash, cash equivalents, and restricted cash, end of period	$ 36,564	$ 44,858
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ 5,036	$ 12
Income taxes	—	2
Supplemental disclosure of non-cash activities:		
Property and equipment purchases included in accounts payable, accrued expenses and due to related parties	$ 1,061	$ 4,267
Right-of-use assets obtained in exchange for operating lease liabilities	911	1,388
Unrealized (losses) gains on marketable debt securities, net	(310)	14

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

In these notes to unaudited condensed consolidated financial statements, the terms "ImmunityBio," "the company," "the combined company," "we," "us," and "our" refer to ImmunityBio and subsidiaries.

Our Business

ImmunityBio, Inc. is a clinical-stage biotechnology company developing next-generation therapies and vaccines that complement, harness, and amplify the immune system to defeat cancers and infectious diseases. We strive to be a vertically-integrated immunotherapy company designing and manufacturing our products so they are more effective, accessible, more conveniently stored, and more easily administered to patients.

Our broad immunotherapy and cell therapy platforms are designed to attack cancer and infectious pathogens by activating both the innate immune system—natural killer (NK) cells, dendritic cells, and macrophages—and the adaptive immune system—B cells and T cells—in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally infected. Our ultimate goal is to employ this approach to establish an "immunological memory" that confers long-term benefit for the patient.

Although such designations may not lead to a faster development process or regulatory review and may not increase the likelihood that a product candidate will receive approval, N-803 (Anktiva™), our novel antibody cytokine fusion protein, has received *Breakthrough Therapy* and *Fast Track* designations in combination with bacillus Calmette-Guérin (BCG) from the United States (U.S.) Food and Drug Administration (FDA) for BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS).

Based on the reported results of our Phase 2/3 trial (QUILT 3.032), we have initiated discussions with the FDA to file a BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS. We held a pre-BLA meeting with the FDA in May and reached agreement with the agency with regard to the content and plan to submit our BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS.

Our platforms include 8 first-in-human therapeutic agents that are currently being studied in 27 clinical trials—18 of which are in Phase 2 or 3 development—across 13 indications in liquid and solid tumors, including bladder, pancreatic and lung cancers. These are among the most frequent and lethal cancer types for which there are high failure rates for existing standards of care or, in some cases, no available effective treatment. In infectious disease, our pipeline currently targets such pathogens as the novel strain of the coronavirus (SARS-CoV-2) and human immunodeficiency virus (HIV).

We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations, and development teams.

The Merger

On December 21, 2020, NantKwest, Inc. (NantKwest) 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 NantKwest and NantCell agreed to combine their 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, RSU or warrant to purchase NantCell common stock was converted using the Exchange Ratio into an option, RSU or warrant, 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 NantKwest 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 Global Chief Scientific and Medical Officer, 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, the symbol for shares of the company's common stock was changed to "IBRX."

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 table provides the impact of the change in reporting entity on our condensed consolidated statements of operations (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)

2. Summary of Significant Accounting Policies

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 U.S. Securities and Exchange Commission (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 and therefore should be read in conjunction with our consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022. These interim financials are not necessarily indicative of results expected for the full fiscal year.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of the company, our wholly owned subsidiaries, and a variable interest entity (VIE) for which we are the primary beneficiary. Any material intercompany transactions and balances have been eliminated upon consolidation. For consolidated entities where we have less than 100% of ownership, we record net loss attributable to noncontrolling interest on the unaudited condensed consolidated statements of operations equal to the percentage of the ownership interest retained in such entities by the respective noncontrolling parties.

We assess whether we are the primary beneficiary of a VIE at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

Liquidity

As of March 31, 2022, the company had an accumulated deficit of $2.1 billion. We also had negative cash flows from operations of $74.9 million for the three months ended March 31, 2022. The company will likely need additional capital to further fund the development of, and to seek regulatory approvals for, our product candidates, and to begin to commercialize any approved products.

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 our common stock that may be issued and sold under an "at-the-market" sales agreement with Jefferies LLC (the ATM), of which we had $330.8 million available for future issuance as of March 31, 2022), 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 and Global Chief Scientific and Medical Officer'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 external 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 potential commercialization of our product candidates in development, we may need additional funds to meet our needs sooner than planned.

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, asset acquisition, and the assessment of our ability to fund our operations for at least the next 12 months from the date of issuance of these condensed consolidated 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.

Significant Accounting Policies

There have been no material changes to our significant accounting policies from those described in Note 2, *Summary of Significant Accounting Policies,* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of our Annual Report on Form 10-K filed with the SEC on March 1, 2022.

Acquisitions

We make certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. We evaluate the inputs, processes, and outputs associated with the acquired set of activities and assets. If the assets in a transaction include an input and a substantive process that together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business.

We account for business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed generally be recorded at their fair values as of the acquisition date. Excess of consideration over the fair value of net assets acquired is recorded as goodwill. Estimating fair value requires us to make significant judgments and assumptions. We perform impairment testing of goodwill annually or more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

In transactions accounted for as asset acquisitions, the cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. In an asset acquisition, upfront payments allocated to in-process research and development projects at the acquisition date are expensed unless there is an alternative future use. In addition, product development milestones are expensed upon achievement. Any contingent consideration, such as payments upon achievement of various developmental, regulatory and commercial milestones, generally is not recognized at the acquisition date.

Basic and Diluted Net Loss per Share of Common Stock

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

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

	As of March 31,	
	2022	2021
	(Unaudited)	
Outstanding stock options	8,819,466	4,978,314
Outstanding RSUs	6,149,411	7,636,132
Outstanding related-party warrants	1,638,000	1,638,000
Total	16,606,877	14,252,446

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) and the NantKwest 2014 Equity Incentive Plan. At the Effective Time, each outstanding option or RSU issued under the 2015 NantCell Stock Incentive Plan and warrants issued by NantCell to purchase or acquire NantCell common stock were converted using the Exchange Ratio into an option, RSU or warrant, respectively, on the same terms and conditions immediately prior to the Effective Time. See Note 11, *Stock-Based Compensation*, for further information.

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Adopted

In May 2021, the FASB issued Accounting Standards Update (ASU) 2021-04, *Earnings Per Share* (Topic 260), *Debt—Modifications and Extinguishments* (Subtopic 470-50), *Compensation—Stock Compensation* (Topic 718), and *Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40). This update provides guidance to clarify and reduce diversity in an accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that is not within the scope of another Topic. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument. This update additionally provides further guidance on measuring the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. This guidance is effective for the fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The company adopted this guidance on January 1, 2022 on a prospective basis. The adoption did not have a material impact on the company's condensed consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, A*ccounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies and clarifies certain calculation and presentation matters related to convertible equity and debt instruments. Specifically, ASU 2020-06 removes requirements to separately account for conversion features as a derivative under ASC Topic 815 and removing the requirement to account for beneficial conversion features on such instruments. In addition, ASU 2020-06 eliminates the treasury stock method when calculating diluted earnings per share for convertible instruments that can be settled in whole or in part with equity and requires the use of the if-converted method. The guidance is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The company adopted this guidance on January 1, 2022 on a modified prospective basis. The adoption did not have a material impact on the company's condensed 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 March 31, 2022 did not, or are not expected to, have a material effect on our condensed consolidated financial statements.

3. Financial Statement Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2022 (Unaudited)	December 31, 2021
Prepaid services	$ 8,435	$ 6,966
Prepaid insurance	2,146	2,266
Prepaid license fees	1,552	1,111
Other	3,983	5,555
Prepaid expenses and other current assets	$ 16,116	$ 15,898

Property, Plant and Equipment, Net

Property, plant and equipment, net, consist of the following (in thousands):

	March 31, 2022 (Unaudited)	December 31, 2021
Leasehold improvements	$ 68,725	$ 62,482
Equipment	58,738	54,284
Construction in progress	31,423	16,575
Software	1,658	1,544
Furniture & fixtures	1,522	1,052
Gross property, plant and equipment	162,066	135,937
Less: Accumulated depreciation and amortization	56,849	53,074
Property, plant and equipment, net	$ 105,217	$ 82,863

Depreciation and amortization expense related to property, plant and equipment totaled $3.8 million and $3.0 million for the three months ended March 31, 2022 and 2021, respectively.

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following (in thousands):

	March 31, 2022 (Unaudited)	December 31, 2021
Accrued litigation payable (Note 7)	$ 17,507	$ 7,118
Accrued construction costs	9,340	8,145
Accrued professional and service fees	8,836	6,909
Accrued preclinical and clinical trial costs	6,027	5,842
Accrued laboratory equipment, supplies and related services	5,499	2,144
Accrued research and development costs	5,033	2,107
Accrued compensation	4,281	5,613
Accrued bonus	3,054	8,316
Other	2,891	5,193
Accrued expenses and other liabilities	$ 62,468	$ 51,387

Interest and Investment Income, Net

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Unrealized gains from equity securities	$ 1,419	$ 8,833
Interest income	1,296	339
Investment amortization expense, net	(1,049)	(225)
Net realized losses on investments	—	(3)
Interest and investment income, net	$ 1,666	$ 8,944

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 March 31, 2022, the weighted-average remaining contractual life, amortized cost, gross unrealized gains, gross unrealized losses and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	March 31, 2022 (Unaudited)				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Corporate debt securities	0.3	$ 147,983	$ 3	$ (307)	$ 147,679
Foreign bonds	0.1	114	—	(1)	113
Mutual funds		34	9	(5)	38
Current portion		148,131	12	(313)	147,830
Noncurrent:					
Foreign bonds	4.8	893	1	(29)	865
Noncurrent portion		893	1	(29)	865
Total		$ 149,024	$ 13	$ (342)	$ 148,695

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

	December 31, 2021				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Corporate debt securities	0.5	$ 129,190	$ 10	$ (36)	$ 129,164
Foreign bonds	0.4	116	—	(1)	115
Mutual funds		35	3	—	38
Current portion		129,341	13	(37)	129,317
Noncurrent:					
Foreign bonds	5.0	719	103	—	822
Noncurrent portion		719	103	—	822
Total		$ 130,060	$ 116	$ (37)	$ 130,139

Accumulated unrealized losses on marketable debt securities that have been in a continuous loss position for less than 12 months and more than 12 months were as follows (in thousands):

	March 31, 2022 (Unaudited)			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	$ 138,072	$ (307)	$ —	$ —
Mutual funds	—	—	32	(5)
Foreign bonds	649	(21)	113	(9)
Total	$ 138,721	$ (328)	$ 145	$ (14)

	December 31, 2021			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	$ 86,158	$ (36)	$ —	$ —
Mutual funds	—	—	34	(2)
Foreign bonds	115	(1)	113	(1)
Total	$ 86,273	$ (37)	$ 147	$ (3)

Realized gains and losses on sales of available-for-sale marketable debt securities were not material for the three months ended March 31, 2022 and 2021.

Marketable Equity Securities

We held investments in marketable equity securities with readily determinable fair values of $8.1 million and $6.7 million as of March 31, 2022 and December 31, 2021, respectively. Unrealized gains recorded on these securities totaled $1.4 million and $8.8 million in *interest and investment income, net*, on the condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021, respectively.

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 (in thousands):

	Fair Value Measurements at March 31, 2022 (Unaudited)			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$ 36,385	$ 36,385	$ —	$ —
Equity securities	8,117	8,117	—	—
Corporate debt securities	147,679	—	147,679	—
Foreign bonds	113	113	—	—
Mutual funds	38	38	—	—
Noncurrent:				
Foreign bonds	865	865	—	—
Total assets measured at fair value	$ 193,197	$ 45,518	$ 147,679	$ —
Liabilities:				
Accrued litigation payable	$ 12,507 (1)	$ 12,507	$ —	$ —
Contingent consideration	401 (2)	380	—	21
Total liabilities measured at fair value	$ 12,908	$ 12,887	$ —	$ 21

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$ 181,101 (3)	$ 51,421	$ 129,680	$ —
Equity securities	6,698	6,698	—	—
Corporate debt securities	129,164	—	129,164	—
Foreign bonds	115	115	—	—
Mutual funds	38	38	—	—
Noncurrent:				
Foreign bonds	822	822	—	—
Total assets measured at fair value	$ 317,938	$ 59,094	$ 258,844	$ —
Liabilities:				
Contingent consideration	$ 409 (2)	$ 388	$ —	$ 21

(1) The accrued litigation payable was measured at fair value as the liability will be settled by the issuance of 2,229,296 shares of the company's common stock. The closing price of our common stock was used to calculate the fair value of the liability as of March 31, 2022, which will be remeasured each period until settlement. See Note 7, *Commitments and Contingencies—Litigation*, for further information.

(2) Contingent consideration is recorded at estimated fair value and revalued each reporting period until the related contingency is resolved. The fair value measurement is 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—Contingent Consideration Related to Business Combinations,* for further information.

(3) Amounts shown as a Level 2 measurement as of December 31, 2021 include government-sponsored securities of $75.0 million, corporate debt securities of $54.2 million, and commercial paper of $0.5 million with original maturities of less than 90 days.

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Fair value, beginning of period	$ 409	$ 972
Net decrease in fair value	(8)	(128)
Fair value, end of period	$ 401	$ 844

6. Collaboration and License Agreements and Acquisition

Collaboration Agreement

Amyris Joint Venture

In December 2021, ImmunityBio and Amyris, Inc. (Amyris) entered into a 50:50 joint venture arrangement and formed a new limited liability company to conduct the business of the joint venture. The purpose of the joint venture is to accelerate commercialization of a next-generation COVID-19 vaccine utilizing an RNA vaccine platform. As part of the limited liability agreement, we agreed to contribute $1.0 million in cash and priority access to our manufacturing capacity for the joint venture product. Amyris agreed to contribute $1.0 million in cash and rights to its license agreement with the Access to Advanced Health Institute (AAHI) (formerly known as the Infectious Disease Research Institute, or IDRI) for an RNA platform for the field of COVID-19. The value of the manufacturing access right and the license right was determined by the board of directors of the joint venture to be $9.0 million each, respectively. Both parties agreed to enter into a separate manufacturing and supply agreement and a sublicense agreement within 150 days of the execution of the joint venture agreement.

The joint venture agreement stipulates the initial terms for equal representation in the management of the newly-formed joint venture. The joint venture is managed by a board of directors consisting of four directors: two appointed by the company and two appointed by Amyris. Both parties agreed to make additional capital contributions in cash, in proportion to their respective interests, as determined by the board of directors of the joint venture.

We considered the joint venture entity as a VIE and determined that we are not the primary beneficiary of the VIE. In February 2022, we made a cash investment totaling $1.0 million in the joint venture's common stock. We accounted for the joint venture using the equity method of accounting, and recorded our 50% share of the net loss from the joint venture totaling $0.2 million in *other expense, net*, on the condensed consolidated statement of operations for the three months ended March 31, 2022. We are not obligated to fund the joint venture's potential future losses, and therefore will not record equity method losses that would result in our equity investment in the joint venture to fall below zero. As of March 31, 2022, the carrying amount of our equity investment in the joint venture was zero, and we have a receivable totaling $2.5 million from the joint venture in *due from related parties*, on the condensed consolidated balance sheet for research and development costs that we paid on behalf of the joint venture during the three months ended March 31, 2022.

License Agreements

The Access to Advanced Health Institute

In May 2021, we entered into two license agreements with the AAHI pursuant to which we received a license to certain patents and know-how relating to AAHI's (i) adjuvant formulations for the treatment, prevention and/or diagnosis of SARS-CoV-2 (the AAHI Adjuvant Formulation License Agreement) and (ii) RNA vaccine platform as further described below (the AAHI RNA License Agreement). Under both agreements, we were obligated to pay one-time, non-creditable, non-refundable upfront cash payments totaling $2.0 million. In addition, under the AAHI Adjuvant Formulation License Agreement we owe milestone payments to a total of up to $2.5 million based on the achievement of certain development and regulatory milestones for the first licensed product and royalties on annual net sales of licensed products on a country-by-country and product-by-product basis of a low-single digit percentage, subject to certain royalty-reduction provisions. No milestone fees were incurred for the three months ended March 31, 2022.

In September 2021, we amended and restated the AAHI RNA License Agreement, pursuant to which AAHI granted us an exclusive, worldwide, sublicensable license to AAHI's rights to an RNA vaccine platform for the development and commercialization of certain therapeutic, diagnostic or prophylactic products for the prevention, treatment or diagnosis of any indication, other than those subject to pre-existing third-party license grants, including, without limitation, SARS-CoV-2. Pursuant to the terms of the amended and restated AAHI RNA License Agreement, we made an additional one-time,

non-creditable, non-refundable, upfront payment to AAHI of $1.5 million. The company is also required to pay license maintenance fees to AAHI as follows: $3.0 million in 2022 and $5.5 million annually from 2023 through 2030. The company may terminate the restated agreement without cause by paying AAHI a $10.0 million one-time early termination fee. In addition, the milestone payments to AAHI based on the achievement of certain development and regulatory milestones for the first licensed product were amended to a total of up to $4.0 million. We are required to pay royalties on annual net sales of licensed products on a country-by-country and product-by-product basis of a low to mid-single digit percentage. We recorded $0.2 million in *research and development expense*, on the condensed consolidated statements of operations for the three months ended March 31, 2022.

In connection with the license agreements, in May 2021 we also entered into a sponsored research agreement with the AAHI pursuant to which we will fund continued research of at least $2.0 million per year, payable in four equal quarterly installments each year until May 2024, or such year of earlier termination. During the three months ended March 31, 2022, $1.2 million of research and development activities that we funded were related to our Amyris joint venture and thus were charged to the joint venture for reimbursement.

EnGeneIC Licensing Agreement

During the fourth quarter of 2021, we signed a binding term sheet with EnGeneIC for an exclusive, worldwide license to develop, manufacture and commercialize their patented endosomal delivery vector (EDV™) nanocell technology as a single agent in certain cancer fields and with respect to the treatment and prevention of COVID-19 and in combination with our COVID-19 vaccine and anti-cancer drugs in a more broadly defined field of use. The companies have agreed to a 50:50 split of the net profit from worldwide sales of EDV-based products, and we have agreed to pay certain periodic license fees. The parties continue to work on definitive agreements for this transaction.

Acquisition

Dunkirk Facility Leasehold Interest

On February 14, 2022, we completed the acquisition of a leasehold interest in approximately 409,000 rentable square feet of current Good Manufacturing Practice (cGMP) ISO Class 5 pharmaceutical manufacturing space in western New York (the Dunkirk Facility) from Athenex, Inc. (the Seller), which we believe provides us with a state-of-the-art biotech production center that substantially expands and diversifies our manufacturing capacity in the U.S. and ability to scale production associated with certain of our product candidates. The company accounted for the transaction as an asset acquisition because the Dunkirk Facility's integrated set of assets and activities does not meet the definition of a business.

The total consideration for the acquisition was approximately $40.5 million, including a cash payment of $40.0 million, and transaction costs of approximately $0.5 million. The following table summarizes the fair value of assets acquired as of the acquisition date (in thousands):

Construction in progress	$	10,043
Leasehold improvements		6,253
Definite-lived intangible assets (1)		21,229
Other depreciable assets and prepaid expenses		2,983
Total consideration	$	40,508

(1) Definite-lived intangible assets consist of favorable leasehold rights totaling $20.4 million and organized workforce totaling $0.8 million as of the acquisition date. We recorded amortization expense of $0.3 million in *research and development expense*, on the condensed consolidated statement of operations for the three months ended March 31, 2022. As of March 31, 2022, the remaining weighted-average amortization period for our definite-lived intangible assets was approximately 9.7 years. Future amortization expense for the favorable leasehold rights is as follows: $1.5 million for the remainder of 2022; $2.0 million for each of the years from 2023 to 2026; and $10.5 million thereafter. Future amortization expense for the organized workforce is as follows: $0.2 million for the remainder of 2022 and $0.3 million for 2023 and 2024.

Upon the closing of the Dunkirk transaction, the company became the tenant of the Dunkirk Facility under the Fort Schuyler Management Corporation Lease, dated October 1, 2021 and as amended as of the February 14, 2022 closing date (as amended, the Dunkirk Lease), with Fort Schuyler Management Corporation, a not-for-profit corporation affiliated with the State of New York (FSMC) as landlord. The Dunkirk Facility, as well as certain equipment, is owned by FSMC and is leased to us under the Dunkirk Lease. Our annual lease payment will be $2.00 per year for an initial 10-year term, with an option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed certain of the Seller's obligations under various third-party agreements (the Facility Agreements), subject to the terms and conditions of the purchase agreement by and between the company and Seller dated as of January 7, 2022, and committed to spend an aggregate of $1.52 billion on operational expenses during the initial term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first 5 years of operations, with 300 such employees to be hired within the first 2.5 years of operation. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above. Failure to satisfy the obligations over the lease term may give rise to certain rights and remedies of governmental authorities including, for example, termination of the lease agreement and other Facility Agreements and potential recoupment of a percentage of the grant funding received by the Seller for construction of the facility and other benefits received, subject to the terms and conditions of the applicable agreements.

7. Commitments and Contingencies

Contingent Consideration Related to Business Combinations

VivaBioCell, S.p.A.

In April 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. In June 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 our acquisition of VBC, we are obligated to pay the former owners contingent consideration upon the achievement of certain milestones related to the GMP-in-a-Box technology. A clinical milestone totaling $0.8 million was earned by the former owners of VivaBioCell, of which $0.4 million was paid during 2021. The remaining $0.4 million was accrued as of March 31, 2022 and is expected to be paid in 2022. If the regulatory milestone is achieved, we are obligated to pay approximately $2.2 million.

Altor BioScience Corporation

In connection with the 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 BLA or foreign equivalent, for N-803 by December 31, 2022 and approximately $304.0 million upon the first calendar year before December 31, 2026 in which worldwide net sales of N-803 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. We may be required to pay the other prior Altor stockholders up to $164.2 million in settlement of the CVRs relating to the regulatory milestone and up to $164.2 million of the CVRs relating to the sales milestone should they choose to have the CVRs paid in cash instead of common stock. 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 the 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 (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 (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 remained: (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 then 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 the 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 the breaches of the "standstill" agreements discussed above and of stockholder releases. The plaintiffs filed an answer denying the counterclaims and asserting defenses. Trial was set to commence on August 8, 2022, but the parties received notice that the Vice Chancellor assigned to the case was retiring, and there may be a new trial date.

The shares of the former Altor stockholders seeking appraisal 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, given that those shares were the subject of the above-described appraisal claims.

In late March 2022, the company agreed to the terms of a settlement with the appraisal petitioners, without any admission of liability or fault. The settlement provides that in exchange for complete releases, the appraisal petitioners, who as a group held 3,167,565 dissenting Altor shares, collectively will receive an aggregate of 2,229,296 shares of the company's common stock issued in a private placement, plus an aggregate of $21.13 in cash in lieu of fractional shares. The company's Board of Directors approved the settlement and stock issuance in April 2022, and the parties are in the process of documenting and obtaining court approval of the settlement. Prior to finalization and court approval, there can be no assurance as to when the settlement will be finalized and approved, and the shares issued.

As of March 31, 2022 and December 31, 2021, we had accrued a total of $12.5 million and $7.1 million, respectively, related to the dissenting share obligation. The accrued litigation payable was measured at fair value based on the total 2,229,296 shares of common stock and the closing price of our common stock at March 31, 2022. Prior to reaching an agreement on the settlement terms, the accrued amount represented the low-end of the range of the then 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.

In late April 2022, the company also agreed to the terms of a settlement with the putative class plaintiffs without any admission of liability or fault. In exchange for class-wide releases, and assuming the settlement receives court approval, the company will make a settlement payment of $5.0 million in cash by December 31, 2022. The parties are in the process of documenting and obtaining court approval of the settlement. Prior to finalization and court approval, there can be no assurance as to when the settlement will be finalized and approved. As of March 31, 2022, we have included $5.0 million of accrued litigation expense related to this settlement on the condensed consolidated balance sheet.

Should either settlement not be approved by the court, we cannot reasonably estimate a range of loss or likelihood of loss beyond the amounts recorded. The company intends to defend the case vigorously should that prove necessary.

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 continued with breaks until early October 2021. The parties completed post-hearing briefing in early May 2022, and summations are scheduled for mid-July 2022.

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 NANTibody arbitration commenced in April 2021 and concluded in early August 2021. After post-hearing briefing was concluded, the parties were notified on November 30, 2021 that the arbitrator in the NANTibody arbitration had passed away. A substitute arbitrator was appointed on February 25, 2022, and the parties have been working with the substitute arbitrator to conclude the proceedings. 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 Co. Ltd. Arbitration

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration. The arbitration relates to a license, development, and commercialization agreement that 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 providing periodic updates to the International Chamber of Commerce confirming a stay of all proceedings during the standstill. 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.

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, several complaints were filed as individual actions in the United States District Courts, and subsequently were voluntarily dismissed. Two complaints were 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), (together, the Merger Actions). The Merger Actions generally allege that the Definitive Proxy Statement filed with the SEC on February 2, 2021 misrepresented and/or omitted 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 asserted violations of Section 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 sought, among other things, an injunction enjoining the stockholder vote on the Merger and the consummation of the Merger unless and until certain additional information was 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 both occurred on March 8 and March 9, 2021, respectively. The Merger Actions were voluntarily dismissed on March 25, 2022.

Commitments

We did not enter into any significant contracts during the three months ended March 31, 2022, 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 7, *Commitments and Contingencies,* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of our Annual Report on Form 10-K filed with the SEC on March 1, 2022.

8. Lease Arrangements

We lease property in multiple facilities across the U.S. (including the Dunkirk Facility in upstate New York) and Italy, including facilities located in El Segundo, CA, that are leased from related parties. Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. See Note 9, *Related-Party Agreements*, for additional information about our related-party leases.

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 ten years, and are included in the lease term when it is reasonably certain that we will exercise the option.

Information regarding our operating leases is as follows:

	March 31, 2022	December 31, 2021
	(Unaudited)	
Weighted average remaining lease term	7.7 years	7.8 years
Weighted average discount rate	9.6 %	9.6 %

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Operating lease costs	$ 2,308	$ 2,147
Variable lease costs	1,182	666
Total lease costs	$ 3,490	$ 2,813

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Cash paid for operating leases (excluding variable lease costs)	$ 2,151	$ 1,679

Future minimum lease payments as of March 31, 2022, including $24.1 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
2022 (excluding the three months ended March 31, 2022)	$ 7,027
2023	8,677
2024	8,102
2025	7,285
2026	5,274
Thereafter	26,098
Total future minimum lease payments	62,463
Less: Interest	19,764
Less: Tenant improvement allowance receivable	2,941
Present value of operating lease liabilities	$ 39,758

Other than the acquisition of a leasehold interest at the Dunkirk Facility discussed in Note 6, *Collaboration and License Agreements and Acquisition*, above, there have been no other material changes related to our existing lease agreements from those disclosed in Note 8 of the Notes to Consolidated Financial Statements of our Annual Report on Form 10-K filed with the SEC on March 1, 2022.

9. Related-Party Agreements

Our related-party promissory notes consist of the following (in thousands):

Related-Party Promissory Notes	Maturity Year	Outstanding Advances	Interest Rate	Total Notes and Interest Payable			
				March 31, 2022 (Unaudited)		December 31, 2021	
Nant Capital, LLC (1)	2022	$ 300,000	SOFR + 5.4%	$ 299,612	(1)	$ 299,236	(1)
Nant Capital, LLC (2)	2025	55,226	5.0%	62,111	(3)	61,367	(3)
Nant Capital, LLC (2)	2025	50,000	6.0%	54,594	(4)	53,810	(4)
Nant Capital, LLC (5)	2025	40,000	6.0%	40,000	(5)	40,000	(5)
NantMobile, LLC (2)	2025	55,000	3.0%	58,791	(6)	58,359	(6)
NantWorks, LLC (2)	2025	43,418	5.0%	54,717	(7)	54,067	(7)
NantCancerStemCell, LLC (2)	2025	33,000	5.0%	39,215	(8)	38,746	(8)
Total related-party promissory notes		$ 576,644		$ 609,040		$ 605,585	

(1) The outstanding advance is due and payable on December 17, 2022. This loan bears interest at Term SOFR + 5.4%, which is compounded annually and payable quarterly commencing on March 17, 2022. As of March 31, 2022, the interest rate on this loan was 5.92%. We paid $4.4 million in interest on this loan during the three months ended March 31, 2022. Accrued and unpaid interest on this note totaled $0.7 million as of March 31, 2022. In the event of a default on the loan (as defined in the promissory note), including if we do not repay the loan at maturity, the company has the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into fully paid and non-assessable shares of the company's common stock at a price per share equal to $5.67. Total amortization on the debt issuance cost of $1.5 million paid to the lender was $0.4 million as of March 31, 2022 and was recorded as a reduction of the principal amount of the note.

(2) All outstanding advances and accrued and unpaid interest is due and payable on September 30, 2025. Interest on related-party promissory notes 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.

(3) Accrued and unpaid interest on this note totaled $6.9 million and $6.1 million as of March 31, 2022 and December 31, 2021, respectively.

(4) Accrued and unpaid interest on this note totaled $4.6 million and $3.8 million as of March 31, 2022 and December 31, 2021, respectively.

(5) The outstanding principal is due and payable on September 30, 2025. Interest on this related-party promissory note is compounded annually and payable quarterly commencing on June 30, 2021. We paid $0.6 million in interest on this loan during the three months ended March 31, 2022. 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.

(6) Accrued and unpaid interest on this note totaled $3.8 million and $3.4 million as of March 31, 2022 and December 31, 2021, respectively.

(7) Accrued and unpaid interest on this note totaled $11.3 million and $10.6 million as of March 31, 2022 and December 31, 2021, respectively.

(8) Accrued and unpaid interest on this note totaled $6.2 million and $5.7 million as of March 31, 2022 and December 31, 2021, respectively.

The following table summarizes our estimated future contractual obligations for related-party promissory notes as of March 31, 2022 (unaudited; in thousands):

	Principal Payments	Interest Payments (1)		Total
2022 (excluding the three months ended March 31, 2022)	$ 300,000	$ 13,792	(2)	$ 313,792
2023	—	2,400		2,400
2024	—	2,407		2,407
2025	276,644	85,823	(3)	362,467
Total principal and estimated interest due on related-party promissory notes	$ 576,644	$ 104,422		$ 681,066

(1) Interest payments on our fixed-rate promissory notes are calculated based on contractual interest rates and scheduled maturity dates. Interest payments on our variable-rate promissory note are calculated based on schedule maturity dates and the Term SOFR rate plus the contractual spread per the loan agreement. The rate on our variable-rate promissory note as of March 31, 2022 was 5.92%.

(2) Interest shown includes $0.7 million of accrued and unpaid interest as of March 31, 2022 related to the $300.0 million variable-rate loan. Interest on our $300.0 million variable-rate promissory note and our $40.0 million fixed-rate promissory notes are payable on a quarterly basis.

(3) Interest shown includes $32.8 million of accrued and unpaid interest of March 31, 2022. Interest on these promissory notes is payable at maturity on September 30, 2025.

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

	March 31, 2022 (Unaudited)	December 31, 2021
Due from related party–Amyris joint venture (Note 6)	$ 2,468	$ —
Due from related party–NantBio, Inc.	1,294	1,294
Due from related parties–Various	131	39
Total due from related parties	$ 3,893	$ 1,333
Due to related party–NantWorks, LLC	$ 2,555	$ 1,113
Due to related party–Duley Road, LLC	1,737	1,380
Due to related party–NantBio, Inc.	943	943
Due to related party–Immuno-Oncology Clinic, Inc.	92	507
Due to related party–Various	268	—
Total due to related parties	$ 5,595	$ 3,943

Our Executive Chairman, Global Chief Scientific and Medical Officer, and principal stockholder founded and has a controlling interest in NantWorks, which is a collection of 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 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 and Global Chief Scientific and Medical Officer.

NantWorks, LLC

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 March 31, 2022 and 2021, we recorded $1.3 million and $1.8 million, respectively, in *selling, general and administrative expense,* on the condensed consolidated statements of operations. For the three months ended March 31, 2022 and 2021, we recorded immaterial and $0.3 million 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 were reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

As of March 31, 2022 and December 31, 2021, we owed NantWorks a net amount of $2.6 million and $1.1 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 $2.8 million and $2.2 million of prepaid expenses for services that have been passed through to the company from NantWorks as of March 31, 2022 and December 31, 2021, respectively, which are included in *prepaid expenses and other current assets*, on the condensed consolidated balance sheets.

In 2015, we entered into a facility license agreement with NantWorks for approximately 9,500 square feet of office space in Culver City, California, which was converted to a research and development laboratory and a cGMP manufacturing facility. In 2020, we amended this agreement to extend the term of this license agreement through December 31, 2021. Commencing on January 1, 2022, the license fee increased by 3% to approximately $56,120 per month, and the space is being rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party. License fee expense for this facility totaling $0.2 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively, was recorded in *research and development expense*, on the condensed consolidated statements of operations. In May 2022, this facility license agreement was amended to increase the square feet rented at this location. See Note 13, *Subsequent Events*, for more information.

Immuno-Oncology Clinic, Inc.

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. Pursuant to the terms of the Clinic agreement (as amended), we made payments totaling $5.6 million in consideration of future services to be performed by the Clinic.

In 2021, we completed a review of alternative structures that could support our more complex clinical trial requirements and made a decision to explore a potential transition of clinical trials at the Clinic to a new structure (including contracting with a new, non-affiliated professional corporation) to be determined and agreed upon by all parties and currently planned for the first half of 2022. Based on this decision to explore a potential transition, we determined that it was more likely than not that the previously recorded prepaid asset would not result in the collection of fees for services performed by the Clinic as contemplated in the original agreements. As a result, we wrote down the remaining value of our prepaid asset and recorded approximately $4.4 million in *research and development expense*, on the condensed consolidated statement of operations for the year ended December 31, 2021.

For the three months ended March 31, 2022 and 2021, we incurred $0.4 million and $0.3 million in *research and development expense*, on the condensed consolidated statements of operations related to clinical trial and transition services provided by the Clinic. As of March 31, 2022 and December 31, 2021, we owed the Clinic $0.1 million and $0.5 million, respectively, for services excluded from the Clinic Agreement.

NantBio, Inc.

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 no revenue for the three months ended March 31, 2022 and 2021. We recorded $0.1 million of deferred revenue for bioreactors that were delivered but not installed in *accrued expenses and other liabilities*, on the condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021. As of March 31, 2022 and December 31, 2021, 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 by 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. As of March 31, 2022 and December 31, 2021, we recorded a net receivable from NantBio of $1.3 million for amounts we paid on behalf of NantBio during the year ended December 31, 2019.

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 and Global Chief Scientific and Medical Officer, for approximately 24,250 rentable 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 one 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 $0.2 million for this facility for the three months ended March 31, 2022 and 2021, respectively, was recorded in *research and development expense*, on the condensed consolidated statements of operations.

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, a related party that is indirectly controlled by our Executive Chairman and Global Chief Scientific and Medical Officer, for approximately 12,000 rentable 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 October 2034. The base rent is approximately $40,700 per month, with annual increases of 3% that began in November 2018. As of March 31, 2022 and December 31, 2021, we recorded rent payable to Duley Road of $0.4 million and $0.2 million, respectively. For the three months ended March 31, 2022 and 2021, we recorded rent expense of $0.1 million and $0.4 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 rentable 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 rentable 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 March 31, 2022 and December 31, 2021, we recorded $0.8 million and $0.9 million of leasehold improvement payables, respectively, and $0.5 million and $0.3 million of lease-related payables to Duley Road, which were included in *due to related parties*, on the condensed consolidated balance sheets. For the three months ended March 31, 2022 and 2021, we recorded $0.1 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.

605 Nash, LLC

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, 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 one 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 March 31, 2022 and 2021, we recorded rent expense of $0.1 million and $0.1 million, respectively, 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. 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 months ended March 31, 2022, we incurred $0.5 million of rent expense related to the Expansion Premises lease agreement.

557 Doug St, LLC

On September 27, 2021, we entered into a Membership Interest Purchase Agreement with Nant Capital, LLC (Nant Capital) (the Purchase Agreement). Nant Capital is a related party controlled by Dr. Patrick Soon-Shiong. The Purchase Agreement transferred all outstanding membership interests in 557 Doug St, LLC from the company to Nant Capital. The only asset owned by 557 Doug St, LLC is the improved property located at 557 South Douglas Street, El Segundo, California with a building area of approximately 36,434 rentable square feet (the Douglas Property).

The purchase price under the Purchase Agreement was $22.0 million, and after the offset prorated property taxes of $0.1 million, the net proceeds from the sale were $21.9 million. An independent appraisal of the Douglas Property assigned the Douglas Property a value of $22.0 million. The net carrying value of the property was $20.5 million as of the closing date. We accounted for the transfer as a sale of an asset to an entity under common control, recorded the transfer at book value and recognized the excess of net consideration over carrying book value of $1.4 million as a capital contribution received from Nant Capital in *additional paid-in capital*, on the condensed consolidated statements of stockholders' deficit in 2021.

In September 2021, we entered into a lease agreement with Nant Capital under which we leased back 557 South Douglas Street for an initial lease term of seven years, which commenced on September 27, 2021. The monthly base rent under the lease is approximately $81,976 per month with an annual increase of 3% on October 1 of each year beginning in 2022 during the initial term and, if applicable, during the option term. For the first two years under the lease we will not be charged rent; we will begin paying rent on October 1, 2023 at the current monthly base rent. We prepaid the first month rent and security deposit totaling $0.2 million upon the execution of the lease. We have an option to extend the lease for two additional seven-year periods when the prior term expires. We have included the first option to extend the lease term for seven years as part of the initial lease term as it is reasonably certain that we will exercise the option, which implies lease expiration on September 30, 2035. The lease is classified as an operating lease. During the three months ended March 31, 2022, we recorded $0.3 million of rent expense for the lease, which was included in *research and development expense*, on the condensed consolidated statements of operations.

420 Nash, LLC

On September 27, 2021, we entered into a lease agreement with 420 Nash, LLC, a related party, whereby we leased an approximately 19,125 rentable square foot property located at 420 Nash Street, El Segundo, California, to be used primarily for the warehousing and storage of drug manufacturing supplies, products and equipment and ancillary office space.

Under the terms of the lease agreement, the lease term began on October 1, 2021 and expires on September 30, 2026. The base rent is approximately $38,250 per month with an annual increase of 3% on October 1 of each year beginning in 2022 during the initial term. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance and operating expenses during the term of the lease. We received a rent abatement for the first month of the lease, and a one-time improvement allowance of $15,000 from the landlord that was credited against base rent obligations for the second month of the lease.

The company has options to extend the lease term for two additional consecutive periods of five years each. At the beginning of each option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3% during the option term. We have included the first option to extend the lease term for five years as part of the initial term of the lease as it is reasonably certain that we will exercise the option, which implies lease expiration in September 2031. During the three months ended March 31, 2022, we recorded $0.1 million of rent expense for the lease, which was included in *research and development expense*, on the condensed consolidated statement of operations.

10. Stockholders' Deficit

Stock Authorized for Issuance

Effective February 1, 2022, ImmunityBio amended and restated its Amended and Restated Certificate of Incorporation to increase the number of shares of common stock that the company is authorized to issue from 500,000,000 shares, $0.0001 par value per share, to 900,000,000 shares, $0.0001 par value per share. The number of shares of preferred stock that the company is authorized to issue remains unchanged at 20,000,000 shares.

Stock Repurchases

No shares of our common stock were repurchased during the three months ended March 31, 2022 and 2021 under the company's 2015 Share Repurchase Program. As of March 31, 2022, $18.3 million remained authorized for repurchase under the program.

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. We issued no shares under the ATM during the three months ended March 31, 2022. As of March 31, 2022, we had $330.8 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.

11. Stock-Based Compensation

2015 Equity Incentive Plan

As of March 31, 2022, approximately 0.3 million shares were available for future grants 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 March 31,	
	2022	2021
	(Unaudited)	
Stock-based compensation expense:		
Stock options	$ 2,022	$ 6,355
RSUs	8,002	8,943
	$ 10,024	$ 15,298
Stock-based compensation expense in operating expenses:		
Research and development	$ 2,985	$ 2,888
Selling, general and administrative	7,039	12,410
	$ 10,024	$ 15,298

Stock Options

The following table summarizes stock option activity and related information for the three months ended March 31, 2022:

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2021	4,124,930	$ 15.62	$ 4,178	5.3
Granted	4,728,634	$ 5.83		
Exercised	(14,767)	$ 5.07		
Forfeited/expired	(19,331)	$ 5.14		
Outstanding at March 31, 2022	8,819,466	$ 10.41	$ 3,492	7.7
Vested and exercisable at March 31, 2022	3,310,293	$ 14.66	$ 3,386	4.2

As of March 31, 2022, the unrecognized compensation cost related to outstanding stock options was $31.5 million, which is expected to be recognized over a remaining weighted-average period of 2.5 years.

The total intrinsic value of stock options exercised during the three months ended March 31, 2022 was immaterial. Cash proceeds received from stock option exercises during the three months ended March 31, 2022 and 2021 totaled $0.1 million and $1.1 million, respectively.

As of December 31, 2021, a total of 3,038,322 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:

	Three Months Ended March 31, 2022
	(Unaudited)
Expected term	5.7 years
Risk-free interest rate	2.3 %
Expected volatility	101.3 %
Dividend yield	0.0 %
Weighted-average grant date fair value	$ 4.59

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 three months ended March 31, 2022:

	Number of Units	Weighted-Average Grant Date Fair Value
Nonvested balance at December 31, 2021	6,515,889	$ 21.88
Vested	(177,783)	$ 18.42
Forfeited/canceled	(188,695)	$ 21.59
Nonvested balance at March 31, 2022	6,149,411	$ 21.98

As of March 31, 2022, there was $99.8 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 3.3 years. The total intrinsic value of RSUs vested during the three months ended March 31, 2022 was $1.0 million.

RSUs awarded to employees and consultants of affiliated companies are accounted for as stock-based compensation in accordance with ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, as the compensation was in exchange for continued support or services expected to be provided to the company over the vesting periods under the NantWorks shared services agreement discussed in Note 9, *Related-Party Agreements*. We have evaluated the associated benefit of these awards to the affiliated companies under common control and determined that the benefit is limited to the retention of their employees. We estimated such benefit at the grant date fair value of $4.0 million and recorded $0.1 million and $0.1 million of deemed dividends for the three months ended March 31, 2022 and 2021 in *additional paid-in capital,* on the consolidated balance sheets, with a corresponding credit to stock-based 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 March 31, 2022. 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.

12. Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California and other states. From inception through March 31, 2022, we have not been required to pay U.S. federal and state income taxes because of current and accumulated net operating losses (NOLs). 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 U.S., Italy, and South Korea because those losses are offset by a full valuation allowance.

The company is no longer subject to income tax examination by the U.S. federal, state or local tax authorities for years ended on or before December 31, 2016. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authorities. No income tax returns are currently under examination by taxing authorities.

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 Code).

13. Subsequent Events

Second Amendment to NantWorks Facility License Agreement

On May 6, 2022, we amended our facility license agreement with NantWorks, a related party, to expand the licensed premises by 36,830 rentable square feet to an aggregate total of 46,330 rentable square feet. Effective May 1, 2022, the license fee is approximately $273,700 per month, which is subject to a 3% increase commencing on January 1 of each year. The space continues to be rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party.

23 Alaska, LLC Lease Agreement

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space.

Under the terms of the agreement, the lease term begins on May 1, 2022 and expires on April 30, 2027. The base rent is approximately $139,400 per month with an annual increase of 3% on May 1 of each year beginning in 2023 during the initial term. We will receive a rent abatement for the second through sixth month of the lease. We are also required to pay $7,600 per month for parking during the initial term and extension term, if exercised. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease.

The company is responsible for the costs associated with the build-out of the premises and will received a one-time tenant improvement allowance of $945,300 from the landlord.

The company has an option to extend the lease term for one additional consecutive five-year period. At the beginning of the option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3% during the option term.

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 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 develop next-generation therapies and vaccines that complement, harness, and amplify the immune system to defeat cancers and infectious diseases;
- our ability to implement and support our SARS-CoV-2 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 vaccines and 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 and the enrollment of patients;
- our expectations regarding our ability to utilize the Phase 1/2 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, self-amplifying RNA (saRNA), hAd5 and yeast constructs, recombinant sub-unit proteins, EDV constructs, toll-like receptor-activating adjuvants, and aldoxorubicin;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned investigational new drug (IND), BLA or New Drug Application (NDA) filings including, without limitation, the anticipated timing of filing a BLA for BCG-unresponsive NMIBC CIS 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 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;

- the ability to transition our clinical trials at the Clinic to a new structure on the anticipated timeline, if at all;
- our ability to finalize and execute definitive agreements with third parties with whom we have entered into term sheets or reached agreements in principle on various potential transactions;
- our expectations regarding 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 expectations regarding the timing of enrollment and submission of our clinical trials, and protocols related to such trials;
- our ability to produce an antibody cytokine fusion protein, a DNA, RNA, or recombinant protein vaccine, a toll-like receptor-activating adjuvant, an NK-cell therapy, or a damage-associated molecular patterns (DAMP) inducer 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 proteins, DNA, RNA or recombinant protein vaccines, toll-like receptor-activating adjuvants, NK-cell therapy, or DAMP inducer platforms, and the fact that our business is based upon the success individually and collectively of these platforms;
- our belief regarding the magnitude or duration for additional clinical testing of our antibody cytokine fusion proteins, DNA, RNA or recombinant protein vaccines, toll-like receptor-activating adjuvants, NK-cell therapy, or DAMP inducers along with other product candidate families;
- even if we successfully develop and commercialize specific product candidates like our Anktiva or PD-L1 t-haNK, our ability to develop and commercialize 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 CVRs held by former Altor stockholders become due and payable in accordance with their terms;
- regulatory developments in the U.S. and foreign countries; and
- the timing of the development and commercialization of our product candidates.

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.

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This Quarterly Report on Form 10-Q contains references to our trademarks and 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.

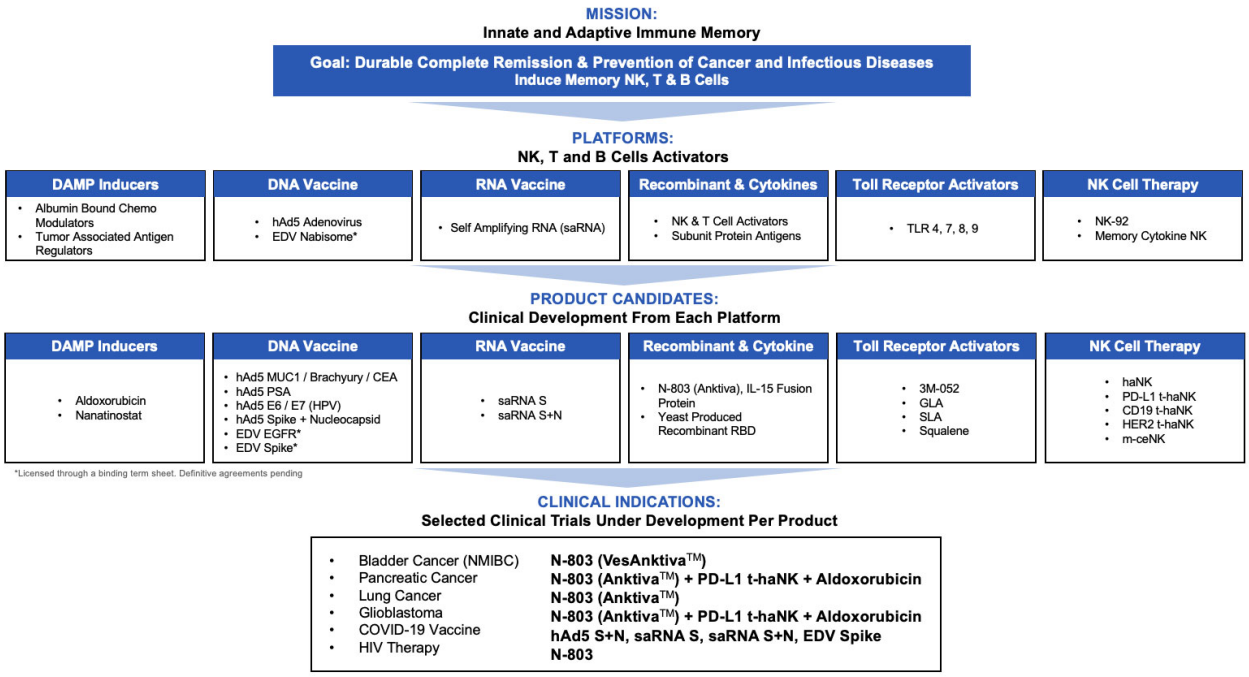
In this Quarterly Report on Form 10-Q, "ImmunityBio," "the company," "the combined company," "we," "us," and "our" refer to ImmunityBio, Inc. and its subsidiaries.

Our Business

ImmunityBio, Inc. is a clinical-stage biotechnology company developing next-generation therapies and vaccines that complement, harness, and amplify the immune system to defeat cancers and infectious diseases. We strive to be a vertically-integrated immunotherapy company designing and manufacturing our products so they are more effective, accessible, more conveniently stored, and more easily administered to patients.

Our broad immunotherapy and cell therapy platforms are designed to attack cancer and infectious pathogens by activating both the innate immune system—NK cells, dendritic cells, and macrophages—and the adaptive immune system—B cells and T cells—in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally infected. Our ultimate goal is to employ this approach to establish an "immunological memory" that confers long-term benefit for the patient.

Our business is based on the foundation of multiple platforms that collectively act on the entire immune response with the goal of targeted, durable, coordinated, and safe immunity against disease. These platforms and their associated product candidates are designed to overcome the limitations of the current standards of care in oncology and infectious diseases, such as checkpoint inhibitors and antiretroviral therapies. We believe that we have established one of the most comprehensive portfolios of immunotherapy and vaccine platforms, which includes:



Our platforms include 8 first-in-human therapeutic agents that are currently being studied in 27 clinical trials—18 of which are in Phase 2 or 3 development—across 13 indications in liquid and solid tumors, including bladder, pancreatic and lung cancers. These are among the most frequent and lethal cancer types for which there are high failure rates for existing standards of care or, in some cases, no available effective treatment. In infectious disease, our pipeline currently targets such pathogens as SARS-CoV-2 and HIV. We believe SARS-CoV-2 currently lacks a vaccine that provides long-term protection against the virus, particularly its variants, while HIV affects tens of millions of people globally and currently has no known cure.

We believe that our innovative approach to orchestrate and combine therapies for optimal immune system response will become a therapeutic foundation across multiple clinical indications. Additionally, we believe that data from multiple clinical trials indicates Anktiva has broad potential to enhance the activity of therapeutic monoclonal antibodies (mAbs), including checkpoint inhibitors (e.g., Keytruda), across a wide range of tumor types. Anktiva is currently being studied in 21 clinical trials (both ImmunityBio and investigator-sponsored) across 13 indications. Although such designations may not lead to a faster development process or regulatory review and may not increase the likelihood that a product candidate will receive approval, N-803, ImmunityBio's novel antibody cytokine fusion protein, has received *Breakthrough Therapy* and *Fast Track* designations in combination with BCG from the FDA for BCG-unresponsive NMIBC CIS.

Based on the reported results of our Phase 2/3 trial (QUILT 3.032), we have initiated discussions with the FDA to file a BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS. We held a pre-BLA meeting with the FDA in May and reached agreement with the agency with regard to the content and plan to submit our BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS. We anticipate that the final internal quality review of the BLA will be completed within the next ten days upon which we will submit our BLA.

We have established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

The Merger

On December 21, 2020, NantKwest and NantCell entered into the Merger Agreement pursuant to which NantKwest and NantCell agreed to combine their businesses. The Merger Agreement provided that a wholly-owned subsidiary of the company would merge with and into NantCell, 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, 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 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, RSU or warrant to purchase NantCell common stock was converted using the Exchange Ratio into an option, RSU or warrant, 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 NantKwest 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 Global Chief Scientific and Medical Officer, 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, the symbol for shares of the company's common stock was changed to "IBRX."

Accounting Treatment of the Merger

The Merger represents a business combination pursuant to FASB ASC Topic 805-50, 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.

COVID-19 Pandemic

The COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. Through the date of this Quarterly Report on Form 10-Q, we have not seen a material adverse impact to our business from the pandemic. However, given the unprecedented and continuously evolving nature of the pandemic, 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. In addition, we anticipate that enrollment of patients in certain studies will likely take longer than previously forecasted and that our clinical trials may require additional time to complete which would in turn impact the timeline of 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, 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.

We continue to monitor the impact of the COVID-19 pandemic on our business, including our clinical trials, manufacturing facilities and capabilities, and ability to access necessary resources. For a discussion of the risks presented by the COVID-19 pandemic to our results of operations and financial condition, see Part II, Item 1A. "Risk Factors."

Operating Results

From inception through the date of this Quarterly Report on Form 10-Q, we have generated minimal revenue from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. We have no clinical products approved for commercial sale and have not generated any revenue from therapeutic and vaccine product candidates that are under development. We have incurred net losses in each year since our inception and, as of March 31, 2022, we had an accumulated deficit of $2.1 billion. Our net losses attributable to ImmunityBio common stockholders were $102.8 million and $79.6 million for the three months ended March 31, 2022 and 2021, respectively. Substantially all of our net losses resulted principally from costs incurred in connection with our ongoing clinical trials and operations, our research and development programs, and from selling, general and administrative costs associated with our operations, including stock-based compensation expense.

As of March 31, 2022, we had 688 employees. Personnel of related companies who provide corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy and other support services under our shared services agreement with NantWorks are not included in this number. For additional information, see Note 9, *Related-Party Agreements,* of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q. In anticipation of the commercialization of select drug candidates, 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 continue to be an integral part of our operations, providing opportunities to leverage our partners' expertise and capabilities to gain access to new technologies and further expand the potential of our technologies and product candidates across relevant platforms. We believe we are well positioned to become a leader in immunotherapy due to our broad and vertically-integrated platforms and through complementary strategic partnerships.

We believe that our innovative approach to orchestrate and combine therapies for optimal immune system response will become a therapeutic foundation across multiple clinical indications. Additionally, we believe that data from multiple clinical trials indicates Anktiva has broad potential to enhance the activity of therapeutic mAbs, including checkpoint inhibitors (e.g., Keytruda), across a wide range of tumor types. Anktiva is currently being studied in 21 clinical trials (both ImmunityBio and investigator-sponsored) across 13 indications. We may also enter into supply arrangements for various investigational agents to be used in our clinical trials. See Part I, Item 1. "*Business—Collaboration and License Agreements*", of our Annual Report on Form 10-K filed with the SEC on March 1, 2022 for a more detailed discussion regarding our collaboration and license agreements.

Agreements with Related Parties

Our Executive Chairman, Global Chief Scientific and Medical Officer and our principal stockholder, founded and has a controlling interest in NantWorks, which is a collection of 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 and Global Chief Scientific and Medical Officer.

Related-Party Promissory Notes

As of March 31, 2022, we have outstanding fixed-rate promissory notes with entities affiliated with Dr. Soon-Shiong in an aggregate amount of $309.4 million, including accrued interest. These notes bear interest at a per annum rate ranging from 3.0% to 6.0%, provide that the outstanding principal is due and payable on September 30, 2025, and accrued and unpaid interest is payable on either upon maturity 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 addition, as of March 31, 2022 we have a $300.0 million variable-rate promissory note with an entity affiliated with Dr. Soon-Shiong that is due and payable on December 17, 2022. This loan bears interest at Term SOFR + 5.4%, which is compounded annually and payable quarterly commencing on March 17, 2022. As of March 31, 2022, the interest rate on this loan was 5.92%. In the event of a default on the loan (as defined in the promissory note), including if we do not repay the loan at maturity, the company has the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into shares of the company's common stock at price of $5.67 per share. There can be no assurance that we can refinance this promissory note or what terms will be available in the market at the time of refinancing. 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 the refinanced indebtedness would increase. These risks could materially adversely affect our financial condition, cash flows and results of operations.

Immuno-Oncology Clinic, Inc.

We entered into multiple agreements with 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.

In 2021, we completed a review of alternative structures that could support our more complex clinical trial requirements and made a decision to explore a potential transition of clinical trials at the Clinic to a new structure (including contracting with a new, non-affiliated professional corporation) to be determined and agreed upon by all parties and currently planned for the first half of 2022. Based on this decision to explore a potential transition, we determined that it was more likely than not that the previously recorded prepaid asset would not result in the collection of fees for services performed by the Clinic as contemplated in the original agreements. As a result, we wrote down the remaining value of our prepaid asset and recorded approximately $4.4 million in *research and development expense*, on the condensed consolidated statement of operations for the year ended December 31, 2021.

For the three months ended March 31, 2022 and 2021, we incurred $0.4 million and $0.3 million in *research and development expense*, on the condensed consolidated statements of operations related to clinical trial and transition services provided by the Clinic.

NantWorks, LLC

On May 6, 2022, we amended our facility license agreement with NantWorks, a related party, to expand the licensed premises to an aggregate total of 46,330 rentable square feet. See *Subsequent Events* for more information.

23 Alaska, LLC

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space. See *Subsequent Events* for more information.

See Note 9, *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

From inception through the date of this Quarterly Report on Form 10-Q, 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, primarily 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 expenses primarily consist 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 have only one product candidate, N-803, currently planned for a BLA submission to the FDA in the near future. However, there can be no assurance that it will be approved for commercial sale in the near term, if ever. We do not expect any of our other product candidates to be commercially available for the foreseeable future, if ever. See "*—Our Business*" above for an update on the anticipated timing of a BLA submission.

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 and equity-method investments, realized gains and losses on both debt and equity securities, and gains and losses on foreign currency transactions.

Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California and other states. From inception through March 31, 2022, we have not been required to pay U.S. federal and state income taxes because of current and accumulated NOLs.

Discussion of Condensed Consolidated Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,			
	2022	2021	$ Change	% Change
	(Unaudited, $ in thousands)			
Revenue	$ 14	$ 139	$ (125)	(90 %)
Operating expenses:				
Research and development (including amounts with related parties)	55,378	41,128	14,250	35 %
Selling, general and administrative (including amounts with related parties)	40,608	45,275	(4,667)	(10 %)
Total operating expenses	95,986	86,403	9,583	11 %
Loss from operations	(95,972)	(86,264)	(9,708)	11 %
Other (expense) income, net:				
Interest and investment income, net	1,666	8,944	(7,278)	(81 %)
Interest expense (including amounts with related parties)	(8,491)	(3,168)	(5,323)	168 %
Loss on equity method investment	(197)	—	(197)	n/a
Other (expense) income, net (including amounts with related parties)	(4)	13	(17)	(131 %)
Total other (expense) income, net	(7,026)	5,789	(12,815)	(221 %)
Loss before income taxes and noncontrolling interests	(102,998)	(80,475)	(22,523)	28 %
Income tax expense	—	(6)	6	(100 %)
Net loss	$ (102,998)	$ (80,481)	$ (22,517)	28 %

Revenue

Revenue decreased $0.1 million for the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The decrease was primarily driven by warranty revenue in 2021.

Research and Development Expense

Research and development expense increased $14.3 million during the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The increase in research and development expense was primarily driven by a $6.0 million increase in compensation expense due to higher headcount to support our continued research and development efforts, a $3.9 million increase in facilities and equipment expense, primarily related to the expansion of our manufacturing facility in El Segundo, California and the Dunkirk Facility leasehold acquisition, a $2.0 million increase in regulatory and consulting costs, a $2.0 million increase in research agreement and contract manufacturing costs, and a $0.4 million increase in shared services costs.

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 decreased $4.7 million during the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The decrease in selling, general and administrative expense was primarily attributable to a $12.6 million decrease in consulting and professional fees mainly due to Merger costs incurred during 2021, a $5.4 million decrease in stock compensation expense mainly driven by option modifications and certain RSU awards granted during 2021, a $1.6 million reduction in shared services costs and a $1.0 million reduction in insurance and other operating costs. These decreases were partially offset by a $10.4 million increase in accruals for a legal settlement, $4.7 million in personnel related costs due to higher headcount and increase international travel, and $0.8 million in higher equipment and license expense.

Other Expense, Net

Other expense, net increased $12.8 million during the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The increase in other expense, net was mainly due to a $7.3 million reduction in net unrealized gains related to our marketable equity securities, a $5.3 million increase in interest expense driven by higher related-party borrowings and a $0.2 million loss on equity method investment.

Financial Condition, Liquidity and Capital Resources

Sources of Liquidity

Our principal sources of liquidity are our existing cash, cash equivalents, and marketable securities. We have historically invested our cash primarily in investment grade short- to intermediate-term corporate debt securities, commercial paper, government-sponsored securities, U.S. treasury securities, and foreign government bonds and classify these investments as available-for-sale. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

As of March 31, 2022, we had cash and cash equivalents, and marketable securities of $193.2 million compared to $317.9 million as of December 31, 2021. On April 30, 2021, we entered into a 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 issued no shares under the ATM during the three months ended March 31, 2022. Although we made a decision to pause our ATM offering in the fourth quarter of 2021 after our $300.0 million promissory note financing with Nant Capital and do not have an active issuance notice with our sales agent, we expect to re-initiate activity at any time based on market dynamics and/or capital requirements. As of March 31, 2022, we had $330.8 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 March 31, 2022, our indebtedness totals $609.0 million (consisting of related-party promissory notes and accrued and unpaid interest, less unamortized debt issuance costs), held by entities affiliated with Dr. Soon-Shiong. Of this amount, $300.0 million is due and payable on December 17, 2022. In the event of a default on the loan (as defined in the promissory note), including if we do not repay the loan at maturity, the company has the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into shares of the company's common stock at price of $5.67 per share. There can be no assurance that we can refinance this promissory note or what terms will be available in the market at the time of refinancing. 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 the refinanced indebtedness would increase. These risks could materially adversely affect our financial condition, cash flows and results of operations.

  The remaining $309.4 million is due and payable on September 30, 2025, including any accrued and unpaid interest. 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 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 N-803 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 N-803 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 be required to pay the other prior Altor stockholders up to $164.2 million in settlement of the CVRs relating to the regulatory milestone and up to $164.2 million of the CVRs relating to the sales milestone should they choose to have the CVRs paid in cash instead of common stock. We may need to seek additional sources of capital to satisfy the CVR obligations if they are achieved.

- In connection with our acquisition of VivaBioCell, we are obligated to pay the former owners approximately $2.2 million of contingent consideration upon the achievement of a regulatory milestone relating to the GMP-in-a-Box technology.

Discussion of Condensed Consolidated Cash Flows

The following discussion of ImmunityBio's cash flows is based on the condensed consolidated statements of cash flows in Item 1. "Financial Statements" and is not meant to be an all-inclusive discussion of the changes in its cash flows for the periods presented below.

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

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	
Cash (used in) provided by:		
Operating activities	$ (74,930)	$ (60,469)
Investing activities	(69,313)	31,845
Financing activities	(298)	38,497
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(175)	(109)
Net change in cash, cash equivalents, and restricted cash	$ (144,716)	$ 9,764

Operating Activities

For the three months ended March 31, 2022, net cash used in operating activities of $74.9 million consisted of a net loss of $103.0 million, partially offset by $18.5 million in adjustments for non-cash items and $9.6 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of $10.0 million in stock-based compensation expense, $4.1 million in depreciation and amortization expense, $3.4 million in non-cash interest related primarily to related-party promissory notes, $1.3 million in non-cash lease expense related to operating lease right-of-use assets, $0.9 million in other non-cash items, and a $0.2 million loss on equity method investment, reduced by $1.4 million in unrealized gains on equity securities driven by an increase in the value of our investments. The changes in net working capital consisted primarily of increases of $10.9 million in accrued expenses and other liabilities and $0.8 million in accounts payable and a decrease of $0.1 million in other assets, partially offset by decreases of $1.6 million with related parties and $0.4 million in operating lease liabilities, and an increase of $0.2 million in prepaid and other current assets.

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

We have historically experienced negative cash flows from operating activities, with such negative cash flows likely to continue for the foreseeable future.

Investing Activities

For the three months ended March 31, 2022, net cash used in investing activities was $69.3 million, which included $34.1 million of purchases of marketable debt securities, $27.3 million of purchases of property, plant and equipment (including construction in process and depreciable property acquired in the Dunkirk acquisition), $21.2 million for purchase of intangible assets (related to the Dunkirk acquisition), and a $1.0 million investment in the joint venture, partially offset by cash inflows of $14.3 million from maturities and sales of marketable debt and equity securities. Our investments in property, plant and equipment are primarily related to acquisitions of equipment that will be used for the manufacturing of our product candidates and expenditures related to the build out of our manufacturing facilities.

For the three months ended March 31, 2021, net cash provided by investing activities was $31.8 million, which included cash inflows of $39.0 million from maturities and sales of marketable debt securities, partially offset by $7.1 million of purchases of property, plant and equipment and $0.1 million in purchases of marketable debt securities. Our investments in property, plant and equipment were related primarily to acquisitions of equipment that will be used for the manufacturing of our product candidates and expenditures related to the build out of our manufacturing facilities.

We expect to accelerate our capital spending as we scale our GMP manufacturing capabilities, which will require significant capital for the foreseeable future.

Financing Activities

For the three months ended March 31, 2022, net cash used in financing activities was $0.3 million, which consisted of $0.4 million related to net share settlement of vested RSUs for payment of payroll tax withholding, partially offset by $0.1 million in proceeds from exercises of stock options.

For the three months ended March 31, 2021, net cash provided by financing activities was $38.5 million, which consisted of $40.0 million in net proceeds from issuances of related-party promissory notes and $1.1 million in proceeds from exercises of stock options, partially offset by $2.6 million related to net share settlement of vested RSUs for payment of payroll tax withholding.

Future Funding Requirements

From inception through the date of this Quarterly Report on Form 10-Q, 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 operating 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 operating 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 and Global Chief Scientific and Medical Officer'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 external 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 U.S., including having a product candidate successfully manufactured consistent with FDA and European Medicines Agency (EMA) 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. Although we made a decision to pause our ATM offering in the fourth quarter of 2021 after our $300.0 million promissory note financing with Nant Capital and do not have an active issuance notice with our sales agent, we expect to re-initiate activity at any time based on market dynamics and/or capital requirements. As of March 31, 2022, we had $330.8 million available for future stock issuances under the ATM. See Note 10, *Stockholders' Deficit*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears 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 equity-linked securities, including convertible debt or 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

We have material cash requirements to pay related party affiliates and third parties under various contractual obligations discussed below:

- We are obligated to make payments to several related party affiliates under written agreements and other informal arrangements. We are also obligated to pay interest and to repay principal under our related-party promissory notes. For information regarding our financing obligations, see Note 9, *Related-Party Agreements—Related-Party Promissory Notes,* 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 are obligated to make payments under our operating leases, which primarily consist of facility leases. For information regarding our lease obligations, see Note 8, *Lease Arrangements,* and Note 9, *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.
- In connection with the acquisitions of Altor and VivaBioCell, we are obligated to pay contingent consideration upon the achievement of certain milestones. For information regarding our contingent consideration obligations, see Note 7, *Commitments and Contingencies—Contingent Considerations Related to Business Combinations,* 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 have contractual obligations to make payments to related-party affiliates and third parties under our unconditional purchase arrangements. For information on these unconditional purchase obligations, see Note 7, *Commitments and Contingencies,* 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 have certain contractual commitments that are expected to be paid within one year, depending on the progress of build outs, completion of services, and the realization of milestones associated with third-party agreements. This amount totals $102.7 million and is primarily related to capital expenditures, open purchase orders as of March 31, 2022 for the acquisition of goods and services in the ordinary course of business, and near term up-front milestone payments to third parties.
- In addition, we have contractual commitments that are expected to be paid in fiscal year 2023 and beyond based on the achievement of various development, regulatory and commercial milestones for agreements with third parties. These payments may not be realized or may be modified and are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring. As of March 31, 2022, the maximum amount that may be payable related to these commitments is $574.6 million.
- In connection with our leasehold interest in the Dunkirk Facility, we committed to spend an aggregate of $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. These amounts are not included in the discussion above. See Note 6, *Collaboration and License Agreements and Acquisition*, 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 additional information.

Critical Accounting Policies and Estimates

In Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K filed with the SEC on March 1, 2022, we disclose 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 as of the date of this Quarterly Report on Form 10-Q.

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements requires us 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. Actual results could differ from those estimates.

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.

Subsequent Events

Second Amendment to NantWorks Facility License Agreement

On May 6, 2022, we amended our facility license agreement with NantWorks, a related party, to expand the licensed premises by 36,830 rentable square feet to an aggregate total of 46,330 rentable square feet. Effective May 1, 2022, the license fee is approximately $273,700 per month, which is subject to a 3% increase commencing on January 1 of each year. The space continues to be rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party.

23 Alaska, LLC Lease Agreement

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space.

Under the terms of the agreement, the lease term begins on May 1, 2022 and expires on April 30, 2027. The base rent is approximately $139,400 per month with an annual increase of 3% on May 1 of each year beginning in 2023 during the initial term. We will receive a rent abatement for the second through sixth month of the lease. We are also required to pay $7,600 per month for parking during the initial term and extension term, if exercised. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease.

The company is responsible for the costs associated with the build-out of the premises and will received a one-time tenant improvement allowance of $945,300 from the landlord.

The company has an option to extend the lease term for one additional consecutive five-year period. At the beginning of the option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3% during the option term.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Financial market risks related to interest rates, foreign currency exchange rates and inflation are described in Item 7A. “Quantitative and Qualitative Disclosures About Market Risk” of our Annual Report on Form 10-K filed with the SEC on March 1, 2022. There have been no material changes to such financial market risks as of the date of this Quarterly Report on Form 10-Q. 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 March 31, 2022. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) of the Exchange Act means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, our CEO and CFO have concluded that, as of March 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fiscal quarter ended March 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

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 the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For additional information regarding our legal proceedings, see Note 7, *Commitments and Contingencies—Litigation*, of the "Notes to Unaudited Condensed Consolidated Financial Statements" that appears in Part I, Item 1. "Financial Statements" of this Quarterly Report on Form 10-Q.

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, NantKwest, Inc. completed the Merger with NantCell, Inc. (formerly known as ImmunityBio, Inc., a private company) (NantCell). After the completion of the 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.
- 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.
- We are a clinical-stage biotechnology 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.

Risks Related to the Discovery, Development and Commercialization of our Product Candidates

- 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.
- We may choose to 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 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.
- Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization. If our trials are not successful, we will be unable to commercialize our product candidates.

Risks Related to Reliance on Third Parties

- 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, to manufacture products and 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 (AE) reporting. Any failure by a third party, related party, or by us to perform as expected, to comply with legal and regulatory requirements or 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 and our ability to commercialize our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.
- 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.
- 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 arrangements, 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.

Risks Related to Healthcare and Other Government Regulations

- 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. For example, 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 are and will be subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal and/or civil liability and other serious consequences for violations, which can harm our business.

Risks Related to Intellectual Property

- If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our product candidates and technologies, we may not be able to compete effectively or operate profitably 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.
- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Risks Related to Our Common Stock

- Dr. Patrick Soon-Shiong, our Executive Chairman, Global Chief Scientific and Medical Officer 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.

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 totaling $609.0 million in indebtedness (consisting of related-party promissory notes and accrued and unpaid interest, less unamortized debt issuance costs) as of March 31, 2022 held by entities affiliated with Dr. Soon-Shiong.

As of March 31, 2022, we held cash, cash equivalents and marketable securities totaling $193.2 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.

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.

To the extent that we raise additional capital through the sale of equity or equity-linked securities, including convertible debt, or through the ATM or other offerings, or if any of our current debt is converted into equity, 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 March 31, 2022, our indebtedness totals $609.0 million, (consisting of related-party promissory notes and accrued and unpaid interest, less unamortized debt issuance costs), held by entities affiliated with Dr. Soon-Shiong.

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 need to refinance a portion of our outstanding debt as it matures. In particular, we have a $300.0 million promissory note with an entity affiliated with Dr. Soon-Shiong that becomes due and payable on December 17, 2022. In the event of a default on the loan (as defined in the promissory note), including if we do not repay the loan at maturity, the company has the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into shares of the company's common stock at a price equal to $5.67 per share. If we decide to convert this note into shares of common stock, it may be dilutive to our current stockholders. There can be no assurance that we can refinance this promissory note or what terms will be available in the market at the time of refinancing. 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 the 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.

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.

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, 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 biotechnology 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 biotechnology company with a limited operating history upon which you can evaluate our business and prospects, and we have a broad 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 biotechnology 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 each year, and, as of March 31, 2022 we had an accumulated deficit of $2.1 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 in the near term, if ever.

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, if ever, is dependent upon, among other things, 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 the Discovery, Development and Commercialization of our Product Candidates

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.

From inception through the date of this Quarterly Report on Form 10-Q, we have generated minimal revenue from non-exclusive license agreements related to our cell lines, and the sale of our bioreactors and related consumables. 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 invested a significant portion of our efforts and financial resources in the development of our main product candidates, our novel antibody cytokine fusion protein (Anktiva or N-803), saRNA and second-generation hAd5 vaccine candidates, and aldoxorubicin, some of which are used in combination with our NK cell therapy candidates. 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 product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs 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 products and product candidates, such as BCG, PD-L1 t-haNK, hAd5 and yeast tumor-associated antigens (TAAs), and aldoxorubicin. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with the therapy used in combination with our product candidate. 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 or increase our cost of development. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. 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.

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.

We may choose to 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 strategic 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 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.

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, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research by third parties, 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.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization. If our trials are not successful, we will be unable to commercialize our product candidates.

Our research and development programs are at various stages of development. 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 U.S. 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 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. The clinical trials for our product candidates under development may not be completed on schedule and regulatory authorities may ultimately disagree with our chosen endpoints or may find that our studies or study results do not support product approval and we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do or accept the therapeutic effects as valid endpoints in clinical trials necessary for market approval or they may find that our clinical trial design or conduct does not meet the applicable approval requirement and more trials could be required before we submit our product candidates for approval. Success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety, tolerability and efficacy traits despite having progressed through preclinical studies and initial clinical trials and after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising.

In addition, 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.

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

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 U.S. may not reimburse for costs typically covered by third-party payors in the U.S., 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.

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. In addition, we have in the past experienced clinical holds imposed upon certain of our or investigator-initiated clinical trials for various reasons, and we may experience further clinical trial holds in the future. 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.

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 contract manufacturing organizations (CMOs) or in our own, or our affiliates', manufacturing facilities in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our product candidates;
- successfully commercialize any of our product candidates that receive regulatory approval;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement for our product candidates;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;

- effectively compete with other therapies or competitors; and
- following launch, assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Even if the FDA approves N-803 (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 r/r 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 NantCell, we assumed the obligation to issue CVRs to the former stockholders of Altor in connection with the acquisition of Altor. These CVRs become payable upon the attainment of certain regulatory and sales milestones related to N-803. 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 are approximately $279.5 million in aggregate.

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 N-803, 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.

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.

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.

Delays or failures in planned patient enrollment or retention 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, or could render further development impossible.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, delay or 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, AEs or unexpected characteristics. Combination immunotherapy that includes our current product candidates may be associated with more frequent AEs or additional AEs. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or 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 regulatory authorities for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical trials, 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. They may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials and which could jeopardize regulatory approval. 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 clinical trials will need to be conducted with product candidates and materials that were produced under cGMP and/or Good Tissue Practice regulations, which are enforced by regulatory authorities. 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.

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.

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 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 contaminants 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.

We may not be successful in managing the build-out of our manufacturing facilities and associated costs or satisfying manufacturing related regulatory requirements.

We have entered into facility leases for our planned manufacturing operations and related activities under which we are responsible for the build-out of the facility space and associated costs. The build-out of these facilities and related equipment purchases are complex and specialized and will involve substantial capital expenditure, and it could take longer, and cost more, than currently expected. Significant delays and/or cost overruns would result in higher expenditures and could be disruptive of operations, any of which could have a negative impact on our financial condition or results of operations. For example, during the first quarter of 2022 we acquired a leasehold interest in the 409,000 square foot Dunkirk Facility as described below. While we believe that governmental funding will assist in funding a small portion of the further build-out of the Dunkirk Facility, we will need to plan and fund most of the additional build-out of, and purchase additional equipment for, the Dunkirk Facility in connection with our planned full operations. In addition, it is possible that, once built, the leased facilities may prove to be less conducive to our operations than is currently anticipated, resulting in operational inefficiencies or similar difficulties that could prove difficult or impossible to remediate and result in an adverse impact on our financial condition or results of operations. We also may not successfully realize the anticipated benefits from the capital expenditure at such facilities based on factors such as delays and uncertainties regarding development, regulatory approval and commercialization of our product candidates, as well as the potential to lose access to the leased facilities. Further, if we transition from our current CMOs to our own manufacturing facilities for one or more of our product candidates in the future, we may need to conduct additional preclinical, analytical or clinical trials. In addition, our planned operations, including our development, testing and future manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that may have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Failure to successfully complete our build-outs and successfully operate our planned manufacturing facilities and satisfy manufacturing-related regulatory requirements could adversely affect the commercial viability of our product candidates and our business.

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.

We currently depend on a small number of suppliers for some of the materials used in, and processes required to develop, our product candidates. 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 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 ability to use NOLs 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 Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change 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 NOL 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 NOL 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.

Our transfer pricing policies may be subject to challenge by the Internal Revenue Service 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.

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, public opinion, third-party reimbursement coverage and the commercial potential of our product candidates, which may impact public perception of us and our product candidates and which may adversely affect our ability to conduct our business and implement our business plans.

Human immunotherapy products are a new category of therapeutics. We use relatively novel technologies involving Anktiva, saRNA, hAd5 and yeast technologies, aldoxorubicin, and cell-based therapies, and our NK cell platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals. 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. Adverse public attitudes may adversely impact our ability to enroll patients in clinical trials. 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. 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. AEs 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.

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. 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. 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. 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. We compete with a variety of multi-national biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. 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 U.S. and internationally. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical, and human resources than we do, as well as significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful in obtaining approval of treatments and achieving widespread market acceptance, 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. Smaller or 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.

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 2 and/or 3 clinical trials or have already obtained emergency regulatory approval in the U.S. and internationally. Even if one of our COVID-19 vaccine candidates 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.

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 a faster development process or regulatory review and may 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, although there is no guarantee, the development and review of products that treat serious or life-threatening conditions. We have been awarded, 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 4 trials. For example, in connection with FDA approval of another company's drug, the FDA required significant post-marketing commitments, including a Phase 4 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 continue to build out 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.

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 AEs 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 approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological 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. There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic 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. 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 U.S. 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 NDA 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 U.S. 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. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.

We are and 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 contract research organizations (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. Further, as many of our employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase.

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. As the cyber-threat landscape evolves, these cyberattacks are increasing in their frequency, sophistication and intensity and are becoming increasingly difficult to detect. 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 and the public and governmental effort to mitigate against the spread of the disease, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, and may have a material adverse effect, on our clinical trials, operations, supply chains, distribution systems, product development, business and results of operations.

Outbreaks of epidemic, pandemic or contagious diseases, such as the ongoing COVID-19 pandemic, and measures taken in response by governments and businesses worldwide to contain its spread have adversely impacted and may continue to significantly disrupt our operations and adversely affect our business, financial condition and results of operations. Many countries including the U.S. implemented measures such as quarantine, shelter-in-place, curfew, travel and activity restrictions and similar isolation measures, including government orders and other restrictions on the conduct of business operations. The continued 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, are affecting and 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 but not limited to, those associated with an increased demand for information technology resources, increased risk of cybersecurity attacks (including social engineering attacks), risks related to internal controls and increased risk of unauthorized dissemination of sensitive personal information or our proprietary or confidential information.

The rapid development and fluidity of the pandemic preclude any prediction as to the ultimate effect of COVID-19 on us. While the U.S. and other countries have begun or will begin to reopen their economies, the extent to which COVID-19 will impact our future operations will depend on many factors which cannot be predicted with confidence, including the duration of the outbreak. Any resurgence in COVID-19 infections could result in the imposition of new mandates and prolonged restrictive measures implemented in order to control the spread of the disease.

U.S. President Biden has issued an Executive Order requiring federal employees and covered contractors to be vaccinated against COVID-19. Additionally, on November 4, 2021, the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) issued a COVID-19 Vaccination and Testing Emergency Temporary Standard requiring all employers with 100 or more employees to ensure that their employees are fully vaccinated or tested for COVID-19 on at least a weekly basis. On January 20, 2022, The U.S. Supreme Court invalidated this requirement. However additional vaccine and testing mandates may be announced in other jurisdictions in which we operate our business. While it is not currently possible to predict with any certainty the exact impact the new regulations would have on us and our suppliers, the implementation of such government mandated vaccination or testing mandates may impact our ability to retain current employees and attract new employees and result in labor disruptions.

We are monitoring a number of risks related to this pandemic, including the following:

- Financial: We expect to continue spending on research and development during the year ending December 31, 2022 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.
- Supply Chain: As the pandemic continues to progress, it has resulted and could continue to result in significant disruptions in our respective supply chains and distribution channels in the future. 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 has slowed and is expected to continue to slow, at least in the short-term, for most of our clinical trials. For ongoing trials, we have seen, and expect to continue to see 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, and may continue to result, 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 continued spread of COVID-19 has led to and could continue to lead to severe disruption and volatility in the U.S. and global capital markets, which could result in a decline in stock price, high inflation, increase our cost of capital and adversely affect our ability to access the capital markets in the future even after local conditions improve. 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. The legislative and regulatory environment governing our businesses is dynamic and changing frequently in response to COVID-19. 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. The pandemic may also result in greater regulatory uncertainty.

Risks Related to Reliance on Third Parties

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, to manufacture products and 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. Any failure by a third party, related party, or by us to perform as expected, to comply with legal and regulatory requirements or 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 and our ability to commercialize our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.

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, which 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. Our CROs 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.

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 BLA or NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CMOs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and 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.

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, 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 (vii) 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, which we may not be able to do on commercially reasonable terms, or at all and which may involve additional cost and time and require management time and focus. 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, it 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 using 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.

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 AE 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 AE 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.

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.

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 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 and Global Chief Scientific and Medical Officer, 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.

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 arrangements, 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 2 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 Phase 2 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, saRNA, hAd5 and yeast technologies, 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 using 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.

Our use of joint ventures, strategic partnerships and alliances may expose us to risks associated with jointly owned investments.

We may operate parts of our business through joint ventures, strategic partnerships and/or alliances with other companies. While such arrangements may, in some cases, give us access to technologies that we may not otherwise have or may give us access to capital, they involve risks not otherwise present in our own investments, including: (i) we may not control the venture, and it may divert management time and resources; (ii) the partner(s) may not agree to distributions that we believe are appropriate; (iii) we may experience impasses or disputes with such partner(s) on certain decisions, which could require us to expend additional resources to resolve such impasses or disputes, including litigation or arbitration; (iv) our partner(s) may become insolvent or bankrupt, fail to fund their share of required capital contributions or fail to fulfil their obligations as a venture partner; (v) the arrangements governing these relationships may contain certain conditions or milestone events that may never be satisfied or achieved; (vi) our partner(s) may have business or economic interests that are inconsistent with our interests and may take actions contrary to our interests; (vii) we may suffer losses as a result of actions taken by the partner(s); and (viii) it may be difficult for us to exit if an impasse arises or if we desire to sell our interest for any reason. In addition, we may, in certain circumstances, be liable for the actions of our partners. Any of the foregoing risks could have a material adverse effect on our business, financial condition and results of operations.

For example, we are in the initial stages of establishing a joint venture relationship with Amyris, and there can be no guarantee that it will be successful.

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 2019, Sorrento Therapeutics, Inc. with which we jointly established a new entity called Immunotherapy NANTibody, LLC 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 2020, Sorrento sent letters purporting to terminate an exclusive license agreement with us and an exclusive license agreement with NANTibody. Additionally, in 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 Condensed Consolidated Financial Statements" that appears in Part I, 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 Global Chief Scientific and Medical Officer, 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 and Global Chief Scientific and Medical Officer. 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 managements' 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;
- significant upfront milestone and/or royalty payments from which we may not realize the anticipated benefits;
- 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 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 U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced 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 U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic currently having an impact throughout the world; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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

We are party to a public-private partnership regarding our manufacturing facility in Dunkirk, New York, and if we or our counterparties fail to meet the obligations of those agreements, it could materially impact our development, operations and prospects.

On February 14, 2022, we acquired a leasehold interest in the Dunkirk Facility from Athenex. The facility provides us with a state-of-the-art biotech production center that we believe substantially expands and diversifies our existing manufacturing capacity in the U.S.

We paid approximately $40.0 million to Athenex, and the leasehold interest in the Dunkirk Facility was transferred to us. Our annual lease payment will be $2.00 per year for an initial 10-year term, with an option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed obligations under various third-party agreements, and committed to spend $1.52 billion on operational expenses during the initial term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first 5 years of operations, with 300 such employees to be hired within the first 2.5 years of operation. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above.

Failure to satisfy the obligations over the lease term, including the milestones we have committed to achieve, may give rise to certain rights and remedies of the lessor and other governmental authorities including, for example, termination of the lease agreement and other related agreements and potential recoupment of a percentage of the grant funding received by the Seller for construction of the facility and other benefits received, subject to the terms and conditions of the applicable agreements. If we lose access to the Dunkirk Facility and related leased equipment, it could disrupt our operations and manufacturing activities, cause us to divert resources to finding alternative facilities, which would not have any subsidies, and could have a significant impact on our operations and financial performance. We may also be subject to lawsuits or claims for damages against us if we are unable to comply with our obligations under these arrangements, which could materially and adversely affect our business, results of operations and financial condition. Furthermore, there is no guarantee that the counterparties to our public-private partnerships will comply with the terms of the agreements, including that their ability to fund their capital commitments under the agreements may be subject to their ability to raise additional capital and that further construction or operational timetables may not be met. Public-private partnerships are also subject to risks associated with government and government agency counterparties, including risks related to government relations compliance, sovereign immunity, shifts in the political environment, changing economic and legal conditions and social dynamics.

Risks Related to Healthcare and Other Government Regulations

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 U.S. 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 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, 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.

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 U.S., 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 U.S., 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. For example, 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 U.S., a company must first submit and receive either 510(k) clearance or pre-marketing approval from the FDA, unless an exemption applies.

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 and similar agencies have significant pre- and post-market authority, including requirements related to product design, development, testing, laboratory and clinical trials and preclinical studies approval, manufacturing processes and quality (including suppliers), labeling, packaging, distribution, AE and deviation reporting, storage, shipping, pre-market clearance or approval, advertising, marketing, promotion, sale, import, export, product change, recalls, submissions of safety and effectiveness, post-market surveillance and reporting of deaths or serious injuries and certain malfunctions, and other post-marketing information and reports such as deviation reports, registration, product listing, annual user fees, and recordkeeping for our product candidates. The FDA may also require a REMS to approve our product candidates, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The FDA may also require post-approval Phase 4 trials. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval.

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 AEs 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 2 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 3 devices are subject to premarket 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.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance. 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) AEs 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 fines, warnings or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions or partial suspension or total shutdown of production, injunctions, consent decrees, civil penalties and criminal prosecution, among other consequences. Additionally, we may face unanticipated expenditures to address or defend such actions and customer notifications for repair, replacement or refunds. 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.

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.

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.

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.

We are and will be subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal and/or civil liability and other serious consequences for violations, which can harm our business.

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, 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. if we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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 and goes into effect in most material respects on January 1, 2023. 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. Certain other state laws impose similar privacy obligations, and all 50 states have laws including obligations to provide notification of security breaches of computer databases that contain personal information to affected individuals, state officers and others. For example, the CCPA has prompted the enactment of several new state laws or amendments of existing state laws, such as in New York, Nevada, Virginia, and Colorado. These laws could mark the beginning of a trend toward more stringent privacy legislation in other U.S. states and have prompted a number of proposals for new federal and state-level privacy legislation. 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 U.S., 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. In addition, in January 2021, following its exit from the EU, the UK transposed the GDPR into its domestic law with its own version of the GDPR (combining the GDPR and the UK Data Protection Act of 2018) (UK GDPR), which currently imposes the same obligations as the GDPR in most material respects and provides for fines of up £17.5 million or up to 4% of the total worldwide annual global revenues of the noncompliant entity, whichever is greater.

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, GDPR and UK 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, UK 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 U.S., the United Kingdom, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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

We and our third-party contractors must comply with environmental, health and safety laws and regulations. A failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and any of our third-party contract manufacturers or suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, generation, manufacture, storage, treatment and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with such environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability, which could exceed our assets and resources.

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 biological or hazardous materials, or wastes arising out of and in the course of employment, 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.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. 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.

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 U.S., 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. Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases. The impact of these regulations and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is currently unknown. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

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. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. 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 co-payments, 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 U.S. 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 U.S. 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 Affordable Care Act (ACA) in 2010, in both the U.S. 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 March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, the American Taxpayer Relief Act of 2012 (ATRA) was approved which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These 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. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact 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 U.S. 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. 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 U.S. 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures. It is possible that additional governmental action is taken to address the COVID-19 pandemic.

Governments outside the U.S. 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 U.S. 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 U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. 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 and regulations 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. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

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 material adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions, including exclusion from government healthcare programs, and serious harm to our reputation. In addition, the approval and commercialization of any of our product candidates outside the U.S. 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 U.S. 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 that protect our Anktiva, saRNA, hAd5 and yeast technologies, cell-based therapies, aldoxorubicin or other product candidates and technologies or that 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, saRNA, hAd5 and yeast technologies, cell-based therapies or other product candidates and 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 U.S. 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 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.

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 U.S., 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 U.S. 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, saRNA, hAd5 and yeast technologies, cell-based therapies or other product candidates and 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, saRNA, hAd5 and yeast technologies, cell-based therapies or other product candidates or 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 U.S. 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 U.S. 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.

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 U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. 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 U.S. 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. Moreover, even if our patents were to survive such a litigation challenge to their validity, the patents might still be held to be valid but unenforceable if a court were to decide that the patents are being enforced in a manner inconsistent with the antitrust laws, or that the patents were obtained through deceit during patent office examination or other such failure of sufficient candor to the patent office. 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 N-803 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 U.S. 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 U.S. 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 U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., 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 U.S. 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 U.S. 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, 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 as well as products enabled by our adenoviral and yeast, including Tarmogen, vaccine 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 N-803 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 U.S. 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. We may be unable to obtain certain 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 N-803. 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 in various jurisdictions throughout the world.

We have limited intellectual property rights outside the U.S. 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 U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. 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 relevant to our business, may have already filed patent applications relevant to our business, 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 per new drug, 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 U.S. 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 rights in 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, including as an inventor or co-inventor. For example, we or our licensors may have 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.

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, saRNA, hAd5 and yeast technologies, cell therapies, 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 will 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 U.S. 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, Global Chief Scientific and Medical Officer and our principal stockholder, has significant interests in other companies which may conflict with our interests.

Our Executive Chairman, Global Chief Scientific and Medical Officer and our principal stockholder, 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 March 31, 2022, Dr. Soon-Shiong and his affiliates beneficially own approximately 78.7% of the company's common stock outstanding.

Additionally, an affiliate of Dr. Soon-Shiong holds a warrant to purchase 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.

During the year ended March 31, 2022, we executed a $300.0 million promissory note with an entity affiliated with Dr. Soon-Shiong that is due and payable on December 17, 2022. In the event of a default on the loan (as defined in the promissory note), including if we do not repay the loan at maturity, the company has the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into shares of the company's common stock at price of $5.67 per share. In addition, entities affiliated with Dr. Soon-Shiong hold promissory notes representing $309.4 million in indebtedness, including interest thereon, of the company as of March 31, 2022. Also Dr. Soon-Shiong has 926,064 stock options outstanding as of March 31, 2022, of which 900,000 are exercisable.

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, 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 the 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 and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, and his affiliates currently beneficially own approximately 78.7% of our outstanding shares of common stock as of March 31, 2022. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

Certain holders of our common stock are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have an adverse effect on the market price of our common stock.

In addition, we expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, including as part of the 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., 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 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 the Board of Directors, on committees of the Board of Directors, or as members of senior management.

If a restatement of our consolidated 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 for 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 and Global Chief Scientific and Medical Officer, Dr. 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.

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

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

We are not subject to the provisions of Section 203 of the Delaware General Corporation Law (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 and Global Chief Scientific and Medical Officer (who, with members of his immediate family and entities affiliated with him, currently beneficially own, in the aggregate, approximately 78.7% of our common stock as of March 31, 2022) 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, president or chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to the 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.

Item 1.01 Entry into a Material Definitive Agreement.

Second Amendment to NantWorks Facility License Agreement

On May 6, 2022, we amended our facility license agreement with NantWorks, a related party, to expand the licensed premises by 36,830 rentable square feet to an aggregate total of 46,330 rentable square feet. Effective May 1, 2022, the license fee is approximately $273,700 per month, which is subject to a 3% increase commencing on January 1 of each year. The space continues to be rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party.

23 Alaska, LLC Lease Agreement

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space.

Under the terms of the agreement, the lease term begins on May 1, 2022 and expires on April 30, 2027. The base rent is approximately $139,400 per month with an annual increase of 3% on May 1 of each year beginning in 2023 during the initial term. We will receive a rent abatement for the second through sixth month of the lease. We are also required to pay $7,600 per month for parking during the initial term and extension term, if exercised. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease.

The company is responsible for the costs associated with the build-out of the premises and will received a one-time tenant improvement allowance of $945,300 from the landlord.

The company has an option to extend the lease term for one additional consecutive five-year period. At the beginning of the option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3% during the option term.

The above description of the second amendment to NantWorks facility license agreement and 23 Alaska, LLC lease agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the respective agreements. Copies of both agreements will be filed with the SEC as exhibits to our Quarterly Report on Form 10-Q for the quarter ending June 30, 2022.

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. (incorporated by reference to Exhibit 2.1 to the company's Current Report on Form 8-K filed with the SEC on December 22, 2020).
10.1††	Purchase Agreement, by and between Athenex, Inc. and ImmunityBio, Inc. dated as of January 7, 2022 (incorporated by reference to Exhibit 10.1 to the company's Current Report on Form 8-K filed with the SEC on January 12, 2022).
10.2*	Fort Schuyler Management Corporation Lease, effective as of October 1, 2021, between Fort Schuyler Management Corporation, as Landlord, and Athenex, Inc., as Tenant.
10.3*	First Amendment to Lease, effective as of February 14, 2022, by and among Fort Schuyler Management Corporation and Immunity, Bio, 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.
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 Label 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).

† Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The company agrees to furnish to the SEC a copy of any omitted schedule or exhibit upon request.

†† Schedules and similar attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The company agrees to furnish to the SEC a copy of any omitted schedule or similar attachment upon request.

* 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 SEC and are not to be incorporated by reference into any filing of ImmunityBio, Inc. under the Securities Act, as amended, or the Exchange Act, 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 Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IMMUNITYBIO, INC.
Registrant

Date: May 10, 2022

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

Date: May 10, 2022

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

FORT SCHUYLER MANAGEMENT CORPORATION LEASE

THIS LEASE ("**Lease**") is entered into effective as of October 1, 2021 ("**Effective Date**") and is between the Landlord and the Tenant hereinafter named.

Landlord: Fort Schuyler Management Corporation
SUNY Polytechnic Institute
NanoFab East 4205
257 Fuller Road
Albany, New York 12203

Tenant: Athenex, Inc. (formerly known as "Kinex Pharmaceuticals, Inc.)
1001 Main Street
Buffalo, New York 14203

ARTICLE 1 Definitions and Basic Provisions

1.1 Tenant shall pay to Landlord Rent (hereinafter defined) upon the terms and conditions set forth in this Lease. "Rent" includes Base Rent (hereinafter defined) and Additional Rent (hereinafter defined). "Base Rent" is $2.00 per year. "Additional Rent" is the other charges which are specified in this Lease and which may be invoiced by Landlord upon the terms set forth below. Base Rent shall be payable in advance before each anniversary of the Effective Date, with the first such payment due on or before the Commencement Date, to Landlord without the need for invoicing from Landlord. Additional Rent shall be due within thirty (30) days of the date of Landlord's invoice. Additional Rent or other sums due and payable pursuant to this Lease remaining unpaid after the due date shall accrue interest at an annual rate of five (5%) percent accruing from the due date until paid.

1.2 Pursuant to that certain Agreement for Medical Technology Research, Development, and Innovation and Commercial Alliance effective as of May 1, 2015, as amended, between Fort Schuyler Management Corporation and Kinex Pharmaceuticals, Inc. (the "**Alliance Agreement**"), the "**Term**" of this Lease is for ten (10) years beginning on the date of the "Manufacturing Facility Completion", as such term is defined in the Alliance Agreement (the "**Commencement Date**") and ending ten (10) years thereafter (the "**Termination Date**"), unless sooner terminated in accordance with the provisions of this Lease. Notwithstanding the foregoing, Manufacturing Facility Completion shall occur before December 31, 2021. Promptly following the determination of the Commencement Date, the parties shall enter into a Commencement Date Agreement setting forth the actual Commencement Date and the Termination Date.

1.3 Tenant leases from Landlord that certain space encompassing approximately 409,000 square feet in the facility located at 3805 Lakeshore Drive East, Dunkirk, New York (the "**Building**") and consisting of approximately 33.6 acres of real property and also referred to as Tax Identification Number 80.01-1-3 and more particularly described on Exhibit A attached hereto (the "**Land**"), and that certain manufacturing equipment to be set forth in more particular detail by the Parties on Exhibit B attached hereto within six (6) months of

the Effective Date (the ‘‘**Manufacturing Equipment**” and collectively with the Building and the Land, the “**Premises**”), together with the right to use all common areas and amenities available for common use at or related to the Premises, including without limitation any walks, driveways, service areas, areas of ingress and egress, landscape areas, retaining walls, fire hydrants, traffic signalization, storm water detention and retention facilities, wastewater treatment facilities, utility systems and parking areas (collectively, the “**Common Areas**”). Tenant expressly acknowledges that as of the Commencement Date it will have inspected the Premises and be fully familiar with the physical conditions thereof. Tenant acknowledges that Landlord (i) has made no representation respecting the physical condition of the Premises, including the existence of any hazardous substances, any defects or other matters concerning their physical condition, except as expressly set forth in this Lease (provided, however, that the Parties acknowledge and agree that the specifications of the Building and the Land, including without limitation the square footage and acreage thereof, have been incorporated herein for reference purposes only and no representations or warranties are being made regarding the same) and (ii) shall have no obligation to do any initial build-out or fit-up work in and to the Premises.

1.4 Option. Landlord hereby grants to Tenant at the expiration of the Term, the option (the “**Option**”) to extend the Lease for an additional ten (10) year term (the “**Renewal Term**”) upon the same terms and conditions as contained herein. Pursuant to Section 4.3 of the Alliance Agreement, in order to exercise the Option, Tenant shall commit to spend or incur at least an additional $1.50 Billion in additional combined capital, operating expenses, raw materials, labor, supplies, equipment, capital expenditures and other costs in the Manufacturing Operation at the Manufacturing Facility (as such terms are described in Section 4.3 of the Alliance Agreement) during the Renewal Term. Pursuant to Section 5.1(i) of the Alliance Agreement, the Parties hereby acknowledge that they have agreed that Tenant’s extension will be in accordance with the provisions of this Lease, including this Section 1.4, and that Tenant shall not have the option to purchase the Building and the Manufacturing Equipment under Section 5.1(i) unless the Parties otherwise agree to the same pursuant to a separate writing.

The foregoing Option may be exercised only by written notice delivered by Tenant to Landlord no later than ninety (90) days prior to the expiration of the Term. Tenant may only exercise the Option if, on the date of delivery of the notice to Landlord, Tenant is not in default of this Lease beyond the applicable notice and cure period and is operating the Manufacturing Operations at the Premises.

1.5 Tenant shall have the right to use the Premises for the Tenant and Tenant’s Affiliates (hereinafter defined) activities in connection with the manufacture of high potency oral and sterile injectable pharmaceutical products and/or any other products and all other activities related thereto, including, but not limited to, general office use, corporate offices, laboratories and cafeteria uses (the “**Permitted Use**”).

1.6 Landlord and Tenant enter this Lease with reference to the Alliance Agreement and that certain Site Access Agreement, effective as of August 9, 2017 between the Parties (the “**Site Access Agreement**”), and Tenant and Landlord acknowledge and agree that Landlord and

Tenant entering into the Lease satisfies Landlord's and Tenant's obligation under the Alliance Agreement to enter into a lease agreement relating to the Premises.

ARTICLE 2 Granting Clause

In consideration of the obligation of Tenant to pay Rent and in consideration of the terms, covenants, and conditions of this Lease, Landlord hereby demises and Leases to Tenant, and Tenant hereby takes from Landlord, the Premises as described in Section 1.3, TO HAVE AND TO HOLD the Premises for the Term, all upon the terms and conditions set forth in this Lease. So long as Tenant is not in default under this Lease beyond any applicable notice and cure period, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet possession of the Premises, subject only to the declarations, easements or other encumbrances of record.

ARTICLE 3 Utilities, Operating and Maintenance Expenses

3.1 Tenant shall be responsible for payment of utilities that are consumed at the Premises.

3.2 Except for Landlord's obligations set forth in Section 3.3 of this Lease, Tenant shall be responsible for the maintenance and repair of the Premises, including without limitation, maintenance and operating expenses, utilities and municipal charges. As of the Commencement Date, Tenant shall be responsible for real estate taxes assessed against the Premises and any amounts paid pursuant to a PILOT Agreement or such other similar agreement with a government entity. Tenant shall be responsible for the maintenance and repair of the Building's insulated metal panel cladding in the locations near the roof elevations as more fully described in that certain Athenex Manufacturing Facility Insulated Metal Panel Deformation Technical Opinion dated March 16, 2020 prepared by Genesis AEC (the "**Roof Panel Cladding**").

3.3 Except for such liability, responsibility and obligations which Tenant expressly agreed to take on and bear pursuant to the Site Access Agreement, including without limitation Sections 3, 4, 5 and 6 thereof, all of which shall be deemed incorporated herein to the same extent as if restated herein in their entirety (and which shall remain Tenant's responsibility under Section 3.2 above), Landlord shall, at its sole cost and expense, keep the foundation, the exterior walls, plate glass windows, exterior entrance doors, exterior entrance door closure devices, and other exterior openings; window and window frames, molding, locks, and hardware; signs, placards, decorations or advertising media of any type, underground utilities, roof exclusive of the Roof Panel Cladding, and furnace of the Building in good order, condition and repair and make all necessary repairs and/or replacements thereto, reasonable wear and tear excepted. Landlord will coordinate any such maintenance and repair work with Tenant so as to minimize the disruption of Tenant's Permitted Use.

Notwithstanding the foregoing, Landlord and Tenant shall solely or jointly, as applicable, enforce all warranties or other contractual rights for maintenance, repair or replacement against any third parties ("**Warranties**") held by Tenant or Landlord covering any portion of the Building or the Manufacturing Equipment. In addition, to the extent requested by

Landlord or otherwise necessary for Landlord to perform its obligations hereunder, Tenant shall take all actions necessary to assign all Warranties on the Building and the Manufacturing Equipment to Landlord to the extent permissible. Tenant shall fully cooperate with Landlord and shall take all necessary action in order to fully enforce all Warranties applicable to the Building and Manufacturing Equipment.

Tenant hereby represents and warrants to Landlord that the AIA Document A141tm 2014, Standard Form of Agreement between Tenant and Exyte U.S., Inc. dated the 29th of December, 2017, as amended, is the only agreement that exists regarding the construction of the Building wherein Tenant is a party and that all other parties who performed construction services relating to the Building did so as subcontractors of Exyte U.S., Inc.

3.4 In the event the Premises should become in need of maintenance, repair or replacement required to be made by either party hereunder, said party will perform said maintenance, repair and replacement activities in compliance with all applicable federal, state, county and municipal laws, ordinances, codes, rules, orders, and regulations. Subject to Article 7, Tenant shall give Landlord such access as is reasonably necessary to carry out its obligations under Section 3.3. If Landlord desires to do any work (for maintenance or repairs or otherwise) that may require an interruption of any utility service to the Premises or cause any interference with Tenant's operations or access to the Premises, Landlord must comply with these requirements (except in the event of any Emergency (hereinafter defined) that precludes compliance with one or more of the following requirements, in which case Landlord will comply with the requirements to the extent reasonably possible): (a) Landlord will give Tenant at least ninety (90) days advance written notice of such planned work, (b) the work may only occur during times reasonably approved by Tenant (and the parties agree that Tenant may require that the work occur outside of normal business hours), (c) any interruptions may not be more than four (4) hours in length, (d) Landlord, at Landlord's cost and expense, will provided for temporary utility services and access to the Premises reasonably satisfactory to Tenant, and (e) in the case of a power interruption, Landlord will reimburse Tenant for the cost of operating Tenant's onsite generators. If Landlord is delayed in fulfilling its obligations under this Lease due to the operation of this paragraph, the time for Landlord's performance of its obligation will be extended on a day-for-day basis by the amount of the delay.

If Tenant notifies Landlord that Landlord's failure to perform Landlord's maintenance and repair obligations under Section 3.3 is having a material and adverse impact on Tenant's operations, Landlord will respond within twenty-four (24) hours with a statement of Landlord's plan to address the failure and the estimated time for cure, will commence the cure as soon as possible (but in any event within forty-eight (48) hours after Tenant's notice), and will diligently pursue and keep Tenant informed of the progress of the cure. If Landlord fails to do so, then Tenant may, in addition to any other remedies available at law or equity, cure Landlord's failure on Landlord's behalf and Landlord will, within ten (10) days after Tenant's written demand, reimburse Tenant for the costs and expenses incurred by Tenant including actual and reasonable attorneys' fees. If Landlord fails to timely reimburse Tenant, then Tenant may offset the amount against the $1.52 Billion required to be spent by Tenant during the Term and the $1.50 Billion required to be spent by Tenant during the Renewal

Term as provided in Section 4.3 of the Alliance Agreement.

ARTICLE 4 Use and Care of Premises

4.1 The Premises may be used only for the Permitted Use, and for no other purposes without the prior written consent of Landlord, which consent shall be in the sole and absolute discretion of the Landlord.

4.2 Tenant shall not, without the Landlord's prior written consent, keep anything within the Premises or use the Premises for any purpose, or create any conditions at the Premises that invalidates any insurance policy carried by Landlord on the Premises or causes the rate of insurance on the Premises to increase. Notwithstanding the foregoing, however, Landlord represents that Tenant's Permitted Use allowed hereunder does not conflict with and will not cause an increase in the rate of fire insurance on the Building.

4.3 If the rate of insurance on the Premises is higher as a result of the failure of Tenant to comply with Section 4.2, then Landlord shall make Tenant aware of such increase and the reason for such increase and give Tenant an opportunity to cure the same, provided that if Tenant cannot cure the same within a reasonable period, Tenant shall reimburse Landlord for the reasonable additional insurance premiums thereafter paid by Landlord after the Landlord's written demand so long as Landlord's written demand includes evidence that reasonably supports such requested increase, which shall be included in Additional Rent.

4.4 All property kept, stored or maintained within the Premises by Tenant shall be at Tenant's sole risk. Landlord shall not be liable for any loss or damage to any such Tenant property, unless caused by the negligence or willful misconduct of Landlord or any Landlord Party (hereinafter defined).

4.5 Tenant shall take good care of the Premises and keep the Premises reasonably free from waste at all times.

4.6 Tenant shall procure, at its sole expense, any permits and/or licenses required for the transaction of its business on the Premises and otherwise comply with all applicable laws, ordinances and governmental regulations. Landlord will reasonably cooperate in the institution and prosecution of any such permits and will execute any documents reasonably required in connection with any permits or licenses.

4.7 Tenant shall not do, and shall not knowingly permit to be done, anything which creates a lien upon the Premises for which proof of removal is not provided within ten (10) days after written notice thereof to Tenant.

ARTICLE 5 Maintenance and Repair of Premises

5.1 Landlord shall be responsible for repairs to the Premises as provided in Section 3.3 of this Lease.

5.2 Except for Landlord's obligations set forth in Section 3.3 of the Lease, Tenant shall keep the Premises in good, clean, habitable condition, subject to reasonable wear and tear and damage by casualty and condemnation. Without limiting the coverage of the previous sentence, it is understood that Tenant's responsibilities include any damage to the extent caused by Tenant or Tenant's Affiliates (hereinafter defined), partners, licensees, sublicensees, sublessees, invitees or agents, or any of their respective officers, directors, employees, contractors, agents or assigns (the "**Tenant Parties**"), wherever located, necessitating any repair and replacement of, in, or to the Premises. If any maintenance, repairs or replacements required to be made by Tenant hereunder or otherwise in this Lease are not initiated within thirty (30) days after written notice delivered to Tenant by Landlord, Landlord may at its option make such repairs without liability to Tenant for any loss or damage which may result by reason of such repairs, and Tenant shall pay to Landlord all costs incurred by Landlord in connection therewith within thirty (30) days of demand as Additional Rent hereunder. Tenant, at its sole cost and expense, shall keep the Premises free of insects, rodents, vermin and other pests and shall pay any reasonable cost incurred by Landlord as a result of a pest infestation in the Premises, which amount shall be Additional Rent. At the expiration of the Lease, Tenant shall surrender the Premises in good condition, excepting reasonable wear and tear, the maintenance obligations of Landlord under Section 3.3, and loss to be restored by Landlord in accordance with Article 11.

ARTICLE 6 Alterations

Except for Pre-Approved Alterations, Tenant shall not have the right to make alterations, additions, and improvements to the Premises ("**Alterations**") without the prior written consent of Landlord, which consent shall not be unreasonably withheld, delayed or conditioned. "**Pre-Approved Alterations**" means (i) the installation of unattached, movable trade fixtures which may be installed without drilling, cutting or otherwise defacing the Premises, (ii) Alterations that are nonstructural and do not involve building penetrations that adversely affect the Building's structure, and (iii) Alterations that are substantially consistent with the conceptual plans and scope of work that have been reviewed and approved by Landlord prior to the date of this Lease. All repairs, alterations, additions, improvements and fixtures (other than Tenant's unattached, readily movable furniture and other equipment) which may be made or installed by either party upon the Premises shall remain upon and be surrendered with the Premises and become the property of Landlord at the termination of this Lease, unless otherwise set forth in this Section 6.

ARTICLE 7 Landlord's Right of Access

Landlord may enter the Premises (excluding the portions of the Premises secured by Tenant for hosting sensitive equipment or materials, which Landlord shall only be able to access after executing a commercially reasonable non-disclosure agreement and, at Tenant's election, when accompanied by a representative or agent of Tenant) during normal business hours on not less than two (2) business days' prior written notice (except in an Emergency, when no notice is required) in order to exercise its rights or perform its obligations under this Lease. "**Emergency**" means a materially unsafe condition with respect to the Premises causing imminent danger to persons or property.

Landlord may enter the Premises (excluding the portions of the Premises secured by Tenant for hosting sensitive equipment and operations, which Tenant shall only be able to access as set forth above) during normal business hours on not less than two (2) business days' written notice for the purposes of showing the Premises to prospective purchasers and lenders, verifying Tenant's Investment & Spending and Employment Targets as required pursuant to the Alliance Agreement, or verifying Tenant's compliance with any other provisions of the Alliance Agreement.

In connection with any entry by Landlord other than in the event of an Emergency, (a) Landlord agrees to collect a duly executed non-disclosure agreement on Tenant's then- current form provided the same is commercially reasonable before permitting any third party (person or entity) to enter the Premises, (b) Tenant may deny access to the Premises to third parties if Tenant determines in its sole discretion that allowing the third party potential exposure to Tenant's proprietary and confidential information within the Premises would be detrimental to Tenant's business interests, and (c) Landlord and any other party will enter the Premises only when accompanied by a representative of Tenant and only in compliance with Tenant's commercially reasonable security programs and confidentiality requirements.

ARTICLE 8 Utilities and Services

Except as expressly set forth herein, Landlord shall not be liable for any interruption whatsoever in utility service or any other service for the Premises. Landlord shall not be liable to Tenant or anyone else for any loss or damage to person, property or business, unless due to the negligence of Landlord or any Landlord Party, nor shall Landlord be liable for any latent defects in the Premises. Landlord or its agents shall not be liable for any damage to property of Tenant or any Tenant Party nor for the loss of or damage to any property of Tenant or any Tenant Party by theft or otherwise, unless due to the negligence or willful misconduct of Landlord or any Landlord Party. Neither Landlord nor its agents shall be liable for any injury or damage to persons or property resulting from fire, explosion, falling ceilings, falling plaster, steam, gas, electricity, water, rain or snow or leaks from any part of the Premises or from pipes, appliances or plumbing works or from the roof, street or subsurface or from any other place or by dampness or by any other cause of whatever nature, including but not limited to the making of repairs and improvements, unless caused by or due to the negligence of Landlord, its agents, servants or employees.

ARTICLE 9 Indemnity and Insurance

9.1 Tenant shall indemnify, hold harmless and defend Landlord, State University of New York Polytechnic Institute of Technology including the Colleges of Nanoscale Science and Engineering, SUNY Polytechnic Foundation, Inc., The Research Foundation for the State University of New York, New York Center for Research, Economic Advancement, Technology, Engineering and Science Corporation, d/b/a NY CREATES, Fuller Road Management Corporation, New York State Urban Development Corporation, d/b/a Empire State Development, the State of New York, and the State University of New York (collectively, the "**Landlord Parties**") and their respective officers, directors, managers,

members, employees, agents, advisors, and assigns (collectively, together with the Landlord Parties, the "**Landlord Indemnified Parties**") from and against all Claims (hereinafter defined), which may be imposed on, incurred by, or asserted against one or more of the Indemnified Parties to the extent arising out of or related to any one or more of the following, except to the extent that such Claims were caused by the negligence or willful misconduct of the Landlord Indemnified Party seeking indemnification hereunder, in which case the indemnity shall not apply to the extent that the subject Landlord Indemnified Party was responsible for the negligence that caused such Claims: (a) any failure by Tenant to perform any of Tenant's agreements, terms, or conditions under this Lease, including but not limited to, any required action of Tenant to fully enforce all Warranties and to assign such Warranties to the Landlord in accordance with Article 3 hereof; (b) any wrongful act or negligent act or omission by one or more of Tenant or any Tenant Party; and (c) any injury to any person or any damage to property on or about the Premises resulting from or related to the use of, or conduct of business in the Premises by Tenant or any Tenant Party. "**Claims**" means any and all third-party claims for losses, liabilities, damages, costs and expenses (including actual and reasonable attorneys' fees).

9.2 The indemnifications set forth in this Article 9 and otherwise in this Lease shall remain operative and in full force and shall survive the termination or expiration or assignment of this Lease. For purposes of this Lease, "**Affiliate**" shall have the meaning set forth in Section 2.1 of the Alliance Agreement.

9.3 Landlord and Tenant shall purchase and maintain, at their sole cost and expense, the types and limits of insurance coverages, and on the other terms and conditions, set forth on Exhibit G of the Alliance Agreement, beginning on the Commencement Date and ending upon the termination or expiration of the Term or Renewal Term, all of which obligations shall be deemed to be fully incorporated herein.

9.4 Tenant shall secure written agreement of its insurance carrier(s) and, upon request, copy same to Landlord, agreeing to notify Landlord in writing no less than thirty (30) days prior to any cancellation or termination of any of the foregoing policies and coverages.

9.5 Such policies or duly executed certificates of insurance shall be promptly delivered to Landlord, but in no event later than five (5) days prior to Tenant's occupancy of the Premises and renewals thereof as required shall be delivered to Landlord at least ten (10) days after the expiration of the respective policy terms. Delivery of such certificates, in form reasonably satisfactory to Landlord, shall be a pre-condition to Tenant's occupancy. If Tenant should fail to comply with the foregoing requirements relating to insurance, and such failure shall continue for ten (10) business days after written notice from Landlord of such failure, Landlord may obtain such insurance and Tenant shall pay to Landlord on demand as Additional Rent the premium cost thereof.

9.6 Tenant may, at Tenant's sole discretion and at Tenant's sole cost and expense, obtain pollution legal liability insurance coverage (the "**PLL Policy**") for the Premises for pre-existing contamination conditions. If Tenant obtains a PLL Policy, then, notwithstanding anything to the contrary in this Lease, Landlord and Landlord Parties covenant and agree that

they shall, and shall require all other parties under their control (including, without limitation: any other tenants, newly proposed or newly authorized easement holders, licensees, and invitees; any prospective purchasers or prospective tenants; and any lenders of Landlord or Landlord Parties or any other party involved with the Premises), to refrain from any activities with respect to the Premises (including but not limited to activities pursuant to Landlord's rights and/or obligations under Section 3.3, Article 5, Article 6, and Article 7) that would cause coverage under the PLL Policy to be denied or otherwise rendered or deemed unavailable for a legitimate claim or actual loss that would have otherwise been afforded coverage under the PLL Policy, including, but not limited to:

(a) Refraining from conducting or requesting the conduct of, any (1) Phase II environmental investigations, including any sampling of soil, groundwater or other environmental media, and/or (2) any other sampling related to the presence or potential presence of hazardous and toxic substances (as defined herein), except when such sampling or investigation is affirmatively required to comply with applicable Environmental Law (as defined herein); or

(b) Refraining from disclosing any data or information regarding any conditions at the Premises to any environmental regulatory authorities, except when such disclosure is affirmatively required to comply with applicable Environmental Law or the New York State Freedom of Information Law.

In the event Tenant obtains a PLL Policy, and if requested by Landlord, Tenant shall name Landlord and any other Landlord Parties identified by Landlord as "additional insured" on the PLL Policy.

9.7 Notwithstanding anything to the contrary in this Lease, Landlord, Landlord Parties, Tenant, Tenant Parties and each of their respective insurers each waive any and all rights to recover against the other, and against the officers, directors, shareholders, partners, joint venturers, employees, of such other party, for any loss or damage to such waiving party arising from any cause covered by any property insurance required to be carried by such party pursuant to this Lease or any other property insurance actually carried by such party to the extent of the limits of such policy. Landlord, Landlord Parties, Tenant and the Tenant Parties from time to time will cause their respective insurers to issue appropriate waiver of subrogation rights endorsements to all property insurance policies carried in connection with some or all of the Premises or the contents therein to each other.

ARTICLE 10 No Liability for Certain Damages

Except to the extent of losses that Landlord is legally liable therefor under the terms of this Lease and except to the extent caused by Landlord's negligence or willful misconduct, Landlord Parties shall not be liable to Tenant for: (i) any injury to person or damage to property caused by Tenant or any Tenant Party or by or through the acts or omissions of other tenants of the Premises; (ii) by Tenant's use or occupancy of or conduct of business in the Premises; (iii) by the backing up of drains, or by gas, water, steam, electricity, or oil leaking, escaping, or flowing into the Premises; (iv) any failure by Tenant to perform any of Tenant's

agreements, terms, or conditions under this Lease; or (v) for any damages resulting from any other circumstances set forth in Article 8.

Neither Landlord nor Tenant will be liable to the other for consequential damages, such as lost profits or interruption of either party's business, except that this sentence (a) will not limit the liability of Landlord or Tenant for third-party claims under Article 9, and (b) will not apply to Landlord's breach of its confidentiality obligations under this Lease.

ARTICLE 11 Damages by Casualty and Condemnation

11.1 Tenant shall give prompt written notice to Landlord of any damage caused to the Premises by fire or other casualty (a "**Casualty Event**").

If the Premises are damaged by a Casualty Event, Landlord will notify Tenant within thirty (30) days after the Casualty Event as to the amount of time Landlord reasonably estimates it will take to restore the Premises. Thereafter, Landlord will promptly restore the Premises to the extent of available insurance proceeds therefor. If Landlord does not complete the restoration within thirty (30) days after the end of Landlord's estimated repair period (subject to extension for Force Majeure for up to thirty (30) days), Tenant may, at its option, complete the restoration of the Premises itself and Landlord will, within ten (10) days after Tenant's written demand, reimburse Tenant for the costs and expenses incurred by Tenant including actual and reasonable attorneys' fees up to the amount of available insurance proceeds therefor. If Landlord fails to timely reimburse Tenant as aforesaid, then Tenant may offset the amount against the $1.52 Billion required to be spent by Tenant during the Term and the $1.50 Billion required to be spent by Tenant during the Renewal Term as provided in Section 4.3 of the Alliance Agreement. For avoidance of doubt, in the event that any Casualty Event necessitates repairs or replacements which are not covered by Landlord's insurance, the Parties shall repair the same in accordance with their obligations hereunder, including without limitation Sections 3.2 and 3.3 hereof.

If, however, the Casualty Event occurs during the last two (2) years of the Term and if the remaining portion of the Premises is not suitable for Tenant's use or if the Premises is not rebuilt within one hundred and eighty (180) days from the Casualty Event, Tenant shall have the right to terminate the Lease; provided, however, that such termination shall not impact, limit, eliminate or otherwise negate Tenant's obligations hereunder to perform any repair or replacement, or otherwise cover the costs arising from, in connection with or as a result of such Casualty Event, including without limitation under Sections 3.2 and Article 9 hereof.

11.2 If the whole of the Premises shall be taken by any public authority under condemnation, the power of eminent domain, or by a sale in lieu thereof under threat of condemnation (collectively "**Taking**" or "**Taken**" as the case may be), then the Term shall cease as of the day of possession pursuant to such Taking, and the Rent shall be paid up to that day.

If less than the whole but more than twenty percent (20%) of the Premises shall be Taken, Tenant shall have the right to terminate this Lease or to continue in possession of the remainder of the Premises and shall notify Landlord in writing within ten (10) days after

notice of such Taking of Tenant's intention. If twenty percent (20%) or less of the Premises shall be so Taken, the Term shall cease with respect to the part so Taken as of the day possession shall be Taken, and Tenant shall pay Base Rent and Additional Rent up to that day for the part so Taken.

Any award for the Taking of all or any part of the Premises under the power of eminent domain or any payment made under threat of the exercise of such power shall be the property of Landlord, whether such award shall be made as compensation for diminution in value of the leasehold or for the Taking of the fee, or as severance damages; provided, however, that Tenant shall be entitled to any award for loss of or damage to Tenant's trade fixtures, moving costs and removable personal property to the extent separately awarded. Tenant shall have the right to negotiate its award separately with the condemning authority.

ARTICLE 12 Assignment and Subletting

12.1 Tenant shall not assign or in any manner transfer all or any part of this Lease or any estate or interest therein, or sublet the Premises or any part thereof, or grant any license, concession or other right of occupancy of any portion of the Premises (each, a "**Transfer**") without the prior written consent of Landlord, which consent shall not be unreasonably withheld (which, for avoidance of doubt, shall not be deemed to limit Landlord's ability to consider, among other things, whether and to what extent the potential assignee can meet the same requirements imposed by Landlord on Tenant, the financial viability of the potential assignee, the experience of the assignee in carrying out the Permitted Use and the potential assignee's contemplated use of the Premises, including without limitation the goods to be manufactured in the Premises). A Change of Control (as defined in Section II.2.2 of the Alliance Agreement) shall constitute a Transfer and shall require the prior written consent of Landlord as set forth in the prior sentence. Notwithstanding the foregoing, Tenant may, without Landlord's consent (i) Transfer the Lease to an Affiliate (as defined in Section II.2.1 of the Alliance Agreement) and (ii) enter into a sublease and sub-leaseback agreement with the County of Chautauqua Industrial Development Agency as provided in that certain Project Agreement entered into between the County of Chautauqua Industrial Development Agency and Athenex, Inc. dated November 1, 2017. Any Transfer by any party other than the originally named "Tenant" herein shall likewise require the prior written consent of the Landlord in accordance with the requirements set forth in this Section 12.1.

12.2 Notwithstanding any assignment or subletting, Tenant shall at all times remain fully responsible and liable for the payment of the Rent herein specified and for compliance with all of its other obligations under this Lease.

12.3 Tenant shall not mortgage, pledge or otherwise encumber its interest in this Lease or in the Premises without Landlord's consent, which consent shall be in the sole and absolute discretion of the Landlord. Notwithstanding the foregoing, Tenant may without Landlords' consent enter into a sublease and sub-leaseback agreement with the County of Chautauqua Industrial Development Agency as provided in the Project Agreement between County of Chautauqua Industrial Development Agency and Athenex, Inc. dated November 1, 2007.

ARTICLE 13 Default by Tenant

The following events shall be deemed to be events of default by Tenant under this Lease:

13.1 Tenant shall fail to pay any Rent or make any other payment of money when due hereunder and such failure shall continue for a period of twenty (20) days after written notice thereof to Tenant.

13.2 Tenant shall materially breach any term, provision or covenant of this Lease, other than as described in subsection Section 13.1 above, and shall not cure such material breach within thirty (30) days after written notice thereof to Tenant (provided that if Tenant is pursuing a remedy in good faith, Tenant shall have such reasonable period as is necessary to cure the breach).

13.3 Tenant shall become insolvent, or shall make a transfer in fraud of creditors, or shall make an assignment for the benefit of creditors.

13.4 Tenant shall file, or have filed against it, a petition under any section or chapter of the national bankruptcy act (and it is not dismissed within ninety (90) days of the filing), as amended, or under any similar law or statute of the United States or any state thereof, or Tenant or any guarantor of Tenant's obligations under this Lease shall be adjudged bankruptcy or insolvent in proceedings filed against Tenant or any guarantor of Tenant's obligations under this Lease.

13.5 A receiver or trustee shall be appointed for the Premises or for all or substantially all of the assets of Tenant.

13.6 Tenant vacates or fails to conduct its business in the Premises or any substantial portion of the Premises for more than ninety (90) consecutive days.

13.7 The failure of Tenant to fulfill its overall total spending obligations as set forth in Section 4.3 (Kinex Investment & Spending in connection with the Manufacturing Facility) of the Alliance Agreement, subject to such cure periods as are set forth in the Alliance Agreement.

13.8 The failure of Tenant to fulfill its obligations as set forth in Section 4.4 (Kinex Employment Targets in connection with the Manufacturing Facility) of the Alliance Agreement, subject to such cure periods as are set forth in the Alliance Agreement.

13.9 Any other actions or inactions on the part of Tenant constituting a default under the Alliance Agreement which results in the termination thereof.

13.10 Upon the occurrence of any such events of default, Landlord shall have the option to pursue any or all remedies permissible at law, including the following:

(a) Landlord may enter upon and take possession of the Premises in order to protect them from deterioration and no notice requirement shall be required prior to Landlord

taking such actions. Landlord may continue to demand from Tenant the Rent and Additional Rent, without any obligation to relet but that if Landlord, in its sole discretion, elects to relet the Premises, such action by Landlord shall not be deemed as an acceptance of Tenant's surrender of the Premises unless Landlord expressly notifies Tenant of such acceptance in writing. Tenant further agrees that in an event of default, Landlord, in its sole discretion, may elect for all Rent and Additional Rent reserved in this Lease from the date of such breach to the expiration date of this Lease, to become immediately due and payable to Landlord.

Tenant hereby acknowledges that if Landlord relets the Premises, Landlord shall be reletting as Tenant's agent and Tenant furthermore hereby agrees to pay to Landlord on demand any deficiency that may arise between the Rent and Additional Rent that are actually collected by Landlord. It is further agreed that in the event of default, Landlord shall have the right to enter upon the Premises, and subject to the limitation of liability provided in the Alliance Agreement, Landlord shall have the right to recover from Tenant any other out of pocket costs or expenses, including reasonable attorneys' fees and court costs, incurred by Landlord as a result of Tenant's default. Notwithstanding the foregoing, Tenant shall not be liable for consequential or other indirect damages (including without limitation, lost profits or business interruption).

(b) Upon the occurrence of any such events of default, Landlord may terminate this Lease with no further prior notice to Tenant except as set forth in Article 13, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which Landlord may have for possession, arrearages in or acceleration of rent, enter upon and take possession of the Premises and expel or remove Tenant or any other person who may be occupying the Premises or any part thereof, as provided by law. In addition, subject to the limitation of liability provided in the Alliance Agreement, Landlord shall have the right to recover from Tenant any other actual, out-of-pocket costs or expenses, including reasonable attorneys' fees and court costs, incurred by Landlord as a result of Tenant's default. Subject to the limitations provided in the Alliance Agreement, Tenant agrees to pay Landlord on demand the amount of all loss and damage that Landlord may be entitled to by law. Notwithstanding the foregoing, Tenant shall not be liable for consequential or other indirect damages (including without limitation, lost profits or business interruption).

13.11 If Landlord elects to exercise any remedy prescribed above, any such election shall in no way prejudice Landlord's rights at any time thereafter to change said election in favor of any other remedy(ies) prescribed. Pursuit of any of the above remedies shall not preclude pursuit of any other remedies prescribed in other sections of this Lease and any other remedies provided by law. Forbearance by Landlord to enforce one or more of the remedies herein provided upon an event of default shall not be deemed or construed to constitute a waiver of such default. It is further agreed that in addition to Rent payments required under this Lease, subject to the limitation of liability provided in the Alliance Agreement, Tenant shall compensate Landlord for any other actual, out-of-pocket costs or expenses, including reasonable attorneys' fees and court costs, incurred by Landlord as a result of Tenant's

default. Notwithstanding the foregoing, Tenant shall not be liable for consequential or other indirect damages (including without limitation, lost profits or business interruption).

ARTICLE 14 Holding Over

In the event Tenant remains in possession of the Premises after the expiration of the Term and without the execution of a new lease, it shall be deemed to be occupying said Premises as a Tenant at sufferance and at a rental equal to the Rent herein provided plus ten percent (10%) of such amount and otherwise subject to all the conditions, provisions and obligations of this Lease in so far as the same are applicable to a month-to-month tenancy.

ARTICLE 15 Subordination

At Landlord's written request, Tenant will subordinate this Lease and Tenant's interest and rights under this Lease to any existing or future Superior Interest (hereinafter defined), provided that the holder of the Superior Interest has executed, acknowledged and delivered to Tenant a commercially reasonable Subordination, Attornment and Non-Disturbance Agreement ("**SNDA**") that provides that: (a) Tenant's possession of the Premises and other rights under the Lease will not be disturbed in any proceeding to foreclose the Superior Interest or in any other action instituted in connection with such Superior Interest provided Tenant is in compliance with the terms hereof, (b) Tenant will not be named as a defendant in any foreclosure action or proceeding which may be instituted by the holder of such Superior Interest, (c) insurance proceeds and proceeds from condemnation awards will be used for any restoration and repair in accordance with Section 11 of this Lease, as applicable, and (d) if the holder of the Superior Interest or any other person acquires title to the Premises through foreclosure or otherwise, the Lease will continue in full force and effect as a direct lease between Tenant and the new owner, and the new owner will assume and perform the Landlord's obligations under this Lease, in all cases provided Tenant is in compliance with the terms hereof. The holder of any Superior Interest may, at any time, subordinate its Mortgage to this Lease, without Tenant's consent, by giving written notice to Tenant.

"**Superior Interest**" means any mortgage, deed of trust, master lease(s), ground lease(s), building loan agreements, leasehold mortgages, spreader and consolidation agreements and other similar documents and instruments, which may now or hereafter affect such leases or the real property of which the Premises form a part and to all renewals, modifications, consolidations, replacements, extensions, assignments, spreaders, and refinancings thereof and to all advances made or hereafter made thereunder. Each Superior Interest whose holder has entered into an SNDA shall be a permitted encumbrance.

ARTICLE 16 Notices

All communications, notices and disclosures required or permitted by this Lease shall be in writing, shall be provided to each of the parties and shall be deemed to have been given at the earlier of the date when actually delivered to each of the parties or when deposited in the United States mail, certified or registered mail, postage prepaid, return receipt requested, by hand delivery, by overnight courier service with signed receipt or by facsimile transmission

(with written confirmation of receipt thereof), and addressed as follows, unless and until any party notifies the other parties in accordance with this Article of a change of address.

In the case of Tenant:

Athenex, Inc.
1001 Main Street, Suite 600
Buffalo, New York 14203
Attn: Johnson Y.N. Lau, CEO

With a copy to:

Harter Secrest & Emery LLP
1600 Bausch & Lomb Place
Rochester, NY 14604
ATTN: Kelly A. Pronti, Esq.

In the case of Landlord:

Fort Schuyler Management Corporation
Scott Bateman, Treasurer
SUNY Polytechnic Institute
NanoFab East 4205
257 Fuller Road
Albany, New York 12203

With a copy to:

Hinman Straub P.C.
Attn: Philip J. Murphy, Esq.
121 State Street
Albany, New York 12207

Fort Schuyler Management Corporation
General Counsel's Office
SUNY Polytechnic Institute
NanoFab East 4205
257 Fuller Road
Albany, New York 12203

ARTICLE 17 Regulations

Tenant shall during the Term of this Lease be in compliance in all material respects with all applicable federal, state and local laws with respect to Tenant's use and occupancy of the Premises, including, without limitation those relating to toxic and hazardous substances and other environmental matters.

If any environmental contamination (including the storage or disposal of petroleum based products) is found on the Premises as result of Tenant's or any Tenant Party's use and occupancy thereof on the termination of this Lease for any reason or the expiration of the Term or Renewal Term for which any removal or remedial action is required pursuant to law, ordinance, order, rule, regulation or governmental action, Tenant shall, at its sole cost and expense, take such removal or remedial action promptly to the satisfaction of the appropriate governmental agency. Tenant agrees to defend, indemnify and hold harmless Landlord and the Landlord Parties from and against any Claims arising out of or in any way related to (i) the present or future disposal, release or presence on the Premises as a result of Tenant's or any Tenant Party's use and occupancy thereof of any hazardous or toxic substances (including, without limitation, any petroleum based products), (ii) any personal injury or property damage arising out of or related to such hazardous or toxic substances caused by the negligence or willful misconduct of Tenant or any Tenant Party, (iii) any lawsuit brought or threatened, settlement reached or government order given or related to such hazardous or toxic substances, and/or (iv) any violation of any law, order, regulation, requirement or demand of any governmental authority which is based upon or related to such hazardous or toxic substances. However, Tenant will not be liable for, and Landlord releases Tenant from, any claims for speculative, indirect or consequential damages, including any lost sales or profits of Landlord. For purposes of this Article, "hazardous and toxic substances" shall include, without limitation, any flammable explosives, radioactive materials, hazardous materials, hazardous wastes, petroleum based products, hazardous or toxic substances or related materials described in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, the Hazardous Materials Transportation Act, as amended, the New York Environmental Conservation Law, the Resource Conservation and Recovery Act, as amended, and the regulations adopted and publications promulgated pursuant thereto.

ARTICLE 18 Miscellaneous

18.1 Tenant covenants not to sue the Landlord Parties for breaches of this Lease, and will look only to Landlord for any claimed damages or breaches of this Lease, except to the extent provided in Section 9.1 of this Lease.

18.2 Tenant shall not for any reason withhold or reduce Tenant's required payments of Rent and other charges provided in this Lease, it being agreed that the obligations of Landlord hereunder are independent of Tenant's obligations except as may be otherwise expressly provided.

18.3 The failure of a party to insist upon strict adherence to any term of this Lease on any occasion shall not be considered a waiver or deprive that party of the right to insist later on adherence thereto, or thereafter to insist upon strict adherence to that term or any other term of this Lease. To be effective, any waiver must be in a writing signed by an authorized representative of the party granting such waiver.

18.4 Whenever a period of time is herein prescribed for action to be taken by either party, such party shall not be liable or responsible for and there shall be excluded from the computation of any such period of time, any delays due to Force Majeure (hereinafter defined). Force

Majeure shall not apply to either party's obligation to make timely payments under this Lease. For the purposes of this Lease, "Force Majeure" shall mean Acts of God, labor disputes, acts of public enemies or terrorists, war, other military conflicts, blockades, insurrections, riots, epidemics, pandemics, quarantine restrictions, landslides, lightning, earthquake, fires, conflagration, storms, floods, washouts, arrests, civil disturbances, restraints by or actions of any governmental body (including export or security restrictions on information, material, personnel, equipment or otherwise), industry-wide shortages, industry-wide unavailability and any other acts or events whatsoever, whether or not similar to the foregoing, not within the control of the acting party.

18.5 The laws of the State of New York, without regard to its conflicts of law provisions, shall exclusively govern the interpretation, validity, performance, and enforcement of this Lease. The venue for any action under this Lease shall be exclusive in the State of New York.

18.6 If any provision of this Lease should be held to be invalid or unenforceable, the validity and enforceability of the remaining provisions of this Lease shall not be affected thereby.

18.7 No amendment or modification of this Lease shall be valid or binding upon the parties unless in a writing executed by each of the parties. Landlord and Tenant acknowledge that they are not relying on any other representation or promise by the other, or of any agency except as may be expressly set forth in this Lease.

18.8 This Lease may be signed in one or more counterparts each of which deemed to be an original and all of which when taken shall constitute the same Lease. Any signed copy of this Lease made by photocopy, facsimile or PDF Adobe form, shall be considered an original.

18.9 All exhibits and addenda attached to this Lease are incorporated into this Lease and made a part of the Lease. In the event of any conflict between such exhibits or addenda and the terms of this Lease, the exhibits or addenda will control.

18.10 It is the express intention of both Landlord and Tenant that this Lease (including its accompanying addenda and exhibits) be considered a lease between Landlord and Tenant for all purposes, including federal and state tax purposes. Nothing in this Lease (including its accompanying addenda and exhibits) will be construed as creating a joint venture, partnership, tenancy-in-common, joint tenancy, financing, agency, or any relationship other than a landlord-tenant relationship between Landlord and Tenant, express or implied, including for federal and state tax purposes. Landlord and Tenant will treat this Lease (including its accompanying addenda and exhibits) as a lease in their separate books and records and in any reports to any third party.

18.11 Each party represents to the other that it has the full right and authority to bind itself without the consent or approval of any other person or entity and that it has full power, capacity, authority and legal right to execute and deliver this Lease and to perform all of its obligations hereunder.

18.12 Tenant may record this Lease or a short form or memorandum version hereof which is

previously approved by Landlord.

18.13 Wherever herein the singular number is used, the same shall include the plural, and the masculine gender shall include the feminine and the neuter genders. The words “breach” or “default” are used interchangeably herein and each shall be deemed to include the other.

18.14 Section titles or captions contained in this Lease are inserted as a matter of convenience and for reference and in no way define, limit, extend or describe the scope of this Lease or any provision hereof. No provision in this Lease is to be interpreted for or against either party because that party or its legal representative drafted such provision.

18.15 In case suit shall be brought for any unlawful detainer of the Premises, for the recovery of any Rent or additional amounts due under the provisions of this Lease, or because of the breach or alleged breach of any other covenant herein contained, the prevailing party shall recover from the non-prevailing party all costs and expenses incurred therein, including reasonable attorneys’ fees and expenses incurred in enforcing any judgment.

18.16 The covenants and conditions herein contained shall, subject to the provisions as to assignments, apply to and bind the heirs, successors, executors, administrators and assigns of the respective parties hereof.

[*Remainder of Page Intentionally Left Blank; Signature Page(s) Follow*]

IN WITNESS WHEREOF, Landlord and Tenant have signed and sealed this Lease on the date and year first above written.

LANDLORD:

FORT SCHUYLER MANAGEMENT COMPANY

By:	/s/ Timothy Taylor
Name:	Timothy Taylor
Title:	Chief Financial Officer

TENANT:

ATHENEX, INC.

By:	/s/ Johnson Yiu-Nam Lau
Name:	Johnson Yiu-Nam Lau
Title:	CFO

Exhibit A

Legal Description

SCHEDULE A

ALL THAT TRACT OR PARCEL OF LAND, situate in the Town of Dunkirk, County of Chautauqua and State of New York, being part of Lot 6 in Township 6 and Range 12 of the Holland Land Company's survey, and more particularly described as follows: Beginning in the southeasterly line of East Lake Road (also known as Lake Shore Drive East or New York State Route 5) as now laid out and occupied (66 feet wide) at the point located 185.16 feet northeasterly along said southeasterly line of East Lake Road from the intersection thereof with the east line of City of Dunkirk; thence southeasterly at an interior angle of 94 degrees 04 minutes a distance of 511 feet along the easterly line of lands of True Temper Corporation (now or formerly) to a steel fence post at a deflection point therein, and passing through an existing iron pin located 17 feet southeasterly along the last described course from said southeasterly line of East Lake Road; thence northeasterly at an interior angle of 86 degrees 47 minutes a distance of 604.29 feet along said easterly line of lands of True Temper Corporation to an existing iron pin at a deflection point therein; thence southeasterly at an interior angle of 273 degrees 12 minutes a distance of 1083 feet along said easterly line of lands of true Temper Corporation to an existing iron pin in the northwesterly line of lands of the New York Central Railroad (now or formerly); thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 135 feet along said northwesterly line of railroad lands to an iron pin at a deflection point therein; thence southeasterly at an interior angle of 270 degrees 00 minutes a distance of 33 feet along said northwesterly line of railroad lands to an iron pin at a deflection point therein; thence northeasterly at an interior angle of 90 degrees 00 minutes a distance of 357.5 feet along said northwesterly line of railroad lands to an iron pin in the southwesterly line of lands of Heffernan (now or formerly); thence northwesterly at an interior angle of 90 degrees 39 minutes a distance of 1268.5 feet along said southwesterly line of Heffernan lands to an iron pin in the southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace by deed recorded in Liber 248 of Deeds at page 228 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 170 feet along said southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace to an existing iron pin at the southerly comer thereof; thence northwesterly at an interior angle of 271 degrees 34 minutes a distance of 220 feet along the southwesterly line of said lands conveyed from Vandette to Lawhon, Wallace and Wallace to an existing iron pin at the southerly comer of lands conveyed from Schweyen to Mekus by deed recorded in Liber 916 of Deeds at page 125 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 70 feet along the southeasterly line of lands conveyed from Schweyen to Kaleta by deed recorded in Liber 919 of Deeds at page 564 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly comer thereof; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 5 feet along the southwesterly line of said Kaleta lands to an existing iron pin in the southeasterly line of lands conveyed from Schweyen to Dubiel by deed recorded in Liber 931 of Deeds at page 104 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 89 degrees 12 minutes a distance of 140 feet along said southeasterly line of Dubiel lands and along the southeasterly line of lands conveyed from Schweyen to Bialaszewski by Deed recorded in Liber

1007 of Deeds at page 281 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly comer of said Bialaszewski lands; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 145 feet along the southwesterly line of said Bialaszewski lands to an existing iron pin in said southeasterly line of East Lake Road; thence southwesterly at an interior angle of 89 degrees 46 minutes a distance of 209.99 feet along said southeasterly line of East Lake Road to an existing iron pin the northeasterly line of lands conveyed from Schweyen to Gates by deed recorded in Liber 1049 of Deeds at page 35 in the office of the Chautauqua County Clerk; thence southeasterly at an interior angle of 89 degrees 29 minutes a distance of 145 feet along said northeasterly line of Gates lands to an existing iron pin at the easterly comer thereof; thence southwesterly at an interior angle of 270 degrees 00 minutes a distance of 147.5 feet along the southeasterly line of said Gates lands and along the southeasterly line of lands conveyed from Schweyen to Bekelske by deed recorded in Liber 963 of Deeds at page 155 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly comer of said Bekelske lands; thence northwesterly at an interior angle of 271 degrees 11 minutes a distance of 145 feet along the southwesterly line of said Bekelske lands to an existing iron pin in said southeasterly line of East Lake Road; thence southwesterly along said southeasterly line of East Lake Road a distance of 290.01 feet to the point or place of beginning, and containing 21.6 acres of land more or less.

ALSO ALL THAT TRACT OR PARCEL OF LAND situate in the Town of Dunkirk, County of Chautauqua, State of New York, being part of Lot 6, Township 6, Range 12 of the Holland Land Company's Survey and being a portion of property conveyed to MULDOWNEY DEVELOPMENT INC. (MULDOWNEY) per L. 2682 of Deeds, P. 729, and being more particularly described as follows:

Commencing at a point in the centerline of Lake Shore Drive East (NYS Rte. 5) with the intersection with the Town and City line of Dunkirk. Thence, the following 2 courses;

1. Thence, North 55° 03' 03" East, in the centerline of Lake Shore Drive East, a distance of 163.30 feet;
2. Thence, South 30° 57' 57" East, a distance of 544.55 feet to the point of beginning.

1. Thence, North 55° 50' 03" East, a distance of 604.29 feet;
2. Thence, South 30° 57' 57" East, a distance of 1083 feet to an iron pipe found in the northerly line of property now or formerly of Consolidation Rail Corp. (CRC):
3. Thence, South 55° 50' 03" West, in the northerly line of said CRC property, a distance of 217.65 feet;
4. Thence, North 31° 21' 05" West, a distance of 85.12 feet;
5. Thence, South 55° 50' 03" West, a distance of 79.35 feet;
6. Thence, North 31° 21'05" West, a distance of 214.88 feet;
7. Thence, South 55° 50' 03" West, a distance of 232.48 feet;
8. Thence, North 31° 21' 05" West, a distance of 436.70 feet;
9. Thence, North 88° 12' 52" West, a distance of 81.00 feet;
10. Thence, North 31° 16' 32" West, a distance of 298.32 feet to the point of beginning.

Containing 521,860 square feet, (11.980+- acres).

Intending to describe “Lot 2” as shown on a plat titled “Subdivision Plan of property owned by N/F by MULDOWNEY DEVELOPMENT INC.” prepared by CHA Inc. project No. 30443.

The above premises are more recently described as shown on a survey map made by Frandina Engineering and Land Surveying, Inc. dated September 23, 2021, as follows:

ALL THAT TRACT OR PARCEL OF LAND, situate in the Town of Dunkirk, County of Chautauqua and State of New York, being part of Lot 6 in Township 6 and Range 12 of the Holland Land Company’s survey, and more particularly described as follows: Beginning in the southeasterly line of East Lake Road (also known as Lake Shore Drive East or New York State Route 5) as now laid out and occupied (66 feet wide) at the point located 185.16 feet northeasterly along said southeasterly line of East Lake Road from the intersection thereof with the east line of City of Dunkirk; thence southeasterly at an interior angle of 93 degrees 55 minutes 32 seconds a distance of 511.52 feet along the easterly line of lands of True Temper Corporation (now or formerly) to a deflection point therein; thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 604.29 feet along said easterly line of lands of True Temper Corporation to a deflection point therein; thence southeasterly at an interior angle of 273 degrees 12 minutes a distance of 1083.00 feet along said easterly line of lands of true Temper Corporation to the northwesterly line of lands of the New York Central Railroad (now or formerly); thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 135.00 feet along said northwesterly line of railroad lands to a deflection point therein; thence southeasterly at an interior angle of 270 degrees 00 minutes a distance of 33.00 feet along said northwesterly line of railroad lands to a deflection point therein; thence northeasterly at an interior angle of 90 degrees 00 minutes a distance of 356.75 feet along said northwesterly line of railroad lands to the southwesterly line of lands of Heffernan (now or formerly); thence northwesterly at an interior angle of 90 degrees 39 minutes 03 seconds a distance of 1268.32 feet along said southwesterly line of Heffernan lands to the southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace by deed recorded in Liber 248 of Deeds at page 228 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 24 minutes 51 seconds a distance of 170.00 feet along said southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace to the southerly comer thereof; thence northwesterly at an interior angle of 271 degrees 34 minutes a distance of 220.00 feet along the southwesterly line of said lands conveyed from Vandette to Lawhon, Wallace and Wallace to the southerly comer of lands conveyed from Schweyen to Mekus by deed recorded in Liber 916 of Deeds at page 125 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 70.00 feet along the southeasterly line of lands conveyed from Schweyen to Kaleta by deed recorded in Liber 919 of Deeds at page 564 in the office of the Chautauqua County Clerk to the southerly comer thereof; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 5.00 feet along the southwesterly line of said Kaleta lands to the southeasterly line of lands conveyed from Schweyen to Dubiel by deed recorded in Liber 931 of Deeds at page 104 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 89 degrees 12 minutes a distance of 140.00 feet along said southeasterly line of Dubiel lands and along the southeasterly line of lands conveyed from Schweyen to Bialaszewski by Deed recorded in Liber 1007 of Deeds at page 281 in the office of the Chautauqua County Clerk to the southerly comer of said Bialaszewski lands; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 145.00 feet along the southwesterly line of said Bialaszewski

lands to said southeasterly line of East Lake Road; thence southwesterly at an interior angle of 89 degrees 50 minutes 44 seconds a distance of 209.72 feet along said southeasterly line of East Lake Road to the northeasterly line of lands conveyed from Schweyen to Gates by deed recorded in Liber 1049 of Deeds at page 35 in the office of the Chautauqua County Clerk; thence southeasterly at an interior angle of 89 degrees 24 minutes 05 minutes a distance of 145 .00 feet along said northeasterly line of Gates lands to the easterly comer thereof; thence southwesterly at an interior angle of 270 degrees 00 minutes a distance of 147.50 feet along the southeasterly line of said Gates lands and along the southeasterly line of lands conveyed from Schweyen to Bekelske by deed recorded in Liber 963 of Deeds at page 155 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly comer of said Bekelske lands; thence northwesterly at an interior angle of 271 degrees 11 minutes a distance of 145.00 feet along the southwesterly line of said Bekelske lands to said southeasterly line of East Lake Road; thence southwesterly along said southeasterly line of East Lake Road a distance of 289.37 feet to the point or place of beginning, and containing 21.553 acres of land more or less.

ALSO ALL THAT TRACT OR PARCEL OF LAND situate in the Town of Dunkirk, County of Chautauqua, State of New York, being part of Lot 6, Township 6, Range 12 of the Holland Land Company's Survey and being a portion of property conveyed to MULDOWNEY DEVELOPMENT INC. (MULDOWNEY) per L. 2682 of Deeds, P. 729, and being more particularly described as follows:

Commencing at a point in the centerline of Lake Shore Drive East (NYS Rte. 5) with the intersection with the Town and City line of Dunkirk. Thence, the following 2 courses;
Thence, North 55° 03' 03" East, in the centerline of Lake Shore Drive East, a distance of 163.30 feet;
Thence, South 30° 57' 57" East, a distance of 544.60 feet to the point of beginning.
Thence, North 55° 50' 03" East, a distance of 604.29 feet;
Thence, South 30° 57' 57" East, a distance of 1083 feet to an iron pipe found in the northerly line of property now or formerly of Consolidation Rail Corp. (CRC):
Thence, South 55° 50' 03" West, in the northerly line of said CRC property, a distance of 217.65 feet;
Thence, North 31° 21' 05" West, a distance of 85.12 feet;
Thence, South 55° 50' 03" West, a distance of 79.35 feet;
Thence, North 31° 21' 05" West, a distance of 214.88 feet;
Thence, South 55° 50' 03" West, a distance of 232.48 feet;
Thence, North 31° 21' 05" West, a distance of 436.70 feet;
Thence, North 88° 12' 52" West, a distance of 81.00 feet;
Thence, North 31° 16' 32" West, a distance of 298.32 feet to the point of beginning.

Containing 521,860 square feet, (11.980+- acres).

Intending to describe "Lot 2" as shown on a plat titled "Subdivision Plan of property owned by N/F by MULDOWNEY DEVELOPMENT INC." prepared by CHA Inc. project No. 30443

Exhibit B

Listing of Manufacturing Equipment

[To be determined in accordance with Section 1.3].

FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "First Amendment to Lease"), effective as of the last date of signature below (the "Effective Date"), by and among **FORT SCHUYLER MANAGEMENT CORPORATION**, a not-for-profit corporation existing under the laws of the State of New York, having its office located at 257 Fuller Road, Albany, New York 12203 ("Landlord"), and **IMMUNITYBIO, INC.** a publicly held corporation under the laws of the state of Delaware and having an office at 3530 John Hopkins Court, San Diego, California 92121 ("Tenant"). Each of Landlord and Tenant may sometimes be referred to herein as a "Party" and, collectively, as the "Parties".

WHEREAS, Landlord and Athenex, Inc., a publicly held Delaware corporation ("Athenex") entered into that certain Site Access Agreement, dated as of August 9, 2017 (the "Site Access Agreement") and that certain Fort Schuyler Management Corporation Lease, dated as of October 1, 2021 (the "Lease") pursuant to which Landlord leased to Athenex that certain Premises (as defined in the Lease), which is inclusive of the Building (as defined in the Lease), Land (as defined in the Lease), and Manufacturing Equipment (as defined in the Lease); and

WHEREAS, pursuant to an Assignment of Lease, dated as of February 14, 2022, by and between Athenex and Tenant, Athenex has sold, assigned, and transferred to Tenant all of Athenex's rights in and to, and delegated to Tenant all of Athenex's duties and obligations under, the Site Access Agreement and the Lease (collectively, the "Assignment Transaction"); and

WHEREAS, the Parties have agreed to enter into this First Amendment to Lease to reflect the amendment to the Lease resulting from the Assignment Transaction and to set forth such other approvals, agreements and concessions as are set forth herein.

NOW, THEREFORE, for and in consideration of the premises and the mutual covenants hereinafter contained, and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the Parties hereto hereby formally covenant, agree and bind themselves as follows:

1. Definitional Matters. All capitalized terms used herein which are not otherwise defined shall have the meanings set forth in the Lease.

2. Amendments. Upon the Effective Date, the Lease is amended as follows:

   a. Section 1.2 is deleted and replaced with the following:

      "The term of this Lease (the "Term") shall commence on October 1, 2021 (the "Commencement Date") and shall continue until September 30, 2031 (the "Termination Date"), unless sooner terminated in accordance with the provisions of this Lease."

   b. Section 1.4 is amended by deleting the second and third sentences thereof and replacing the same with the following:

"In order to exercise the Option, Tenant and/or its Affiliates shall commit to spend or incur at least an additional $1.50 Billion in additional combined capital, operating expenses, raw materials, labor, supplies, equipment, capital expenditures and other costs at the Premises during the Renewal Term."

c. Section 1.5 is amended by deleting the following clauses therein: (i) "high potency oral and sterile injectable"; and (ii) "and/or any other products and".

d. Section 1.6 is amended by deleting the following clauses therein: (i) "the Alliance Agreement and"; and (ii) ", and Tenant and Landlord acknowledge and agree that Landlord and Tenant entering into the Lease satisfies Landlord's and Tenant's obligations under the Alliance Agreement to enter into a lease agreement relating to the Premises".

e. Section 3.4 is amended by deleting the last sentence thereof and replacing the same with the following:

"If Landlord fails to timely reimburse Tenant, then Tenant may, at its option and in its sole discretion, offset the amount against the $1.52 Billion required to be spent by Tenant during the Term and the $1.50 Billion required to be spent by Tenant during the Renewal Term as provided in this Lease. Otherwise, Landlord shall promptly reimburse Tenant for such costs and expenses."

f. Article 7 is amended by deleting the clause "Tenant's Investment & Spending and Employment Targets as required pursuant to the Alliance Agreement" set forth therein and replacing the same with "Tenant's investment, spending and employment targets as required pursuant to this Lease".

g. Section 9.2 is amended by deleting the second sentence thereof and replacing the same with the following: "For purposes of this Lease, (i) "Affiliate" shall mean an entity that Controls, is Controlled by, or is under common Control with, another entity, but only during the period that such control exists; and (ii) "Control" means the power to direct the affairs of any individual, corporation, partnership, joint venture, trust, business association, governmental entity or other entity by reason of ownership of voting stock, asset acquisition, contract or otherwise. For purposes of this Lease, Landlord's Affiliates shall be deemed to include, The Research Foundation for The State University of New York ("Foundation"), Fuller Road Management Corporation ("FRMC"), The State University of New York ("SUNY"), the State University of New York's Polytechnic Institute ("SUNY Poly"), the SUNY Polytechnic Institute Foundation, Inc. ("SUNY Poly Foundation"), and New York Center for Research, Economic Advancement, Technology, Engineering and Science Corp. (d/b/a NY CREATES) ("NYCREATES")."

h. Section 9.3 is deleted in its entirety and replaced with the following:

"Landlord and Tenant shall purchase and maintain during the entirety of the Term, at their sole cost and expense, the types and limits of insurance coverages, and on the other terms and conditions, as set forth in Exhibit C attached hereto."

i. A new Exhibit B in the form attached hereto as Exhibit A is added to the Lease as Exhibit B.

j. A new Exhibit C in the form attached hereto as Exhibit B is added to the Lease as Exhibit C.

k. A new Section 9.8 is added following existing Section 9.7 which provides as follows:

"9.8 Each of the Party's total cumulative liability for any and all Claims that relate to damage or destruction to real or personal property, tools and equipment, to the extent such matters or claims are not covered by insurance that is required to be carried by a party under this Lease or any use agreement or similar agreement for the Manufacturing Equipment, shall be limited to damages and/or payments which shall not exceed, in each case of such damage or destruction, the sum of (i) the insured value of the Premises, including the Land, the Building and the Manufacturing Equipment, and (ii) Five Million and 00/100 U.S. Dollars ($5,000,000.00), in the aggregate. Notwithstanding the foregoing limitation, Tenant's total cumulative liability for any and all such Claims brought in connection with Sections 13.7, 13.8, 13.9, 18.17, 18.18 and 18.19 of this Lease shall be limited to damages and/or payments which shall not exceed the Unamortized Investment. The "Unamortized Investment" means an amount equal to (i) the lesser of $208,000,000 and the amount actually expended by FSMC and/or Empire State Development Corporation prior to the termination, multiplied by (ii) a percentage, the numerator of which is equal to the difference between (x) $1,520,000,000 and (y) the amount of capital, operational and other costs incurred or spent by Tenant under Section 13.7 through the effective date of termination, and the denominator of which is equal to $1,520,000,000."

l. Section 11.1 is amended by deleting the clause "as provided in Section 4.3 of the Alliance Agreement" and replacing the same with "as provided in this Lease".

m. Section 12.1 is amended by deleting the second and third sentences thereof and replacing the same with the following new sentence:

"For avoidance of doubt, a "Transfer" shall be deemed to (i) include any transaction or series of transactions that result in a non-Affiliate third party obtaining, directly or indirectly, either all or a majority of the assets of the

Tenant or Control of the Tenant; and (ii) not include (a) a sale of capital stock in one or more financing transactions provided such one or more financing transactions do not result in a change of Control of Tenant, (b) a sale of assets not otherwise described in clause (i) above, or (c) a Transfer by Tenant of the Lease to an Affiliate of Tenant."

n. Section 12.3 is amended by deleting the second sentence thereof and replace the same with following:

"Notwithstanding the foregoing, Tenant may without Landlord's consent enter into the (i) Assignment and Assumption of Company Lease Agreement, (ii) Assignment and Assumption of PILOT Agreement, (iii) Assignment and Assumption of Project Agreement, and (iv) Assignment and Assumption of Lease Agreement in respect of the sublease and sub-leaseback agreement with the County of Chautauqua Industrial Development Agency as it relates to the Assignment Transaction".

o. Section 13.6 is deleted in its entirety and replaced with the following:
"13.6 Tenant vacates the Premises, fails to conduct its business in the Premises, or once manufacturing commences at the Premises, fails to manufacture pharmaceutical products at the Premises for a period of more than ninety (90) consecutive days, other than pursuant to:

(i) a Casualty Event, provided that (i) Tenant promptly takes commercially reasonable steps to remediate such Casualty Event and continues such remediation efforts in good faith until completion of the same, and (ii) such Casualty Event was not intentionally caused by Tenant or any Tenant Party,

(ii) Force Majeure, or

(iii) other closures which may not qualify as Force Majeure, provided that (a) Tenant shall maintain substantially all of its employees located at the Premises on payroll during such period, (b) Tenant restarts manufacturing at the Premises within sixty (60) days of the expiration of the ninety (90) day period, and (c) Tenant shall only be allowed to avail itself of this Section 13.6(iii) once during the Term."

p. Section 13.7 is deleted in its entirety and replaced with the following:

"13.7 The failure of Tenant and/or its Affiliates to invest and spend $1.52 Billion at the Premises, including raw material supplies, labor and other operational costs, including equipment, during the first ten (10) years following the Commencement Date and an additional $1.5 Billion during the Renewal Term, if applicable, as follows:

	Initial Term Years 1-10	Renewal Term Years 11-20
Raw Materials	$300 Million	$300 Million
Supplies	$250 Million	$250 Million
Labor	$570 Million	$570 Million
Other Operating	$400 Million	$380 Million
Total	$1.52 Billion	$1.50 Billion

For the avoidance of doubt, as of the Effective Date Athenex has represented and warranted that it has invested and spent $40,00,000 in accordance with the investment obligations set forth in this Section 13.7. Such $40,000,000 expended by Athenex, which is the amount Tenant will be paying to Athenex in the form of the purchase price at the closing of the Assignment Transaction, shall be counted towards Tenant's investment obligations set forth in this Section 13.7. As of the Effective Date, the remaining balance that the Tenant must invest and spend at the Premises during the Initial Term, in accordance with the investment obligations set forth in this Section 13.7, is $1,480,000,000."

q. Section 13.8 is deleted in its entirety and replaced with the following:

"13.8 The failure of Tenant and/or its Affiliates to (i) create and hire employee personnel for 450 direct permanent high tech jobs at the Premises, at least 300 of which jobs shall be created over the first 2.5 years following the Commencement Date, with 450 jobs achieved during the 5th year following the Commencement Date, (ii) retain such jobs during the Term and, if applicable, Renewal Term, or (ii) work with Landlord and funding agency(ies) to assist in attracting and locating an additional 450 jobs from companies that provide supplies, machinery, equipment, materials, and/or supplies or goods at the Premises (all such jobs referenced in this Section 13.8 being expected to meet the commercially reasonable requirements of the agency(ies) that provided funding for the Tenant's Permitted Use of the Premises). For the avoidance of doubt, employees hired by Tenant from Athenex shall be counted towards the total number of jobs to be created and retained in accordance with and subject to this Section 13.8 provided that they continue to meet the requirements set forth in this Section 13.8, including without limitation the retention obligation."

r. Section 13.9 is deleted in its entirety and replaced with the following:

"13.9 Tenant acknowledges New York State's desire to use as much local manufacturing product as is practical in support of the Tenant's Permitted Use of the Premises. Tenant and/or its Affiliates shall make reasonable efforts and provide first consideration to New York based suppliers of equipment, materials and other items required for the Tenant's Permitted Use of the Premises."

s. Section 13.10(a) is amended by deleting the clause "subject to the limitation of liability provided in the Alliance Agreement".

t. Section 13.10(b) is amended by deleting the clauses "subject to the limitation of liability provided in the Alliance Agreement" and "Subject to the limitations provided in the Alliance Agreement".

u. Section 13.10 is amended by adding a new Section 13.10(c) as follows:
"(c) Notwithstanding the foregoing provisions of this Section 13.10, in the event that Tenant defaults in fulfilling any of the obligations, covenants and agreements of Tenant as set forth in Section 13.6 hereof, then (i) Landlord shall serve a written fifteen (15) days' notice upon Tenant specifying the nature of said default, (ii) upon the expiration of said fifteen (15) days, if the complained of default has not been remedied to the reasonable satisfaction of Landlord, Landlord may serve a further written five (5) days' notice of cancellation of this Lease upon Tenant and, upon the expiration of said five (5) days, (a) this Lease and the Term or Renewal Term, as the case may be, shall end and expire as fully and completely as if the expiration of such five (5) day period were the day herein definitely fixed for the end and expiration of this Lease and the term thereof, (b) Tenant shall then quit and surrender the Premises to Landlord, provided, for avoidance of doubt, that Tenant shall remain liable hereunder, and (c) Landlord may, without notice, re-enter the Premises either by force or otherwise, and dispossess Tenant by summary proceedings or otherwise, and the legal representative of Tenant or other occupant of Premises and remove their effects and hold the Premises as if this Lease had not been made, and Tenant hereby waives the service of notice of intention to re-enter or to institute legal proceedings to that end."

v. Section 13.10 is amended by adding a new Section 13.10(d) as follows:
"(d) Notwithstanding the foregoing provisions of this Section 13.10, in the event that Tenant defaults in fulfilling any of the obligations, covenants and agreements of Tenant as set forth in Sections 13.7 or 13.8 hereof, then (i) Landlord shall serve a written thirty (30) days' notice upon Tenant specifying the nature of said default, (ii) upon the expiration of said thirty

(30) days, if the complained of default has not been remedied to the reasonable satisfaction of Landlord, Landlord may serve a further written fifteen (15) days' notice of cancellation of this Lease upon Tenant and, upon the expiration of said fifteen (15) days, (a) this Lease and the Term or Renewal Term, as the case may be, shall end and expire as fully and completely as if the expiration of such fifteen (15) day period were the day herein definitely fixed for the end and expiration of this Lease and the term thereof, (b) Tenant shall then quit and surrender the Premises to Landlord, provided, for avoidance of doubt, that Tenant shall remain liable hereunder, and (c) Landlord may, without notice, re-enter the Premises either by force or otherwise, and dispossess Tenant by summary proceedings or otherwise, and the legal representative of Tenant or other occupant of Premises and remove their effects and hold the Premises as if this Lease had not been made, and Tenant hereby waives the service of notice of intention to re-enter or to institute legal proceedings to that end. If Tenant shall make default hereunder prior to the date fixed as the commencement of any renewal or extension of this Lease, Landlord may cancel and terminate such renewal or extension agreement by written notice."

w. Section 13.11 is amended by deleting the clause "subject to the limitation of liability provided in the Alliance Agreement".

x. Article 16 is amended to provide the following new notice information for Tenant:

"ImmunityBio, Inc.
3530 John Hopkins Court
San Diego, California 92121
Attn: Richard Adcock, CEO and President"

y. New Section 18.17 set forth below is incorporated into the Lease:

"18.17 Tenant and/or its Affiliates shall use commercially reasonable efforts to work with Landlord to help recruit, relocate and train the workforce necessary to staff the Premises. This may include participation in one or more workforce development programs that Landlord, Foundation or the State University of New York Polytechnic Institute ("SUNY POLY") has or will commence in New York."

z. New Section 18.18 set forth below is incorporated into the Lease:

"18.18 Tenant and/or its Affiliates shall use commercially reasonable efforts to guide and execute the activities below:

- Work to develop next generation pharmaceutical product educational curriculum and workforce training content;

- Deliver joint education programs, seminars, and conferences;
- Offer internships that will enable SUNY POLY students to participate in the development, manufacture, and distribution of next generation pharmaceutical products; and
- Participate, as and when appropriate, in the medical, biomedical and life sciences related centers SUNY POLY has established or will in the future establish."

aa. New Section 18.19 set forth below is incorporated into the Lease:

"18.19 Tenant shall provide Landlord with reports verifying Tenant's and/or its Affiliates investment, job creation and such other information as is reasonably requested by Landlord, with such reports being duly acknowledged by an officer of Tenant and in such form as reasonably requested by Landlord. Landlord or its accounting firm may examine and copy Tenant's books, records, documents, and other supporting data relating to this Lease. Tenant shall maintain accurate books, records, documents, and other supporting data which relate to its obligations under this Lease for seven (7) years from the date of termination of this Lease. Landlord shall notify Tenant in writing before any examination of Tenant's books, records, documents and other supporting date relating to this Lease and will conduct such examination at reasonable times."

3. Miscellaneous. This Amendment may be executed in several counterparts, each of which shall be an original and all of which shall constitute but one and the same instrument. Any signed copy of this Amendment made by reliable means (e.g., photocopy, facsimile, or PDF Adobe Acrobat) shall be considered an original. This Amendment shall be governed, construed and enforced in accordance with the laws of the State of New York. This Amendment may not be assigned without the prior written consent of all of the Parties hereto. This Amendment and the attachments hereto constitutes the entire agreement of the Parties with respect to the subject matter hereof. In the event of any conflict or inconsistency between the terms and conditions of this Amendment and Lease, the terms and conditions of this Amendment shall control.

[***Remainder of Page Intentionally Left Blank; Signature Page(s) Follow***]

IN WITNESS WHEREOF, Landlord and Tenant have caused this First Amendment to be executed in their respective names by their authorized representatives as of the Effective Date.

LANDLORD:

FORT SCHUYLER MANAGEMENT CORPORATION

By: /s/ Timothy Taylor
Name: Timothy Taylor
Title: Chief Financial Officer
Date: 2/14/2022

TENANT:

IMMUNITYBIO, INC.

By: /s/ Richard Adcock
Name: Richard Adcock
Title: Chief Executive Officer and President
Date: 2/14/2022

[***Signature Page to First Amendment to Lease***]

Exhibit A
To
First Amendment to Lease

Exhibit B

Listing of Manufacturing Equipment

1. One (1) Bausch Advance Technologies Syringe Filler
2. One (1) Two-person scissor lift (ATX ID 942)
3. One (1) One-person mobile lift (ATX ID 935)
4. One (1) Articulating one-person boom lift (ATX 935)

Exhibit B
To
First Amendment to Lease

Exhibit C

Tenant shall obtain and maintain during the entirety of the Term the following insurance coverage and/or limits:

(a) Tenant shall maintain (or cause to be secured and maintained) for the benefit of Landlord, annual comprehensive general public liability insurance (or a combination of commercial general liability insurance, self-insurance and/or umbrella liability insurance) with a combined single limit per occurrence of not less than $15 Million, and an aggregate limitation of not less than $15 Million, which insurance covers bodily injury, disease and death and property damage (including, to the extent such insurance is reasonably available therefor, environmental damage), and which applies to any such liabilities Tenant may have under this Agreement.

(b) Business Automobile Liability with limits of insurance of not less than $1,000,000.00 each accident.

(c) Workers Compensation & Employers Liability with limits of insurance of not less than the amount required by New York State and which contains an All States Endorsement.

(d) Property Insurance (PI) in the amount of $65 Million that includes coverage for the personal property/equipment of others and/or property that is in the care, custody and control of Tenant (other than Manufacturing Equipment). This policy should provide "all-risk" coverage and shall include coverage for the perils of "testing", "calibrating" and "mechanical breakdown." Landlord shall be named as Loss Payee on the PI policy maintained by Tenant.

(e) Tenant will name FRMC, Foundation, SUNY, SUNY Poly and the State of New York as additional insureds (the “Additional Insureds”). Purchase and maintenance of such insurance shall in no way be interpreted as relieving Tenant of any of its responsibilities or liabilities under this Lease, and Tenant may carry, at its expense, such additional insurance amounts and coverage as it deems necessary. The general public liability insurance for the Additional Insureds shall be as broad as the coverage provided for the named insured party. Except due to claims caused by the negligence of Landlord, it shall apply as primary and non-contributing insurance before any insurance maintained by the Additional Insureds. Tenant shall maintain coverage for itself and all Additional Insureds for the duration of the Term.

(g) Tenant shall secure written agreement of its insurance carrier(s) and, upon request, copy same to Landlord and to the parties set forth in the Notice section, agreeing to notify Landlord in writing no less than thirty (30) days prior to any cancellation, termination or material modification of any of the foregoing policies and coverages.

Landlord shall, at its sole cost, purchase and maintain for the duration of the Term Property Insurance (PI) that includes coverage for Building and the Manufacturing Equipment, for the replacement cost thereof, including builder's risk insurance on the Building while it is under construction. This policy should provide "all-risk" coverage and shall include coverage for the perils of "testing", "calibrating" and "mechanical breakdown."

Each Party hereby agrees as follows:

(1) Notwithstanding anything to the contrary in the Lease, each Party and its respective insurers waives all rights against the other Party and the Additional Insureds, as well as such entities' officers, directors, trustees and employees, for recovery of damages to the extent said damages are covered by insurance required to be maintained by such Party per the requirements stated above.

(2) Upon signing of this Agreement and immediately upon renewal or replacement of any and all insurance policies required hereunder, each Party shall furnish to the other Party certificates of insurance evidencing all coverages required hereunder, to which copies of all additional named insured endorsements and loss payee endorsements required hereunder, executed by the insurers, shall be attached. Landlord additionally shall have the right to review all insurance policies maintained by Tenant hereunder upon request.

Exhibit C

Assignment

[To be attached]

ASSIGNMENT OF LEASE

THIS ASSIGNMENT OF LEASE (this "**Assignment**") is made as of the 14th day of February, 2022 (the "**Effective Date"**), by and between ATHENEX, INC., a Delaware corporation ("**Assignor**"), and IMMUNITYBIO, INC., a Delaware corporation ("**Assignee**").

Recitals

WHEREAS, pursuant to that certain Site Access Agreement, dated as of August 9, 2017 (the "**Site Access Agreement**") and that certain Fort Schuyler Management Corporation Lease dated as of October 1, 2021 (the "**FSMC Lease**"), both by and between Fort Schuyler Management Corporation ("**FSMC**"), as landlord, and Assignor, as tenant, FSMC leased to Assignor certain premises (the "**Premises**") located on the property described in Exhibit A attached hereto and known as 3805 Lakeshore Drive East, Dunkirk, New York;

WHEREAS, Assignor and Assignee are parties to that certain Purchase Agreement, dated as of January 7, 2022 (the **"Purchase Agreement"**), pursuant to which, among other things, Assignor has agreed to assign its interest in the Site Access Agreement and the FSMC Lease to Assignee, and Assignee has agreed to assume the FSMC Lease; and

WHEREAS, pursuant to the Purchase Agreement, Assignor and Assignee have agreed to execute and deliver this Assignment to evidence and effect such assignment and assumption of the Site Access Agreement and the FSMC Lease.

NOW THEREFORE, for and in consideration of the premises and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Assignment and Assumption. Effective as of the Effective Date, Assignor hereby assigns and transfers to Assignee and its successors and assigns all of its right, title and interest in and to the Site Access Agreement and the FSMC Lease. Assignee hereby agrees to and does accept the assignment, and in addition, expressly assumes and agrees to keep, perform, and fulfill all the terms, covenants, conditions and obligations required to be kept, performed, and fulfilled by Assignor as the tenant under the Site Access Agreement and the FSMC Lease, arising thereunder from and after the Effective Date.

2. Purchase Agreement. This Assignment is subject in all respects to the terms and conditions of the Purchase Agreement. To the extent of any conflict between the terms of the Purchase Agreement and this Assignment, the Purchase Agreement shall control. Nothing contained in this Assignment shall be deemed to supersede any of the covenants, agreements, representations or warranties of Assignor and Assignee contained in the Purchase Agreement.

3. General. This Assignment may not be changed or discharged orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification or discharge is sought. The covenants, agreements, terms, provisions and conditions contained in this Assignment shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns.

4. Governing Law. This Assignment and its interpretation and enforcement shall be governed by the laws of the State of New York.

5. Counterparts. This Assignment may be executed in counterparts, each of which shall be deemed an original, and all of which when taken together shall constitute one and the same instrument.

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties hereto have executed this Assignment as of the day and year first above written.

ASSIGNOR:

ATHENEX, INC.

By: /s/ Jeffrey Yordon

Name: Jeffrey Yordon

Title: Chief Operating Officer

ASSIGNEE:

IMMUNITYBIO, INC.

By: /s/ Richard Adcock

Name: Richard Adcock

Title: Chief Executive Officer and President

STATE OF NEW YORK)
) ss.:
COUNTY OF ERIE)

On the 13th day of February in the year 2022 before me, the undersigned, a Notary Public in and for said state, personally appeared Jeffrey Yordon, personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument.

/s/ Staci L. Holquist
Notary Public

CALIFORNIA ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles }

On Feb. 11, 2022 before me, J. Theodore Israel Benito, A Notary Public
Date *Here Insert Name and Title of the Officer*

personally appeared Richard Adcock
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that he/~~she/they~~ executed the same in his/~~her/their~~ authorized capacity(~~ies~~), and that by his/~~her/their~~ signature(~~s~~) on the instrument the person(~~s~~), or the entity upon behalf of which the person(~~s~~) acted, executed the instrument.

J. THEODORE ISRAEL BENITO
Notary Public - California
Los Angeles County
Commission # 2232505
My Comm. Expires Feb 26, 2022

Place Notary Seal and/or Stamp Above

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature J. Theodore Israel Benito
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Corporate Officer – Title(s): _____	☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General	☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer is Representing: _____	Signer is Representing: _____

EXHIBIT A

Land Description

ALL THAT TRACT OR PARCEL OF LAND, situate in the Town of Dunkirk, County of Chautauqua and State of New York, being part of Lot 6 in Township 6 and Range 12 of the Holland Land Company's survey, and more particularly described as follows: Beginning in the southeasterly line of East Lake Road (also known as Lake Shore Drive East or New York State Route 5) as now laid out and occupied (66 feet wide) at the point located 185.16 feet northeasterly along said southeasterly line of East Lake Road from the intersection thereof with the east line of City of Dunkirk; thence southeasterly at an interior angle of 94 degrees 04 minutes a distance of 511 feet along the easterly line of lands of True Temper Corporation (now or formerly) to a steel fence post at a deflection point therein, and passing through an existing iron pin located 17 feet southeasterly along the last described course from said southeasterly line of East Lake Road; thence northeasterly at an interior angle of 86 degrees 47 minutes a distance of 604.29 feet along said easterly line of lands of True Temper Corporation to an existing iron pin at a deflection point therein; thence southeasterly at an interior angle of 273 degrees 12 minutes a distance of 1083 feet along said easterly line of lands of true Temper Corporation to an existing iron pin in the northwesterly line of lands of the New York Central Railroad (now or formerly); thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 135 feet along said northwesterly line of railroad lands to an iron pin at a deflection point therein; thence southeasterly at an interior angle of 270 degrees 00 minutes a distance of 33 feet along said northwesterly line of railroad lands to an iron pin at a deflection point therein; thence northeasterly at an interior angle of 90 degrees 00 minutes a distance of 357.5 feet along said northwesterly line of railroad lands to an iron pin in the southwesterly line of lands of Heffernan (now or formerly); thence northwesterly at an interior angle of 90 degrees 39 minutes a distance of 1268.5 feet along said southwesterly line of Heffernan lands to an iron pin in the southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace by deed recorded in Liber 248 of Deeds at page 228 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 170 feet along said southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace to an existing iron pin at the southerly corner thereof; thence northwesterly at an interior angle of 271 degrees 34 minutes a distance of 220 feet along the southwesterly line of said lands conveyed from Vandette to Lawhon, Wallace and Wallace to an existing iron pin at the southerly corner of lands conveyed from Schweyen to Mekus by deed recorded in Liber 916 of Deeds at page 125 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 70 feet along the southeasterly line of lands conveyed from Schweyen to Kaleta by deed recorded in Liber 919 of Deeds at page 564 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly corner thereof; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 5 feet along the southwesterly line of said Kaleta lands to an existing iron pin in the southeasterly line of lands conveyed from Schweyen to Dubiel by deed recorded in Liber 931 of Deeds at page 104 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 89 degrees 12 minutes a distance of 140 feet along said southeasterly line of Dubiel lands and along the southeasterly line of lands conveyed from Schweyen to Bialaszewski by Deed recorded in Liber 1007 of Deeds at page 281 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly corner of said Bialaszewski lands; thence northwesterly at an interior angle of

270 degrees 48 minutes a distance of 145 feet along the southwesterly line of said Bialaszewski lands to an existing iron pin in said southeasterly line of East Lake Road; thence southwesterly at an interior angle of 89 degrees 46 minutes a distance of 209.99 feet along said southeasterly line of East Lake Road to an existing iron pin the northeasterly line of lands conveyed from Schweyen to Gates by deed recorded in Liber 1049 of Deeds at page 35 in the office of the Chautauqua County Clerk; thence southeasterly at an interior angle of 89 degrees 29 minutes a distance of 145 feet along said northeasterly line of Gates lands to an existing iron pin at the easterly corner thereof; thence southwesterly at an interior angle of 270 degrees 00 minutes a distance of 147.5 feet along the southeasterly line of said Gates lands and along the southeasterly line of lands conveyed from Schweyen to Bekelske by deed recorded in Liber 963 of Deeds at page 155 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly corner of said Bekelske lands; thence northwesterly at an interior angle of 271 degrees 11 minutes a distance of 145 feet along the southwesterly line of said Bekelske lands to an existing iron pin in said southeasterly line of East Lake Road; thence southwesterly along said southeasterly line of East Lake Road a distance of 290.01 feet to the point or place of beginning, and containing 21.6 acres of land more or less.

ALSO ALL THAT TRACT OR PARCEL OF LAND situate in the Town of Dunkirk, County of Chautauqua, State of New York, being part of Lot 6, Township 6, Range 12 of the Holland Land Company's Survey and being a portion of property conveyed to MULDOWNEY DEVELOPMENT INC. (MULDOWNEY) per L. 2682 of Deeds, P. 729, and being more particularly described as follows:

Commencing at a point in the centerline of Lake Shore Drive East (NYS Rte. 5) with the intersection with the Town and City line of Dunkirk. Thence, the following 2 courses;

1. Thence, North 55° 03' 03" East, in the centerline of Lake Shore Drive East, a distance of 163.30 feet;
2. Thence, South 30° 57' 57" East, a distance of 544.55 feet to the point of beginning.

1. Thence, North 55° 50' 03" East, a distance of 604.29 feet;
2. Thence, South 30° 57' 57" East, a distance of 1083 feet to an iron pipe found in the northerly line of property now or formerly of Consolidation Rail Corp. (CRC):
3. Thence, South 55° 50' 03" West, in the northerly line of said CRC property, a distance of 217.65 feet;
4. Thence, North 31° 21' 05" West, a distance of 85.12 feet;
5. Thence, South 55° 50' 03" West, a distance of 79.35 feet;
6. Thence, North 31° 21' 05" West, a distance of 214.88 feet;
7. Thence, South 55° 50' 03" West, a distance of 232.48 feet;
8. Thence, North 31° 21' 05" West, a distance of 436.70 feet;
9. Thence, North 88° 12' 52" West, a distance of 81.00 feet;
10. Thence, North 31° 16' 32" West, a distance of 298.32 feet to the point of beginning.

Containing 521,860 square feet, (11.980+- acres).

Intending to describe "Lot 2" as shown on a plat titled "Subdivision Plan of property owned by N/F by MULDOWNEY DEVELOPMENT INC." prepared by CHA Inc. project No. 30443.

The above premises are more recently described as shown on a survey map made by Frandina Engineering and Land Surveying, Inc. dated September 23, 2021, as follows:

ALL THAT TRACT OR PARCEL OF LAND, situate in the Town of Dunkirk, County of Chautauqua and State of New York, being part of Lot 6 in Township 6 and Range 12 of the Holland Land Company's survey, and more particularly described as follows: Beginning in the southeasterly line of East Lake Road (also known as Lake Shore Drive East or New York State Route 5) as now laid out and occupied (66 feet wide) at the point located 185.16 feet northeasterly along said southeasterly line of East Lake Road from the intersection thereof with the east line of City of Dunkirk; thence southeasterly at an interior angle of 93 degrees 55 minutes 32 seconds a distance of 511.52 feet along the easterly line of lands of True Temper Corporation (now or formerly) to a deflection point therein; thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 604.29 feet along said easterly line of lands of True Temper Corporation to a deflection point therein; thence southeasterly at an interior angle of 273 degrees 12 minutes a distance of 1083.00 feet along said easterly line of lands of true Temper Corporation to the northwesterly line of lands of the New York Central Railroad (now or formerly); thence northeasterly at an interior angle of 86 degrees 48 minutes a distance of 135.00 feet along said northwesterly line of railroad lands to a deflection point therein; thence southeasterly at an interior angle of 270 degrees 00 minutes a distance of 33.00 feet along said northwesterly line of railroad lands to a deflection point therein; thence northeasterly at an interior angle of 90 degrees 00 minutes a distance of 356.75 feet along said northwesterly line of railroad lands to the southwesterly line of lands of Heffernan (now or formerly); thence northwesterly at an interior angle of 90 degrees 39 minutes 03 seconds a distance of 1268.32 feet along said southwesterly line of Heffernan lands to the southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace by deed recorded in Liber 248 of Deeds at page 228 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 24 minutes 51 seconds a distance of 170.00 feet along said southeasterly line of lands conveyed from Vandette to Lawhon, Wallace and Wallace to the southerly corner thereof; thence northwesterly at an interior angle of 271 degrees 34 minutes a distance of 220.00 feet along the southwesterly line of said lands conveyed from Vandette to Lawhon, Wallace and Wallace to the southerly corner of lands conveyed from Schweyen to Mekus by deed recorded in Liber 916 of Deeds at page 125 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 88 degrees 26 minutes a distance of 70.00 feet along the southeasterly line of lands conveyed from Schweyen to Kaleta by deed recorded in Liber 919 of Deeds at page 564 in the office of the Chautauqua County Clerk to the southerly corner thereof; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 5.00 feet along the southwesterly line of said Kaleta lands to the southeasterly line of lands conveyed from Schweyen to Dubiel by deed recorded in Liber 931 of Deeds at page 104 in the office of the Chautauqua County Clerk; thence southwesterly at an interior angle of 89 degrees 12 minutes a distance of 140.00 feet along said southeasterly line of Dubiel lands and along the southeasterly line of lands conveyed from Schweyen to Bialaszewski by Deed recorded in Liber 1007 of Deeds at page 281 in the office of the Chautauqua County Clerk to the southerly corner of said Bialaszewski lands; thence northwesterly at an interior angle of 270 degrees 48 minutes a distance of 145.00 feet along the

southwesterly line of said Bialaszewski lands to said southeasterly line of East Lake Road; thence southwesterly at an interior angle of 89 degrees 50 minutes 44 seconds a distance of 209.72 feet along said southeasterly line of East Lake Road to the northeasterly line of lands conveyed from Schweyen to Gates by deed recorded in Liber 1049 of Deeds at page 35 in the office of the Chautauqua County Clerk; thence southeasterly at an interior angle of 89 degrees 24 minutes 05 minutes a distance of 145 .00 feet along said northeasterly line of Gates lands to the easterly corner thereof; thence southwesterly at an interior angle of 270 degrees 00 minutes a distance of 147.50 feet along the southeasterly line of said Gates lands and along the southeasterly line of lands conveyed from Schweyen to Bekelske by deed recorded in Liber 963 of Deeds at page 155 in the office of the Chautauqua County Clerk to an existing iron pin at the southerly corner of said Bekelske lands; thence northwesterly at an interior angle of 271 degrees 11 minutes a distance of 145.00 feet along the southwesterly line of said Bekelske lands to said southeasterly line of East Lake Road; thence southwesterly along said southeasterly line of East Lake Road a distance of 289.37 feet to the point or place of beginning, and containing 21.553 acres of land more or less.

ALSO ALL THAT TRACT OR PARCEL OF LAND situate in the Town of Dunkirk, County of Chautauqua, State of New York, being part of Lot 6, Township 6, Range 12 of the Holland Land Company's Survey and being a portion of property conveyed to MULDOWNEY DEVELOPMENT INC. (MULDOWNEY) per L. 2682 of Deeds, P. 729, and being more particularly described as follows:

Commencing at a point in the centerline of Lake Shore Drive East (NYS Rte. 5) with the intersection with the Town and City line of Dunkirk. Thence, the following 2 courses;
Thence, North 55° 03' 03" East, in the centerline of Lake Shore Drive East, a distance of 163.30 feet;
Thence, South 30° 57' 57" East, a distance of 544.60 feet to the point of beginning.
Thence, North 55° 50' 03" East, a distance of 604.29 feet;
Thence, South 30° 57' 57" East, a distance of 1083 feet to an iron pipe found in the northerly line of property now or formerly of Consolidation Rail Corp. (CRC):
Thence, South 55° 50' 03" West, in the northerly line of said CRC property, a distance of 217.65 feet;
Thence, North 31° 21' 05" West, a distance of 85.12 feet;
Thence, South 55° 50' 03" West, a distance of 79.35 feet;
Thence, North 31° 21' 05" West, a distance of 214.88 feet;
Thence, South 55° 50' 03" West, a distance of 232.48 feet;
Thence, North 31° 21' 05" West, a distance of 436.70 feet;
Thence, North 88° 12' 52" West, a distance of 81.00 feet;
Thence, North 31° 16' 32" West, a distance of 298.32 feet to the point of beginning.

Containing 521,860 square feet, (11.980+- acres).

Intending to describe "Lot 2" as shown on a plat titled "Subdivision Plan of property owned by N/F by MULDOWNEY DEVELOPMENT INC." prepared by CHA Inc. project No. 30443.

Exhibit 31.1

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

I, Richard Adcock, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

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

Exhibit 31.2

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

I, David C. Sachs, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial 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 March 31, 2022 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2022

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

Exhibit 32.2

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

I, David C. Sachs, the chief financial officer of ImmunityBio, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

i. the Quarterly Report of the Company on Form 10-Q for the quarter ended March 31, 2022 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2022

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