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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 5, 2021

ImmunityBio, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37507**	**43-1979754**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3530 John Hopkins Court **San Diego, California** **(Address of principal executive offices)**	**92121** **(Zip Code)**

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

NantKwest, Inc.
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, $0.0001 par value per share	**IBRX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Explanatory Note

On December 21, 2020, ImmunityBio, Inc. (formerly known as NantKwest, Inc.) (the "Company"), NantCell, Inc. (formerly known as ImmunityBio, Inc.) ("ImmunityBio"), and Nectarine Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), providing for, under the terms and subject to the conditions contained therein, the merger of Merger Sub with and into ImmunityBio (the "Merger"), with ImmunityBio surviving the Merger as a wholly owned subsidiary of the Company. The Merger Agreement was approved by the Board of Directors of the Company (the "Board") based upon the unanimous recommendation of a special committee of independent and disinterested directors of the Company. On March 9, 2021, following the satisfaction of the closing conditions set forth in the Merger Agreement, the Merger was completed.

Item 2.01 Completion of Acquisition or Disposition of Assets.

On March 9, 2021, the Company 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 common stock, par value $0.001 per share, of ImmunityBio (each an "ImmunityBio Share"), that was issued and outstanding immediately prior to the Effective Time (subject to certain exceptions as set forth in the Merger Agreement) was converted into the 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. In addition, upon completion of the Merger, (i) each outstanding option to purchase ImmunityBio Shares (each, an "ImmunityBio Option") was converted into an option, on the same terms and conditions applicable to such ImmunityBio Option immediately prior to the Effective Time, to purchase a specified number of shares of Company Common Stock with an adjusted exercise price, each calculated pursuant to the terms of the Merger Agreement, (ii) each outstanding restricted stock unit award of ImmunityBio (each, an "ImmunityBio RSU Award") was converted into an award of Company restricted stock units covering a number of shares of Company Common Stock (rounded to the nearest whole share) equal to the product of (x) the number of ImmunityBio Shares subject to such ImmunityBio RSU Award immediately prior to the Effective Time multiplied by (y) the Exchange Ratio, and (iii) each outstanding warrant to purchase ImmunityBio Shares was converted into a warrant, on the same terms and conditions applicable to such warrant, to purchase a specified number of shares of Company Common Stock at an adjusted exercise price, each calculated pursuant to the terms of the Merger Agreement.

In connection with the Merger, the Company changed its name from "NantKwest, Inc." to "ImmunityBio, Inc." (the "Name Change"). The shares of Company Common Stock, previously trading on the Nasdaq Global Select Market through the close of business on March 9, 2021 under the ticker symbol "NK," will commence trading on the Nasdaq Global Select Market under the ticker symbol "IBRX" on March 10, 2021, as of which time the Company Common Stock will be represented by a new CUSIP number, 45256X103.

The issuance of the shares of Company Common Stock to the former stockholders of ImmunityBio was registered with the Securities and Exchange Commission (the "SEC") on a Registration Statement on Form S-4 (Reg. No. 333-252232) (the "Form S-4"). Immediately following the Effective Time, the former stockholders of ImmunityBio held approximately 72% of the outstanding shares of Company Common Stock and the stockholders of the Company as of immediately prior to the Merger held approximately 28% of the outstanding shares of Company Common Stock, each on a fully diluted basis as described in the Form S-4. The issuance of the shares of Company Common Stock to certain holders of ImmunityBio Options and ImmunityBio RSU Awards will be registered with the SEC on a Registration Statement on Form S-8.

Dr. Patrick Soon-Shiong serves as the Executive Chairman of the Company and, together with certain of his affiliates, beneficially owned in excess of a majority of the outstanding shares of Company Common Stock as of immediately prior to the Effective Time. Dr. Soon-Shiong also served as Chairman and Chief Executive Officer of ImmunityBio and, together with certain of his affiliates, beneficially owned in excess of a majority of the outstanding ImmunityBio Shares immediately prior to the Effective Time. As a result of the Merger and immediately following the Effective Time, Dr. Soon-Shiong and his affiliates beneficially own, in the aggregate, approximately 82% of the outstanding shares of Company Common Stock. Prior to the Merger, the Company also has been involved in certain strategic collaborations, licensing or other commercialization arrangements and agreements with ImmunityBio and its subsidiaries as described in the Form S-4.

The foregoing description of the Merger Agreement and the transactions contemplated thereby, including the Merger, does not purport to be complete, and is qualified in its entirety by reference to the full text of the Merger Agreement, which is included as Exhibit 2.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

As of the Effective Time, ImmunityBio had outstanding promissory notes with certain entities affiliated with Dr. Soon-Shiong in an aggregate principal amount of approximately $276.6 million, excluding accrued interest. The notes bear interest at a per annum rate ranging from 3.0% to 6.0%, compounded annually and computed on the basis of 365 or 366 days. The notes provide that all outstanding principal is due and payable on September 30, 2025, and accrued and unpaid interest is payable either on the maturity date or, with respect to one of the notes, on a quarterly basis. ImmunityBio may prepay the outstanding amount of any advance, together with accrued and unpaid interest at any time, either in whole or in part, without premium or penalty. An "Event of Default" would occur under such notes: (a) upon the initiation by ImmunityBio of any voluntary case under any bankruptcy, insolvency or other similar law; (b) if an involuntary case under any bankruptcy, insolvency or other similar law is commenced against ImmunityBio with respect to it or its debt and such involuntary case remains undismissed or unstayed for a period of 90 days; or (c) upon a general assignment of assets by ImmunityBio for the benefit of creditors. Upon the occurrence of any Event of Default, all amounts outstanding thereunder in respect of the principal amount of any advance under such notes and all unpaid interest having accrued thereon, will be accelerated and become immediately due and payable. The foregoing description of the promissory notes does not purport to be complete, and is qualified in its entirety by reference to the full text of such promissory notes, which are included as Exhibits 10.9, 10.10, 10.11, 10.12, 10.13 and 10.14 to this Current Report on Form 8-K and incorporated herein by reference.

In connection with a previous acquisition, ImmunityBio issued contingent value rights, or CVRs, under which ImmunityBio agreed to pay the prior stockholders of the acquired company approximately $304.0 million upon successful approval of a Biologics License Application or foreign equivalent for Anktiva by December 31, 2022 and approximately $304.0 million upon the first calendar year prior to December 31, 2026 in which worldwide net sales of Anktiva exceed $1.0 billion (with the payments payable in cash or shares of common stock or a combination of both). Dr. Soon-Shiong and certain of his affiliates hold approximately $279.5 million in the aggregate of CVRs and they have irrevocably agreed to receive shares of common stock in satisfaction of their CVRs. If all other holders of such CVRs were to choose to receive any payments for such CVRs in cash, the aggregate payments would be $164.2 million for the CVRs tied to the achievement of the regulatory milestone and $164.2 million for the CVRs tied to the achievement of the sales milestone. The foregoing description of the CVRs does not purport to be complete, and is qualified in its entirety by reference to the full text of the related FDA Milestone Contingent Value Rights Agreement and Sales Milestone Contingent Value Rights Agreement, which are included as Exhibits 10.15 and 10.16, respectively, to this Current Report on Form 8-K and incorporated herein by reference.

ImmunityBio leases office space, laboratory and warehouses under various operating leases, which expire at various dates through September 2026. Among these leases, ImmunityBio is a party to three lease agreements with Duley Road, LLC, a related party that is controlled by Dr. Soon-Shiong, related to an office and cGMP manufacturing facility and a second building located in El Segundo, California. As of December 31, 2020, total future lease payments required under these leases was approximately $11.3 million.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers.

Appointment of Directors

On March 5, 2021, pursuant to the Merger Agreement and effective as of immediately following the Effective Time, the Board increased its size from six (6) to nine (9) directors, and the following directors of ImmunityBio were appointed to the Board to fill the vacancies created thereby, each to hold such office until the 2021 annual meeting of stockholders and until his or her successor is duly elected or appointed:

John Brennan — Mr. Brennan served for 25 years in a variety of roles at the CIA, rising from analyst to station chief, and finally being appointed as the agency's Director by President Barack Obama. He also served as Deputy National Security Advisor for Homeland Security and Counterterrorism. Brennan earned a Bachelor of Arts degree from Fordham University, and is a Distinguished Fellow at the Fordham University Law School. He earned a Master of Arts from the University of Texas at Austin, where he currently serves as a Distinguished Non-Resident Scholar and a senior advisor to the University's Intelligence Studies Projects.

Wesley Clark — General Clark served for 34 years in the U.S. Army, rising through the ranks to earn his fourth star as a full general in 1996. He served as the Supreme Allied Commander Europe of NATO where he commanded Operation Allied Force in the Kosovo War. Highly decorated throughout his career, General Clark was awarded the U.S. Presidential Medal of Freedom by President Bill Clinton. He is a graduate of the U.S. Military Academy at West Point, where he was class valedictorian. After graduating from West Point, General Clark was awarded a Rhodes Scholarship to the University of Oxford where he earned degrees in Philosophy, Politics and Economics. He earned a master's degree in military science from the Command and General Staff College. General Clark runs Wesley K. Clark and Associates consulting firm and is Chairman and CEO of Enverra, a boutique investment bank.

Christobel Selecky — Ms. Selecky is a chief executive, entrepreneur and board member with more than 30 years of healthcare industry experience. Ms. Selecky held several leadership positions over her 14-year career at FHP International Corporation, including as President of the FHP California Health Plan. She subsequently co-founded, and served as President, CEO, and Executive Chairman of LifeMasters Supported SelfCare, a national leader in the field of disease and population health management. Ms. Selecky serves on corporate and not-for-profit boards of directors and, as a consultant helping improve patient engagement, population health outcomes, and healthcare cost management. She currently serves on the Boards of Directors of Paris-based Teleperformance, Satellite Healthcare, and Griswold Home Care. She is active in several board governance organizations such as NACD and Women Corporate Directors and is also a lecturer in Healthcare Entrepreneurship in the MBA program at the University of California, Irvine.

The Company has not yet determined the Board committees on which Mr. Brennan, General Clark and Ms. Selecky may sit. The newly appointed directors have no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor are any such transactions currently proposed. Other than the Merger Agreement, there were no arrangements or understandings between the Company's newly appointed directors and any person pursuant to which they were appointed.

In connection with their appointment to the Board, each of Mr. Brennan, General Clark and Ms. Selecky will receive an equity grant to be determined by the Compensation Committee of the Board, and for their respective service on the Board and any committees of the Board, such director will receive the same compensation payable by the Company to its other non-employee directors for their service on the Board and committees as described in the Company's amended Outside Director Compensation Policy, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference. Each of the newly appointed directors also will enter into the Company's standard indemnification agreement, which has been previously entered into with each of the Company's directors and the form of which has been filed by the Company as Exhibit 10.2 hereto and is incorporated herein by reference.

Appointment of Principal Officers

On March 5, 2021 and effective as of immediately following the Effective Time, the Board appointed David Sachs as Chief Financial Officer of the Company. In such capacity, Mr. Sachs will serve as the principal financial officer and the principal accounting officer of the Company. Mr. Sachs succeeded Sonja Nelson, who has been appointed as Senior Vice President, Finance of the Company and no longer serves as the Company's principal financial officer and principal accounting officer.

Mr. Sachs, age 43, has served as chief financial officer of ImmunityBio since July 2019. Mr. Sachs also served as chief financial officer of Integrity Healthcare, LLC, a NantWorks subsidiary and the former management company for Verity Health, from February 2018 to August 2020. From April 2011 to June 2019, Mr. Sachs held various executive positions at NantWorks and its subsidiaries, including serving as chief financial officer of NantHealth, Inc. from 2013 to 2015. Mr. Sachs also served as Verity Health's executive vice president, strategy and development from July 2017 to February 2018 and as Verity Health's interim and then permanent chief financial officer from August 2017 to August 2018. Prior to NantWorks, Mr. Sachs served in business development roles at Celgene and Abraxis and as an investment banker with Bank of America Merrill Lynch. Mr. Sachs has served on the board of directors of ZioSoft, KK since 2013 and PacketFabric, Inc. since 2016. He received his B.A. in Economics from the University of California at Los Angeles and his M.B.A. in Finance and Strategy from the UCLA Anderson School of Management.

Pursuant to Mr. Sachs' offer letter with ImmunityBio, Mr. Sachs is entitled to receive an annual base salary of $387,000 and is eligible to receive an annual discretionary bonus of up to 50% of his base salary, upon the achievement of certain performance targets to be determined by the Board in its sole discretion. Mr. Sachs also is eligible for a severance payment if his employment is terminated without "cause" or if he resigns for good reason (each as defined in his offer letter). Such severance payment will be equal to: (i) 10 months of his base salary plus (ii) a prorated bonus paid out at 100% of his annual bonus. The foregoing description of Mr. Sachs' offer letter does not purport to be complete, and is qualified in its entirety by reference to the full text of such offer letter, which is included as Exhibit 10.3 to this Current Report on Form 8-K and incorporated herein by reference. As part of his compensatory arrangement with ImmunityBio, Mr. Sachs also held an ImmunityBio RSU Award immediately prior to the Effective Time that was assumed in the Merger and converted into an award of Company restricted stock units with respect to 169,231 shares of Company Common Stock. Mr. Sachs also will enter into the Company's standard indemnification agreement, which has been previously entered into with each of the Company's executive officers and the form of which has been filed by the Company as Exhibit 10.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Also, on March 5, 2021 and effective as of immediately following the Effective Time, the Board appointed Richard Adcock, the Company's Chief Executive Officer, to the additional office of President of the Company. Mr. Adcock succeeded Barry Simon, M.D., who has been appointed as Chief Corporate Affairs Officer of the Company and no longer serves as the Company's President. Mr. Adcock, age 52, has served as Chief Executive Officer of the Company since October 2020. Further information regarding Mr. Adcock is included in Item 5.02 of the Company's Current Report on Form 8-K filed with the SEC on October 26, 2020, which is incorporated herein by reference.

The newly appointed principal officers have no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K promulgated under the Exchange Act, nor are any such transactions currently proposed. There are no family relationships among any of the Company's newly appointed principal officers with the directors and executive officers of the Company. Other than the Merger Agreement, there were no arrangements or understandings between the Company's newly appointed principal officers and any person pursuant to which they were appointed.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On March 9, 2021, following completion of the Merger, the Company filed an amendment to the Company's Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the Name Change (the "Name Change Amendment"). A copy of the Name Change Amendment is attached as Exhibit 3.1 to this Current Report on Form 8-K.

Item 5.07 Submission of Matters to a Vote of Security Holders.

On March 8, 2021, the Company held a special meeting of stockholders (the "Special Meeting"). As of the close of business on January 29, 2021, the record date for the Special Meeting, there were 108,997,270 shares of Company Common Stock issued and outstanding and entitled to vote at the Special Meeting. A quorum of 94,118,154 shares of Company Common Stock was present or represented by proxy at the Special Meeting (representing approximately 86.35% of the shares entitled to vote at the Special Meeting). The number of votes cast for or against, as well as abstentions, with respect to each proposal is set forth below (there were no broker non-votes at the Special Meeting):

Proposal 1 — Stock Issuance Proposal. The proposal to approve the issuance of Company Common Stock in the Merger to the security holders of ImmunityBio, as contemplated by the Merger Agreement, was approved by the holders of Company Common Stock as follows:

Votes For	Votes Against	Abstentions
93,835,900	138,118	144,136

Proposal 2 — Merger Proposal. The proposal to approve the Merger, as contemplated by the Merger Agreement, was approved by the holders of a majority of the outstanding shares of Company Common Stock not held by Dr. Soon-Shiong, Cambridge Equities, LP or Chan Soon-Shiong Family Foundation or any of their controlled affiliates or any of the directors or executive officers of the Company or ImmunityBio (which consisted of a total of 35,152,997 outstanding shares of Company Common Stock entitled to vote) as follows:

Votes For	Votes Against	Abstentions
20,665,277	106,064	103,655

Proposal 3 — Adjournment Proposal. Stockholder action on the proposal to approve the adjournment of the Special Meeting to a later date or dates, if necessary, to permit further solicitation and vote of proxies in the event that there were insufficient votes for, or otherwise in connection with, the approval of the Stock Issuance Proposal or the Merger Proposal was not required and no vote was taken on that proposal.

Item 7.01 Regulation FD Disclosure.

On March 9, 2021, the Company issued a press release announcing the completion of the Merger. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01, including Exhibit 99.1 furnished herewith, is “furnished” and not “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section. Such information shall not be incorporated by reference in another filing by the Company under the Exchange Act or the Securities Act of 1933, as amended, except to the extent such other filing specifically incorporates such information by reference.

Item 8.01 Other Events.

In connection with the completion of the Merger, the Company has updated its disclosures regarding its business and risk factors. The revised disclosure is filed herewith as Exhibits 99.2 and 99.3, and such disclosure is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(a) *Financial Statements of ImmunityBio, Inc.*

The Company will file the financial statements required to be filed by this Item 9.01(a) not later than seventy-one (71) calendar days after the date on which this Current Report on Form 8-K is required to be filed.

(b) *Pro Forma Financial Information.*

The Company will file the financial statements required to be filed by this Item 9.01(b) not later than seventy-one (71) calendar days after the date on which this Current Report on Form 8-K is required to be filed.

(d) *Exhibits*. Below is a list of exhibits included with this Current Report on Form 8-K:

Exhibit No.	Description
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 herein by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K filed with the SEC on December 22, 2020)

3.1	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. (f/k/a NantKwest, Inc.) dated March 9, 2021
10.1	ImmunityBio, Inc. (f/k/a NantKwest, Inc.) Amended Outside Director Compensation Policy
10.2	Form of Indemnification Agreement between ImmunityBio, Inc. (f/k/a NantKwest, Inc.) and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (Reg. No. 333-205124) filed with the SEC on June 19, 2015)
10.3#^	Offer Letter, dated August 3, 2020, between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and David Sachs (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.4#	NantCell, Inc. (f/k/a ImmunityBio, Inc.) 2015 Stock Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.5+	Common Stock Purchase Warrant, dated June 30, 2016, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to NantWorks, LLC (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.6†	Agreement and Plan of Merger, dated March 31, 2017, by and among NantCell, Inc. (f/k/a ImmunityBio, Inc.), Bio Merger Sub Inc., Liquid Genomics, Inc. and the Stockholder Representative thereunder (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.7†	Agreement and Plan of Merger, dated May 19, 2017, by and among NantCell, Inc. (f/k/a ImmunityBio, Inc.), Altor Acquisition LLC, Altor BioScience Corporation and Shareholder Representative Services LLC (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.8†	Agreement and Plan of Merger, dated May 15, 2018, by and among NantCell, Inc. (f/k/a ImmunityBio, Inc.), Receptome Acquisition Corporation, Receptome, Inc., and the Selling Stockholder thereunder (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.9	Amended and Restated Promissory Note, dated July 28, 2020, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to Nant Capital, LLC (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.10	Amended and Restated Promissory Note, dated July 28, 2020, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to NantWorks, LLC (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.11	Amended and Restated Promissory Note, dated July 28, 2020, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to NantCancerStemCell, LLC (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.12	Amended and Restated Promissory Note, dated July 28, 2020, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to NantMobile, LLC (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)

10.13	Promissory Note, dated September 30, 2020, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to Nant Capital, LLC (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.14	Promissory Note, dated February 22, 2021, issued by NantCell, Inc. (f/k/a ImmunityBio, Inc.) to Nant Capital, LLC
10.15	FDA Milestone Contingent Value Rights Agreement, dated July 31, 2017, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and the Stockholder Representative thereunder (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.16	Sales Milestone Contingent Value Rights Agreement, dated July 31, 2017, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and the Stockholder Representative thereunder (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.17	Exclusive License Agreement, dated April 21, 2015, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and Sorrento Therapeutics, Inc. (incorporated by referenced to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed by Sorrento Therapeutics, Inc. with the SEC on August 7, 2015)
10.18	Exclusive License Agreement, dated July 27, 2017, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and CytRx Corporation (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by CytRx Corporation with the SEC on August 1, 2017)
10.19+	Exclusive License Agreement, dated February 16, 2016, by and between NantBioScience, Inc. and Etubics Corporation (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.20+	Exclusive License Agreement, dated January 1, 2020, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and GlobeImmune, Inc. (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.21	Exclusive License Agreement, dated August 7, 2020, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and iosBio Ltd. (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.22	Assignment Agreement, dated July 31, 2017, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantOmics, LLC (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.23	Shared Services Agreement, dated May 13, 2015, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantWorks, LLC (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.24	Amendment #1 to Shared Services Agreement, dated January 1, 2016, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantWorks, LLC (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)

10.25+	Supply Agreement, dated August 15, 2018, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantBio, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.26	Shared Services Agreement, dated April 4, 2019, by and between NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantBio, Inc. (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.27	Assignment Agreement, dated July 2, 2017, by and between NantPharma, LLC and Immunotherapy NANTibody, LLC (incorporated by reference to Exhibit 10.25 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.28	Letter Agreement, dated February 14, 2018, by and between NantPharma, LLC and Immunotherapy NANTibody, LLC (incorporated by reference to Exhibit 10.26 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.29+	Commercial Lease, dated February 1, 2017, by and between Duley Road, LLC and Altor BioScience Manufacturing Company, LLC (incorporated by reference to Exhibit 10.27 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.30+	Commercial Lease, dated January 28, 2019, by and between Duley Road, LLC and NantCell, Inc. (f/k/a ImmunityBio, Inc.) (incorporated by reference to Exhibit 10.28 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.31+	Commercial Lease, dated January 28, 2019, by and between Duley Road, LLC and NantCell, Inc. (f/k/a ImmunityBio, Inc.) (incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
10.32†	Common Stock Purchase Agreement, dated April 30, 2018, by and among NantCell, Inc. (f/k/a ImmunityBio, Inc.) and NantBio, Inc. (incorporated by reference to Exhibit 10.30 to the Company's Registration Statement on Form S-4 (Reg. No. 333-252232) filed with the SEC on January 19, 2021)
99.1	Press Release issued by ImmunityBio, Inc. (f/k/a NantKwest, Inc.) on March 9, 2021 (furnished and not filed)
99.2	Business Section of ImmunityBio, Inc. (f/k/a NantKwest, Inc.)
99.3	Risk Factors Section of ImmunityBio, Inc. (f/k/a NantKwest, Inc.)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† 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 exhibits 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 exhibit upon request.

# Indicates a management contract or compensatory plan.

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

SIGNATURES

Pursuant to the requirements of the Securities 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.

By: /s/ Richard Adcock
Name: Richard Adcock
Title: Chief Executive Officer and President

Date: March 9, 2021

Exhibit 3.1

CERTIFICATE OF AMENDMENT

OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF NANTKWEST, INC.

NantKwest, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is NantKwest, Inc. The Corporation's original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on March 12, 2014 under the name Conkwest, Inc., and the Corporation's Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on July 31, 2015 (the "Amended and Restated Certificate of Incorporation").

2. The Board of Directors of the Corporation duly adopted resolutions declaring advisable the amendment of the Amended and Restated Certificate of Incorporation set forth in paragraph 4 of this Certificate of Amendment.

3. The amendment to the Amended and Restated Certificate of Incorporation set forth in paragraph 4 of this Certificate of Amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

4. Article I of the Amended and Restated Certificate of Incorporation is hereby deleted in its entirety and replaced by the following Article I in lieu thereof:

"The name of the corporation is ImmunityBio, Inc. (the "Corporation")."

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this 9th day of March, 2021.

By: /s/ Richard Adcock
Name: Richard Adcock
Title: Chief Executive Officer

[Signature Page to Name Change Amendment]

Exhibit 10.1

IMMUNITYBIO, INC.

OUTSIDE DIRECTOR COMPENSATION POLICY

(As reviewed and approved March 9, 2021 immediately prior to the closing of the merger with private ImmunityBio, Inc.)

ImmunityBio, Inc. (the "**Company**") believes that providing cash and equity compensation to its members of the Board of Directors (the "**Board**," and members of the Board, the "**Directors**") represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the "**Outside Directors**"). This Outside Director Compensation Policy (the "**Policy**") is intended to formalize the Company's policy regarding cash compensation and grants of equity awards to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such term in the Company's 2015 Equity Incentive Plan (the "**Plan**"). Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity and cash payments such Outside Director receives under this Policy.

This Policy is effective, as revised, as of March 9, 2021 (the "**Effective Date**").

1. CASH COMPENSATION

Annual Cash Retainer

Each Outside Director will be paid an annual cash retainer of $50,000. There are no per-meeting attendance fees for attending Board meetings. This cash compensation will be paid quarterly in arrears on a prorated basis.

Committee Membership and Committee Chairperson Annual Cash Retainer

As of the Effective Date, each Outside Director who serves as the chair or a member of a committee of the Board will be eligible to earn additional annual fees (paid quarterly in arrears on a prorated basis) as follows:

Chairperson of Audit Committee:	$10,000
Lead Independent Director	$20,000
Chairperson of the Compensation Committee	$ 7,500
Chairperson of the Nominating and Corporate Governance Committee	$ 7,500
Chairperson of the Related Party Transaction Committee	$ 7,500
Chairperson of the Special Committee	$15,000

Member of Audit Committee:	$10,000
Member of Compensation Committee	$ 7,500
Member of the Nominating and Corporate Governance Committee	$ 7,500
Member of the Related Party Transaction Committee	$ 7,500
Member of the Special Committee	$15,000

For clarity, each Outside Director who serves as the chair of a committee will receive both the additional annual fee as the chair of the committee and the additional annual fee as a member of the committee.

2. EQUITY COMPENSATION

Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 2 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

(b) [OMITTED]

(c) [OMITTED]

3. CHANGE IN CONTROL

In the event of a Change in Control, each Outside Director will fully vest in his or her outstanding Company equity awards, provided that the Outside Director continues to be an Outside Director through such date.

4. ANNUAL COMPENSATION LIMIT

No Outside Director may be paid, issued or granted, in any Fiscal Year, cash compensation and Awards with an aggregate value greater than $750,000 (with the value of each Award based on the value on the grant date for purposes of the limitation under this Section 4). Any cash compensation paid or Awards granted to an individual for his or her services as an Employee, or

for his or her services as a Consultant (other than as an Outside Director), will not count for purposes of the limitation under this Section 4.

5. TRAVEL EXPENSES/CONTINUING EDUCATION

Each Outside Director's reasonable, customary and documented travel expenses to Board meetings will be reimbursed by the Company. In addition, each Outside Director shall be eligible to be reimbursed by the Company, including travel expenses, for up to two (2) days of in-person or on-line continuing education classes/seminars regarding corporate governance, directors' fiduciary duties or similar items of interest related to the Outside Director's duties.

6. ADDITIONAL PROVISIONS

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

7. ADJUSTMENTS

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

8. SECTION 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) the 15th day of the 3rd month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) the 15th day of the 3rd month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

9. REVISIONS

The Compensation Committee in its discretion may change and otherwise revise the terms of Awards granted under this Policy, including, without limitation, the number of Shares subject

thereto, for Awards of the same or different type granted on or after the date the Compensation Committee determines to make any such change or revision.

PROMISSORY NOTE

February 22, 2021
Culver City, California

1. Principal and Interest. For value received, ImmunityBio, Inc. (formerly named NantCell, Inc.), a Delaware corporation, with offices at 9920 Jefferson Boulevard, Culver City, California 90232 (the "Company"), promises to pay to the order of Nant Capital, LLC, with offices at 9922 Jefferson Boulevard, Culver City, California 90232 ("Holder"), or to the order of Holder's registered assigns, the principal amount of each advance (each, an "Advance" and, collectively, the "Advances") made by Holder to the Company pursuant to this Promissory Note (this "Note"), in immediately available funds, at the times and in the manner set forth herein.

(a) Advances. The principal amount of each Advance made by Holder to the Company hereunder, the date on which each such Advance is made, the amount of any prepayment or partial prepayment of any such Advance, and the outstanding principal amount of each such Advance, shall be specified in Schedule A attached hereto. The Company shall be entitled to update Schedule A hereto from time to time to reflect updated information relating to the Advances made by Holder to the Company hereunder and any prepayments or partial prepayments of the outstanding principal amounts of any such Advances. The information reflected in any such updated version of Schedule A delivered by the Company to Holder shall, in the absence of manifest error, constitute *prima facie* evidence of the accuracy of the information recorded, provided, however, that the failure of the Company to update the information specified in Schedule A in connection with the making by Holder to the Company of any Advance or the payment or partial prepayment by the Company of any such Advance shall not affect the obligations of the Company hereunder to repay the principal amount of any such Advance (and any interest unpaid having accrued thereon) in accordance with the terms of this Note.

(b) Interest and Payments. The outstanding principal amount of each Advance made by Holder to the Company pursuant to this Note shall bear interest from and including the date such Advance is made to but excluding the date such Advance is paid in full at a per annum rate equal to six percent (6%), compounded annually and computed on the basis of the actual number of days elapsed and a year of 365 or 366 days, as the case may be. Payments of accrued but unpaid interest shall be due and payable quarterly commencing on June 30, 2021 (*i.e.*, June 30, 2021, September 30, 2021, December 31, 2021, March 31, 2022, etc.). All amounts of principal of and, to the extent permitted by law, interest due and payable with respect to any Advance not paid within 5 business days of when due or upon the acceleration thereof pursuant to Section 2 hereof, shall bear interest ("Default Interest") from the date due until the date paid in full at an overdue rate per annum equal to eight percent (8%). Such Default Interest shall be payable on demand and such increased rate of interest shall continue until such delinquent amount(s), with interest thereon at such increased rate, shall have been paid in full. Acceptance of any delinquent payments by Holder shall not waive or affect any prior default.

(c) Maturity Date. The unpaid principal of each Advance, and any accrued and unpaid interest thereon, shall be due and payable on September 30, 2025. The Company may prepay the outstanding amount of any Advance (together with accrued and unpaid interest thereon) at any time, either in whole or in part, without premium or penalty and without the prior consent of Holder.

2. Events of Default. An "Event of Default" occurs (a) upon the initiation by the Company of any voluntary case under any bankruptcy, insolvency or other similar law; (b) if an involuntary case under any bankruptcy, insolvency or other similar law is commenced against the Company with respect to it or its debt and such involuntary case remains undismissed or unstayed for a period of 90 days; or (c) upon a general assignment of assets by the Company for the benefit of creditors. Upon the occurrence of any Event of Default, all amounts outstanding hereunder in respect of the principal amount of any Advance and all unpaid interest having accrued thereon, shall be accelerated and become immediately due and payable without notice to or demand on the Company.

3. Miscellaneous.

(a) Notice. Any notice, request or other communication required or permitted hereunder shall be in writing and shall be deemed to have been duly given if personally delivered or mailed by registered or certified mail, postage prepaid, or by recognized overnight courier or personal delivery at the respective addresses of the parties as set forth herein or on the register maintained by the Company. Any party hereto may by notice so given change its address for future notice hereunder. Notice shall conclusively be deemed to have been given where received.

(b) No Waiver. No failure or delay by Holder to exercise any right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege preclude any other right, power or privilege.

(c) Severability. If one or more provisions of this Note are held to be unenforceable under applicable law, such provision shall be excluded from this Note and the balance of the Note shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Entire Agreement. This Note expresses the entire understanding of the parties with respect to the transactions contemplated hereby.

(e) Default Rates; Usury. In the event any interest is paid on this Note which is deemed to be in excess of the then legal maximum rate, then that portion of the interest payment representing an amount in excess of the then legal maximum rate shall be deemed a payment of principal and applied against the principal of this Note.

(f) Waiver by the Company. The Company hereby expressly waives presentment, protest, notice of protest, notice of default, notice of dishonor and all other demands and notices relating to his Note of any kind or nature whatsoever.

(g) Governing Law. **THE NOTE AND ALL ACTIONS ARISING OUT OF OR IN CONNECTION WITH THIS NOTE SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, WITHOUT APPLICATION OF CONFLICTS OF LAW PRINCIPLES**.

(Remainder of page intentionally left blank)

IN WITNESS WHEREOF, the Company has caused this Promissory Note to be issued as of the date first written above.

IMMUNITYBIO, INC.

By: /s/ David Sachs
Name: David Sachs
Title: Chief Financial Officer

AGREED AND ACCEPTED:

NANT CAPITAL, LLC

By: /s/ Charles Kenworthy
Name: Charles Kenworthy
Title: Manager

SCHEDULE A

TO PROMISSORY NOTE

ADVANCES

Date of Advance	Original Principal Amount of Advance	Amount and Date(s) of Prepayments of Advance	Outstanding Principal Balance of Advance
February 26, 2021	$ 40,000,000.00	N/A	$ 40,000,000.00

ImmunityBio and NantKwest Complete Merger

Creates Leading Immunotherapy and Cell Therapy Company

CULVER CITY & EL SEGUNDO, Calif., March 9, 2021 — ImmunityBio, Inc. and NantKwest, Inc. (NASDAQ: NK) today announced the completion of their previously announced 100% stock-for-stock merger. This follows the satisfaction of all customary closing conditions, including approval of the merger by a majority of unaffiliated shareholders of NantKwest at its Special Meeting held on March 8, 2021. The combined company will operate under the name ImmunityBio, Inc. ("ImmunityBio") and its shares of common stock will commence trading on NASDAQ on March 10, 2021 under the new ticker "IBRX."

"ImmunityBio is the culmination of a decades-long quest to orchestrate natural killer cells and T cells to induce what we call 'immunogenic cell death'. By integrating novel immunotherapy molecules with a state-of-the-art natural killer cell therapy and viral vectors, we are now in the position to transform treatments for patients afflicted with cancer and infectious diseases by activating the host immune system," said Patrick Soon-Shiong, M.D., Executive Chairman of the ImmunityBio Board. "With the merger complete, ImmunityBio has the scale that will allow us to advance our development of more novel therapies in oncology and infectious diseases, and accelerate work on our unique COVID-19 vaccine, which we believe is key to creating long-term immunity to the SARS-CoV-2 virus."

"We are excited to bring together these innovative organizations and talented teams to create a leading immunotherapy and cell therapy company," said Rich Adcock, Chief Executive Officer of ImmunityBio. "Together we expect to deliver important new treatments for patients, as we leverage our best-in-class platforms, expertise and resources to further accelerate our pipeline. We believe that our teams are prepared to seamlessly execute our go-forward strategy. We are excited to deliver on our mission on behalf of our shareholders, partners, and other stakeholders."

Transaction Details

Pursuant to the merger, the former stockholders of ImmunityBio are entitled to receive 0.8190 of a share of NantKwest common stock for each outstanding share of ImmunityBio common stock that they held immediately prior to the merger. Former ImmunityBio stockholders should contact American Stock Transfer & Trust Company, LLC, the exchange agent for the transaction, by calling toll-free at (877) 248-6417 or at (718) 921-8317, if they have any questions regarding the consideration to which they are entitled.

About ImmunityBio

ImmunityBio, Inc. (NASDAQ: IBRX) is a late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company's immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term "immunological memory."

ImmunityBio's platform is based on the foundation of four separate modalities: Antibody cytokine fusion proteins, synthetic immunomodulators, second-generation human adenovirus (hAd5) and yeast vaccine technologies, and state-of-the-art, off-the-shelf natural killer cells, including autologous and allogenic cytokine-enhanced memory NK cells.

The company has an unparalleled immunotherapy clinical pipeline of over 40 clinical trials in Phase 1, 2, 3 development across 19 indications in solid and liquid cancers and infectious diseases. ImmunityBio has an expansive clinical-stage pipeline and intellectual property portfolio with 17 first-in-human antibody cytokine fusion proteins, chemo immuno-modulators, vaccine vectors, and cell therapies in 25 Phase II to III clinical trials. Anktiva™ (ImmunityBio's lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC).

ImmunityBio is the leading producer of cryopreserved and clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise, ready-to-scale facilities, extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. For more information, please visit: www.immunitybio.com

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues", "could", "estimates," "expects," "intends," "may," "plans," "potential", "predicts", "projects," "seeks," "should," "will," and variations of such words or similar expressions. These forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, (i) potential adverse effects or changes to relationships with employees, suppliers or other parties resulting from the announcement or completion of the proposed transaction, (ii) the outcome of any legal proceedings that may be instituted against the parties and others related to the merger, (iii) unexpected costs, charges or expenses resulting from the merger, (iv) uncertainty of the expected financial performance of the combined company following completion of the merger, including the possibility that the expected synergies and value creation from the merger will not be realized or will not be realized within the expected time period, (v) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (vi) inability to retain and hire key personnel, and (vii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trial milestones and/or ImmunityBio's operations or operating expenses. More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in NantKwest's most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") and in subsequent filings made by ImmunityBio with the SEC, which are available on the SEC's website at www.sec.gov. ImmunityBio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information in this press release, except to the extent required by law.

Contacts

Investors
Sarah Singleton
ImmunityBio
844-696-5235, Option 5

Media

Amy Jobe, Ph.D.
LifeSci Communications
315-879-8192
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BUSINESS OF IMMUNITYBIO & NANTKWEST AS A COMBINED ENTITY

I. OUR VISION

We established ImmunityBio, Inc. “ImmunityBio” (NASDAQ: IBRX) to advance the next generation of immunotherapies and to address unmet needs within oncology and infectious disease. Our platform is designed to overcome limitations of the current standards of T cell-based immunotherapies, including checkpoint inhibitors and CAR-T cells. Fundamentally, our platform activates cytokines, NK cells, T cells and tumoricidal macrophages along with generating CD4+ and CD8+ memory T cells. By doing so, our platform not only harnesses the patient’s own immune response to fight disease shortly after administration of therapy, but can also induce long-term “immunological memory,” or longer-term protection against disease.

Since a subset of patients with solid tumors fail checkpoint therapy alone, there is a great need to develop a next-generation immunotherapy beyond checkpoint inhibitors. We have developed a next-generation immunotherapy platform that stimulates the immune system beyond the current paradigm while seeking to address the limitations of current standards of immunotherapy care. This platform is based on the foundation of four separate modalities: (1) activating NK and T cells using antibody cytokine fusion proteins, (2) activating tumoricidal macrophages using synthetic immunomodulators, (3) generating memory T cells using vaccine candidates developed with our hAd5 technology and yeast vector platform and (4) off-the-shelf natural killer cells from the NK-92 cell line and memory-like cytokine-enhanced natural killer cells (m-ceNK) from allogenic and autologous donors. We have focused our efforts to date on difficult-to-treat oncological and infectious disease indications with unmet need and we believe our platform will also be applicable to other cancers and infectious diseases more broadly.

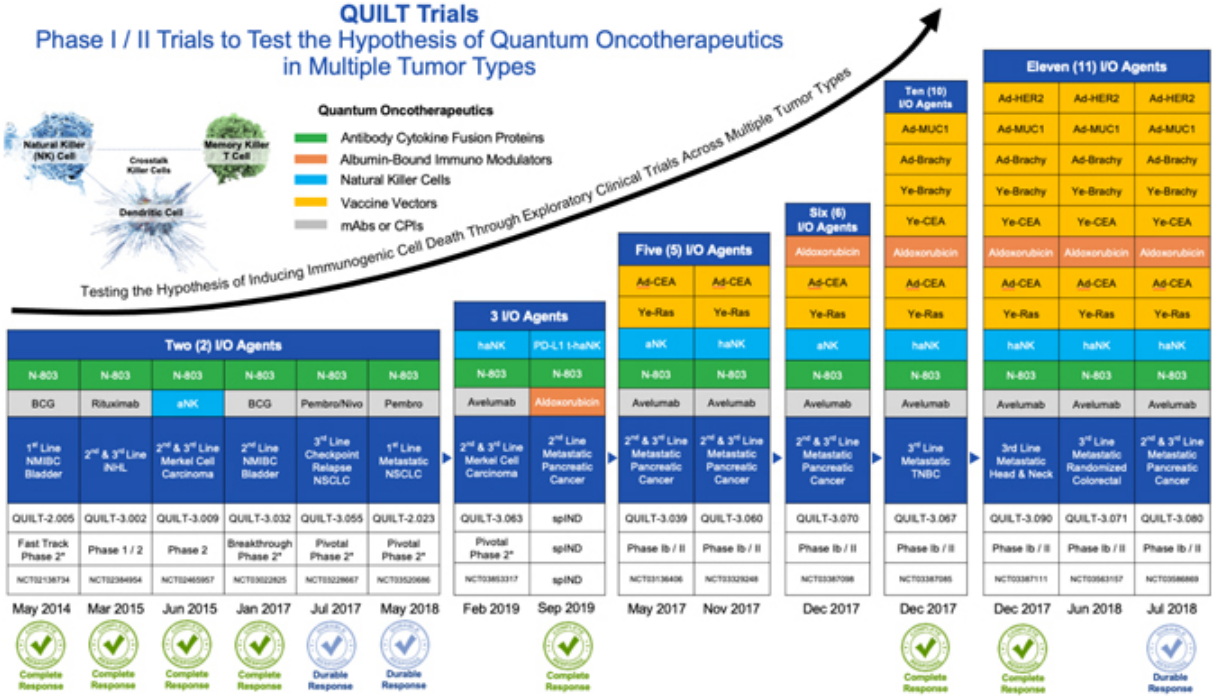
II. HISTORY

Over the last two decades, our Founder and Executive Chairman, Dr. Patrick Soon-Shiong, investigated mechanisms to activate the immune system and to gain insight into how tumors evade and escape the body’s defense mechanisms. The newly merged ImmunityBio is Dr. Soon-Shiong’s culmination of his decades long quest to orchestrate the innate immune system (natural killer cells, macrophages, and dendritic cells) with the adaptive immune system (CD4+ and CD8+ T cells) to generate immunogenic cell death and transform the treatment for patients afflicted with cancer and life-threatening infectious diseases.

The journey began in the 1990s with the discovery that natural killer cells were key components involved in cancer cell death and that activating macrophages in the tumor microenvironment using albumin-based paclitaxel at low doses could immunomodulate the tumor, thus treating the host as well as the disease. In 2005, a nanoparticle albumin-bound (Nab) paclitaxel, invented by Dr. Soon-Shiong was approved (Abraxane) for the treatment of breast cancer. Today, it is also approved for lung and pancreatic cancer and has reached blockbuster status achieving over a billion dollars in sales globally. By 2010, Dr. Soon-Shiong was instrumental in selling the two publicly traded pharmaceutical companies he founded, American Pharmaceutical Partners (Sold in 2008 to Fresenius) and Abraxis Biosciences (Sold in 2010 to Celgene, now Bristol Meyers-Squibb). In 2011, he began the formation and acquisition of the underlying companies now established as ImmunityBio (NASDAQ: IBRX), including the natural killer cell platform which was launched as NantKwest (NASDAQ: NK). Over the past decade, Dr. Soon-Shiong has acquired and developed the platforms needed to orchestrate the entire immune system including antibody cytokine fusion proteins, albumin-bound chemo-immunomodulators, peptide immunomodulators, and vaccine vectors.

Dr. Soon-Shiong founded ImmunityBio to focus on the next generation of immunotherapies to address life-threatening unmet needs within oncology and infectious diseases which then launched the QUILT trials (QUantum Integrative Lifelong Trials) to explore the safety and early efficacy signals of orchestrating these novel first in human immunotherapy molecules across multiple tumor types. We believe the studies shown below were the first immunotherapy exploratory trials to combine multiple novel-novel agents (QUILT Trials) to explore the safety and early efficacy signals of these combinations in an outpatient setting. The term “Quantum Oncotherapeutics” was coined by Dr. Soon-Shiong to denote the temporal-spatial nature of the treatment regimens to accomplish the sequential induction of DAMPs (damage-associated molecular patterns), activation of natural killer cells, education of dendritic cells and proliferation of killer T cells in the tumor microenvironment.

Encouraging data across multiple tumor types in late-stage advanced cancers showed durable complete remissions in many patients with metastatic disease including pancreatic cancer, triple negative breast cancer, head and neck cancer, merkel cell carcinoma, bladder cancer, indolent non-hodgkin’s lymphoma and multiple myeloma.



ImmunityBio, together with its merger with NantKwest, has now progressed into a leading late-stage clinical company with a broad immunotherapy clinical-stage pipeline of over 40 clinical trials in Phase I, II and III development (company sponsored and investigator initiated) across 19 indications in solid and liquid cancers and infectious diseases. Our lead antibody cytokine fusion protein, Anktiva, (our IL-15 superagonist, also known as N-803) has received United States Food and Drug Administration, or FDA Breakthrough Therapy designation for BCG unresponsive CIS NMIBC.

The expansive clinical-stage pipeline and intellectual property portfolio with 17 first in human antibody cytokine fusion proteins, chemo immuno-modulators, vaccine vectors and cell therapies in clinical trials, including 25 in Phase II to III clinical trials, as well as a strong global intellectual property portfolio of issued and pending worldwide patent applications with patent life extending to 2035 and beyond, places ImmunityBio in a leading position to transform immunotherapy care beyond current standards of care. In addition, the company has

adopted the strategy of establishing GMP manufacturing capacity at scale and to date, the company has cutting-edge cell manufacturing expertise, ready-to-scale facilities, with extensive and seasoned R&D, clinical trial, and regulatory operations and development teams, which together will occupy over 400,000 square feet of manufacturing and R&D facilities.

GMP Large Scale Adeno, Protein and Cell Therapy Manufacturing Capacity

Upon completion of the NantKwest IPO in 2015, the company embarked upon a strategy to develop large-scale manufacturing processes of off-the-shelf natural killer cells which could be cryopreserved and retain activity upon thawing and administering at the bedside in an outpatient setting. To our knowledge, ImmunityBio is the first NK cell therapy based company that has accomplished this scale of manufacture, scale of cryopreserved storage of NK cells, and scale of administration. To date, over 3 trillion off-the-shelf NK cells (haNK, PD-L1 t-haNK) have been manufactured with over a trillion cells in storage and over a trillion cells administered.

GMP Large Scale Manufacturing Facilities
Over 3 Trillion Cryopreserved NK Cells Manufactured and Stored

III. IMMUNITYBIO: A LEADING LATE-STAGE IMMUNOTHERAPY COMPANY WITH LARGE SCALE GMP MANUFACTURING CAPACITY

ImmunityBio is a leading late-stage immunotherapy company activating both the innate (NK cell and macrophage) and adaptive (T cell) immune system to treat serious unmet needs within oncology and infectious diseases. We are a leading producer of clinical dose forms of off-the-shelf natural killer (NK) cell therapies, autologous/allogenic memory NK cells (m-ceNK), together with a comprehensive platform of antibody cytokine fusion proteins, albumin bound chemo-immunomodulators and vaccine vectors. By combining these NK, macrophage and T cell activation platforms, we believe ImmunityBio leads the field of immunotherapy with late-stage clinical development across multiple tumor types and infectious diseases.

We believe our immunotherapy product candidates have the potential to address both the innate and adaptive immune system in an orchestrated fashion, as follows:

- a broad clinical-stage pipeline and intellectual property portfolio with 17 first in human antibody cytokine fusion proteins, chemo immuno-modulators, vaccine vectors and cell therapies in clinical trials, including 25 in Phase II to III clinical trials, as well as a strong global intellectual property portfolio of issued and pending worldwide patent applications with patent life extending to 2035 and beyond;
- differentiated technology and assets including best-in-class combined discovery and development platforms for novel therapies and next-generation early-stage candidates across immunotherapy, neoepitopes and molecules enhancing allogeneic and autologous NK and T-cell therapies;
- being well-positioned to combine expertise, platforms and resources of cell therapy, fusion proteins, vaccine platforms and albumin-bound chemo-immunomodulators to address patients across oncology and infectious disease;
- cutting-edge cell manufacturing expertise and ready-to-scale facilities for cell therapy and adenovirus vectors, with extensive and seasoned R&D, clinical trial, and regulatory operations and development teams, which together will occupy over 400,000 square feet of manufacturing and R&D facilities; and
- the ability to combine cell therapy platforms and immunotherapies, on behalf of patients to drive better outcomes in the fight against oncology and infectious disease.

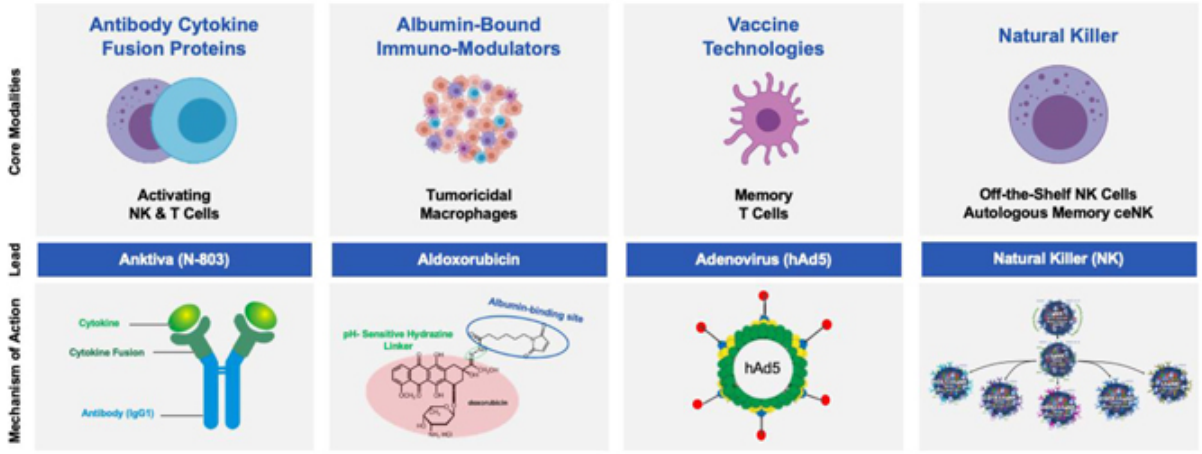
IV. OUR STRATEGY

We seek to become the leading global immunological discovery and therapeutics company by creating the next generation of immunotherapies to address serious unmet needs within oncology and infectious diseases. To achieve this goal, the key elements of our strategy include:

- Continuously scrutinizing our clinical pipeline and assessing our strategic priorities to maximize opportunities for regulatory approval and to meet unmet medical needs;
- Accelerating our immunotherapy platform and product candidates with registrational intent, to address difficult to treat oncological and infectious disease indications;
- Advancing the approval and commercialization of our lead antibody cytokine fusion protein, Anktiva, which has received FDA Breakthrough Therapy designation, as a backbone of all immunotherapy combinations, including with checkpoint inhibitors;

- Continuing to develop our platform and product candidates across modalities, both as single agent and combination therapies, in order to activate and coordinate the innate and adaptive immune system to generate cell memory against multiple tumor types and infectious diseases;
- Optimizing investment in our discovery, development and manufacturing capabilities for our next generation targeted antibody cytokine fusion proteins and vaccine candidates, as well as for cell therapies including utilizing our just-in-time, decentralized advanced cell therapy GMP-in-a-box manufacturing technologies; and
- Cultivating new and expanding existing collaborations for late-stage programs to efficiently scale globally.

V. BROAD IMMUNOTHERAPY & CELL THERAPY PLATFORMS ACTIVATING THE IMMUNE SYSTEM



A. Antibody Cytokine Fusion Proteins

Antibody cytokine fusion proteins are a novel class of biopharmaceuticals that have the potential to amplify the therapeutic capability of cytokines and promote lymphocyte infiltration at a site of disease.

Anktiva is our lead antibody cytokine fusion protein, activating NK and T cells through its proprietary IL-15 superagonist, and is in late-stage clinical development. Multiple Phase I and Phase II trials in both liquid and solid tumors have been completed as of March 1, 2021 in over 700 patients. It is currently in late-stage clinical development including in an ongoing registrational Phase II / III NMIBC study. Anktiva has achieved FDA Breakthrough Therapy designation, in addition to Fast Track designation, for the treatment of BCG unresponsive patients with NMIBC CIS as well as Fast Track designation for BCG unresponsive papillary NMIBC and BCG naive CIS NMIBC. However, there can be no assurance that these designations will lead to a faster development or regulatory review process or increase the likelihood of FDA approval. In addition, Anktiva is in late-stage clinical trials for multiple solid tumors, including lung cancer, pancreatic cancer, TNBC, and glioblastoma, in combination with check-point inhibitors, chemotherapy, cell therapy and other immune stimulating agents. Based on patient readout data that was submitted with our application in September 2019 to obtain our Breakthrough Therapy designation, Anktiva achieved its primary endpoint of complete response rate at any time in the ongoing registrational Phase II / III trial.

In addition to Anktiva, we are developing novel antibody cytokine fusion proteins to further enhance NK and T cell activation directed to the infectious disease or tumor microenvironment, and to modulate the

systemic and local immune response to further amplify immunogenic cell death. Prioritized pipeline constructs include antibody cytokine fusion proteins **N-820** (targeting CD20), N-809 (targeting PD-L1), **N-812** (delivering IL-12 to necrotic tumor cells) and **N-830** (delivering TGF-ß Trap to necrotic tumor cells).

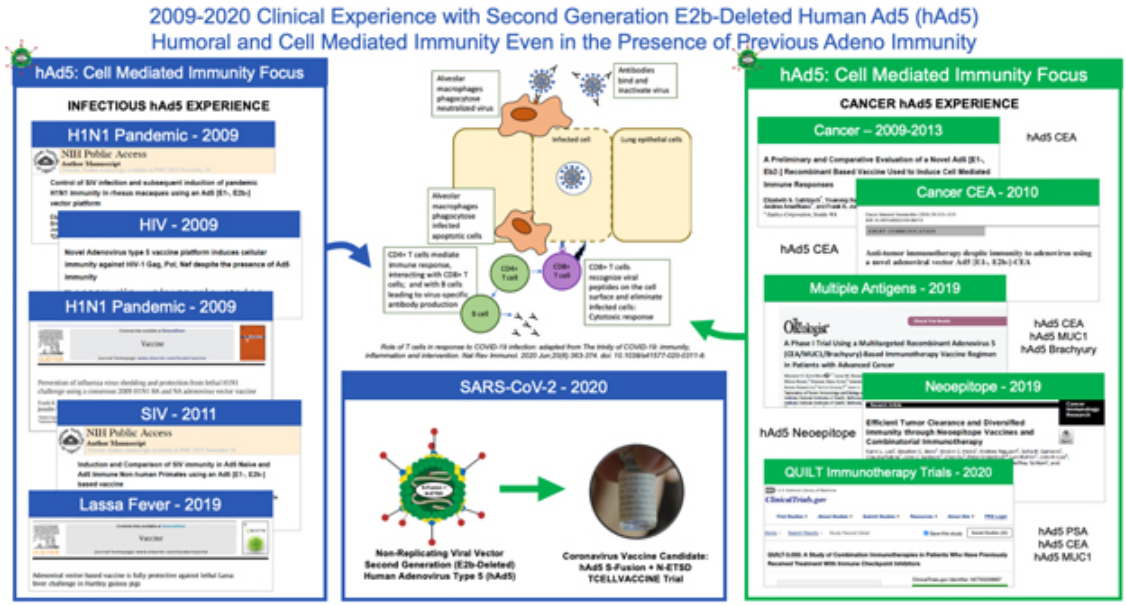
B. Albumin-Bound Chemo Immunomodulators

Synthetic immunomodulators target delivery of the chemotherapy agent to the tumor microenvironment, activate tumoricidal macrophages and/or condition the tumor microenvironment towards tumor suppression. **Aldoxorubicin** is an albumin-linked formulation of doxorubicin which has completed multiple Phase II trials in sarcoma and glioblastoma. Its molecular structure, which includes an acid labile albumin linker, provides favorable properties that distinguishes it from doxorubicin, an anthracycline chemotherapy that has been approved for use in 14 indications including breast cancer, Hodgkin lymphoma and SCLC. Phase II trials have demonstrated that aldoxorubicin crosses the blood-brain barrier, and has an improved cardiotoxicity profile. The improved cardiotoxicity profile allows aldoxorubicin to be given at significantly higher individual and cumulative doses compared with doxorubicin.

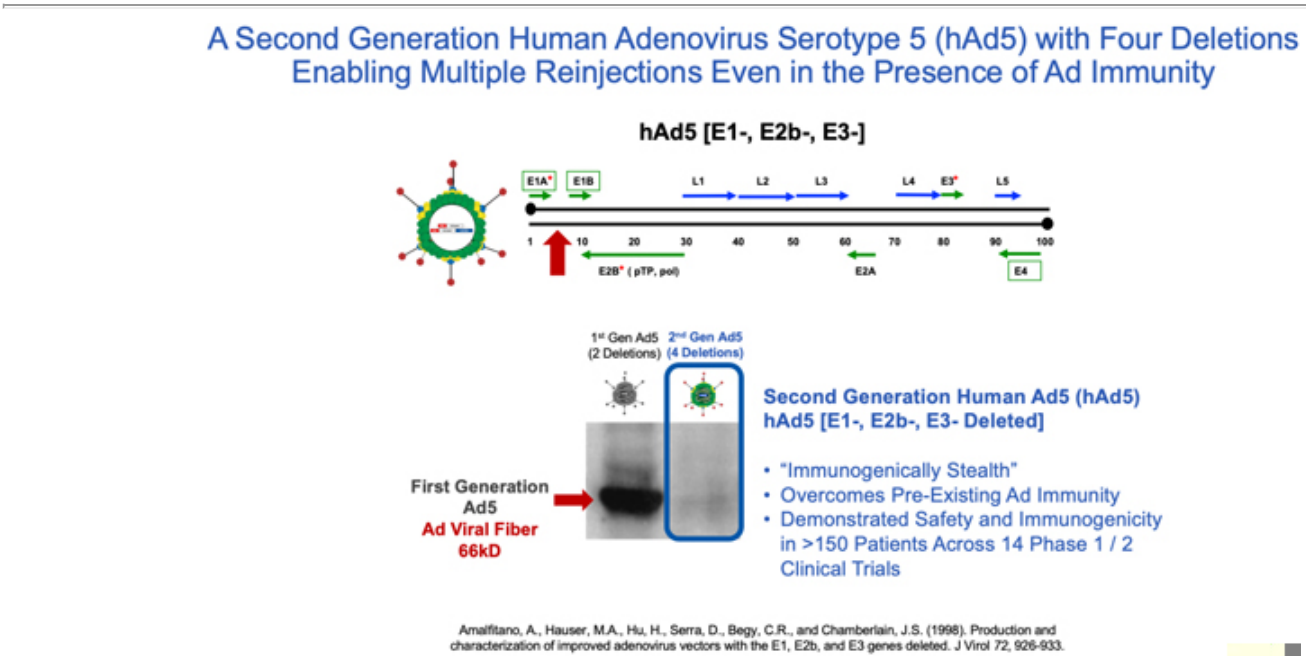
C. Vaccine Technologies

1. Second Generation Human Adenovirus 5 (hAd5) Program

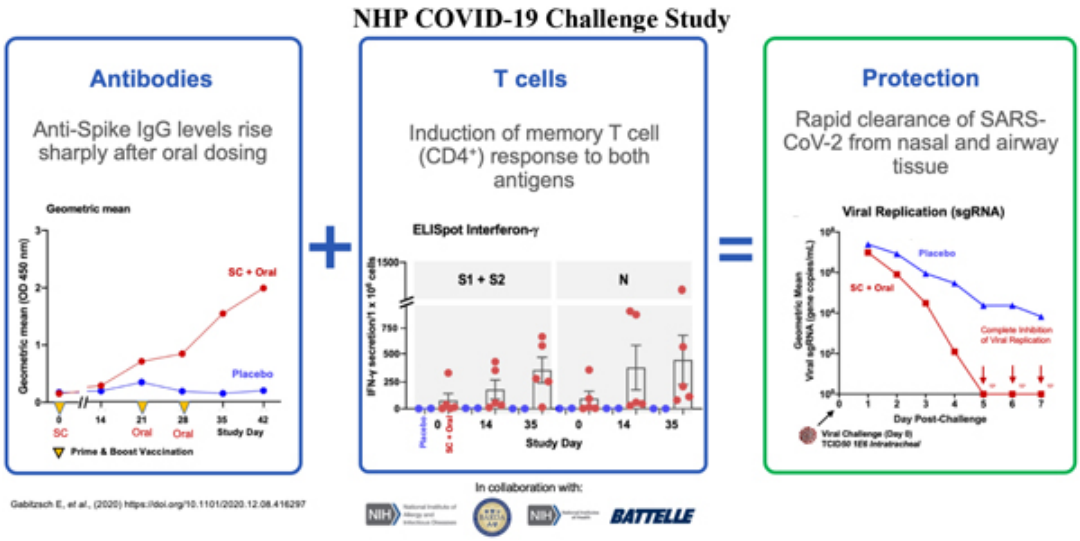
We have developed vaccine technologies to deliver tumor-associated antigens, or TAAs, and neoepitopes (expressed only by cancer cells), including hAd5, a second-generation adenovirus. Our vaccine technologies have the capability to induce T cell memory due to the activation of both CD4+ and CD8+ T cells along with antibody (or humoral) responses.



Our hAd5 technology has produced several product candidates, which have been studied in multiple Phase I and Phase II clinical trials as potential vaccines for the treatment of certain cancers. Importantly, these product candidates have shown an ability to overcome previous adenovirus immunity in cancer patients and in preclinical models. The hAd5 technology has also been used with common TAAs to establish memory T cells in multiple clinical trials.

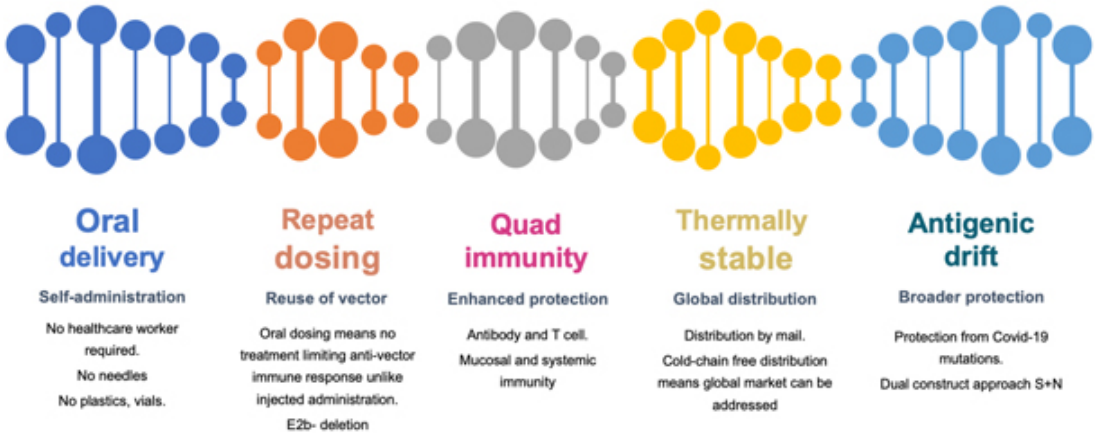


In addition, we are pursuing development of a hAd5 COVID-19 vaccine. While there are a number of vaccine candidates in development, we believe most are limited by their focus on antibody responses to the spike (S) protein. Our candidate uses a combination of S-Fusion and N-ETSD, our novel constructs of COVID-19 spike (S) and nucleocapsid (N) proteins, which has been shown to generate CD4+ and CD8+ T cell mediated immunity and neutralizing antibodies in small animal models.



In a pre-clinical non-human primate study funded by BARDA, subcutaneous and oral capsule administration of our vaccine candidate protected rhesus macaques from SARS-CoV-2 live virus challenge, eliciting memory B and T cell responses that resulted in rapid clearance of replicating virus to levels below detection in nasal and lung passages.

Potential to disrupt vaccine delivery



On October 13, 2020, the FDA authorized the Phase I, open-label, dose-finding study to examine the safety, reactogenicity and immunogenicity of the low-dose ($5x10^{10}$ VP) and intermediate-dose ($1x10^{11}$ VP) in healthy volunteers. The vaccine was given as a subcutaneous prime on day 1 and a boost on day 22 at Hoag Hospital in Southern California. No significant adverse event, or SAEs, were observed, and the vaccinations elicited Th1-biased T cell and antibody responses in the volunteers. Simultaneously, we are also pursuing development for oral and sublingual administration to provide durable humoral, cell-mediated and mucosal immunity. In addition, the company submitted an amendment to the FDA to our study protocol to add sublingual administration to the subcutaneous shot in various prime and boost combinations. Separately, we submitted an IND for our vaccine candidate in an oral capsule formulation to test it in conjunction with subcutaneous administration. Both of these trials were authorized by the FDA in early 2021 and began enrollment in February 2021.

In addition to these trials in the United States, on March 3rd, 2021 we began a Phase I study of subcutaneous administration of our vaccine candidate in Cape Town, South Africa, setting the stage for further studies in Africa utilizing our sublingual and oral formulations without the cold chain requirements of some of the vaccines currently approved for use.

One Vaccine, Three Routes of Immune Protection

hAd5 S+N COVID-19 Vaccine
Subcutaneous (2-8°C)

hAd5 S+N COVID-19 Vaccine
Oral Capsule (Room Temp)

hAd5 S+N COVID-19 Vaccine
Sublingual Pill - Under Tongue (Room Temp)

2. Yeast Program:

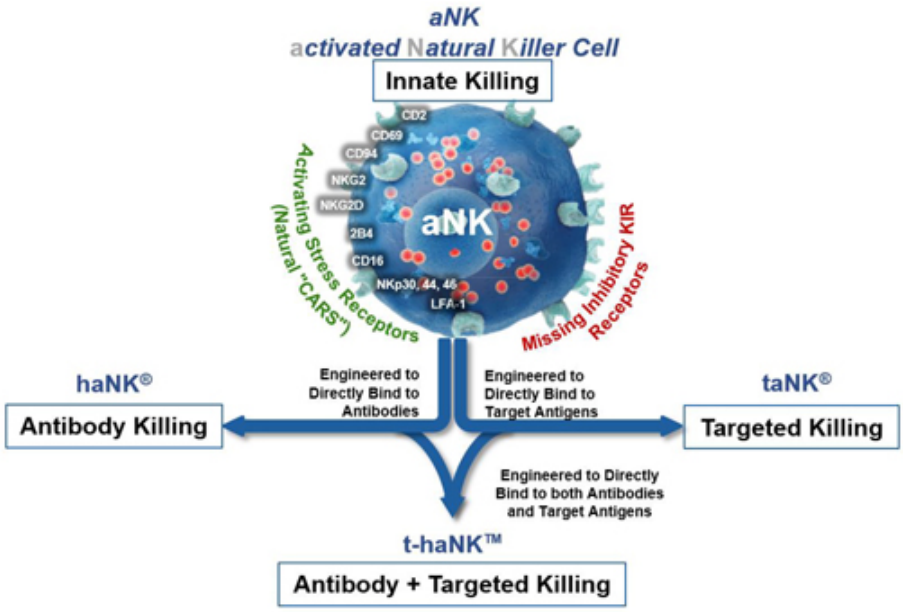
ImmunityBio's yeast vaccine platform, licensed from our subsidiary GlobeImmune Inc., has been administered to over 800 patients with cancer or infectious diseases in FDA-regulated clinical trials with no SAEs. This platform technology consists of a heat-killed, recombinant *S. cerevisiae* yeast-based vaccine engineered to express immunogens such as tumor-associated antigens (TAA), pathogen antigens, and tumor-specific neoepitopes. Immunization with this platform elicits CD4+ and CD8+ T-cell responses capable of eliminating tumor cells or pathogen-infected cells.

ImmunityBio recently conducted a first-in-human Phase I clinical trial of a yeast vaccine engineered to express patient and tumor-specific neoepitopes. Patients with cancer were administered yeast vaccines expressing multiple neoepitopes identified through a proprietary algorithm incorporating analysis of tumor vs normal DNA sequence, tumor RNA expression, and predicted human leukocyte antigen (HLA)-neoepitope binding.

Since its licensure, ImmunityBio has improved the potency of the yeast vaccine by further processing the whole cell product into a lysate, thus directly exposing the immunogen and yeast immunogenic proteins to lymphocytes. This new product further accentuates a tumor-suppressive Th1 dominant response, while also potentially furthering the patent life cycle for this platform.

Finally, ImmunityBio has developed a robust, scalable, and economical manufacturing process for the yeast platform, conducive to producing large scale products such as TAA or pathogen vaccines or rapid production of sufficient doses for N of 1 products such as the neoepitope vaccines.

D. Off-The-Shelf Natural Killer Cell Platform



Our NK platforms have demonstrated the ability to induce cell death in cancers and virally infected cells through a variety of concurrent mechanisms including innate killing, antibody-mediated killing, CAR-directed killing and a combination of both antibody-mediated and CAR-directed killing.

	aNK (NK-92)	haNK	PD-L1 t-haNK	CD-19 t-haNK	HER2 t-haNK	EGFR t-haNK
Innate Immunity Without Major Inhibitory Receptors	NKG2D	NKG2D	NKG2D	NKG2D	NKG2D	NKG2D
High-Affinity CD16	X	CD16	CD16	CD16	CD16	CD16
erIL2	X	erIL2	erIL2	erIL2	erIL2	erIL2
CAR Insertion(s)	X	CD16	PD-L1	CD19	HER2	EGFR
Clinical Indication	Core Cell Line	Registrational Merkel Cell*	Pancreatic NSCLC	Lymphoma	Breast	Head & Neck
Current Status	Universal NK Cell Line	Phase II Jan 2019	Phase II June 2020	IND Auth. June 2019	IND Planned Q1 2021	IND Planned Q3 2021

*Registrational Intent

1. aNK Platform: Innate Killing

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

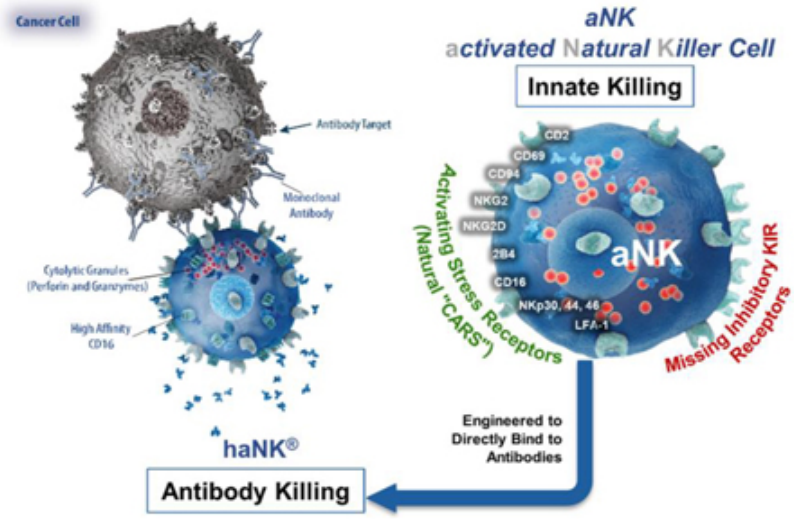
i. rapidly growing cancer cells due to oxidative and metabolic stress, nutrient deprivation and waste accumulation that typically occurs when cell growth outpaces the capacity of local circulation; and

ii. virally infected cells where the cellular machinery is hijacked to produce an abundance of viral proteins and virions.

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

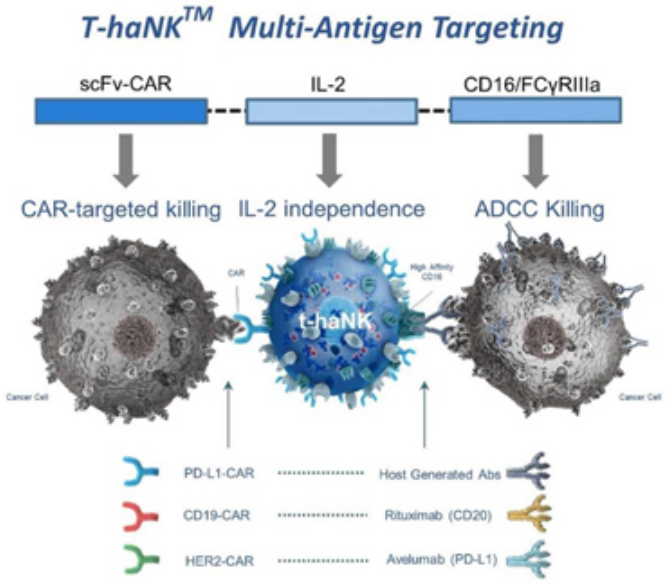
Several Phase I safety studies with aNK cells have been conducted in a variety of bulky hematological cancers and solid tumors, enrolling 49 patients in a range of dose levels and schedules with encouraging evidence of single-agent activity and a durable remission, including some complete responses in liquid tumors. Based on these earlier clinical trials, we have further modified our aNK platform through virus- free molecular engineering designed to leverage additional modes of killing available to aNKs, including antibody-mediated killing, the haNK platform, and both antibody-mediated and CAR-directed antigen targeted killing, the t-haNK platform.

2. haNK Platform: Antibody-Mediated Killing



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

3. t-haNK Platform: CAR-Directed and Antibody-Mediated Killing



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

In the taNK and t-haNK cell lines, the activation signaling that results from the binding of the CARs to the tumor-specific antigens can be strong enough to overcome both cancer escape mechanisms and suppressive factors present in the tumor microenvironment. These tumor antigens encompass three categories of proteins, all of which can be targeted individually by our engineered taNK products:

i. Checkpoint ligands, such as PD-L1;

ii. Well-established tumor proteins such as CD19, HER2 and EGFR; and

iii. Novel surface antigens associated with cancer stem cells.

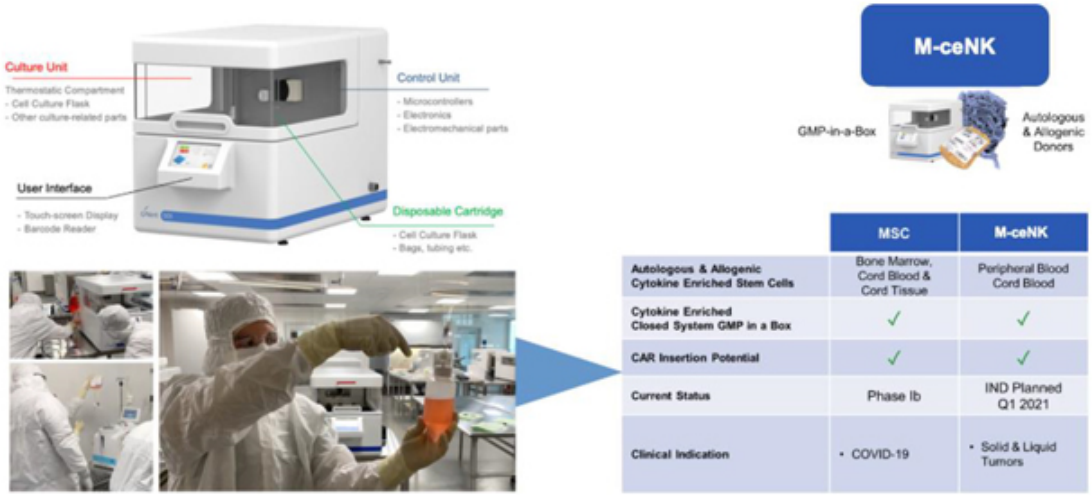
E. Memory Cytokine Enriched Natural Killer Cells—M-ceNK (Allogenic / Autologous) in GMP in a Box

Cytokine-induced memory-like NK cells are a unique set of lymphocytes that differentiate after a brief pre-activation with interleukin-12 (IL-12), IL-15, and IL-18 and exhibit enhanced responses to cytokine re-stimulation that include enhanced interferon-g production and cytotoxicity against leukemic cell lines. These cells have been isolated and characterized by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade.

Based on published literature, we believe the ability to generate these memory-like cells at clinically meaningful quantities has been limited to the work performed at Washington University by T.A. Fehniger, et al. Published data so far has been limited to the acute myeloid leukemia patient population in the post-allogeneic, haploidentical stem cell transplantation setting, for which the Fehniger group has generated enough cells to provide a one-time dose of these cytokine-activated, memory-like natural killer cells.

Our cytokine enriched natural killer cell program is based on the ability to enrich and expand donor-sourced natural killer cells in a GMP facility to a clinically relevant scale, which allows for the production of a pure cytokine activated and expanded NK cell population that possesses the unique phenotype we specifically refer to as M-ceNK cells.

We have developed a unique ability to generate a portfolio of distinct ceNK cell products through the application of our proprietary GMP-in-a-Box bioreactors and cytokines and our proprietary methods and overall expertise in scale manufacturing of NK cell-based products.



	MSC	M-ceNK
Autologous & Allogenic Cytokine Enriched Stem Cells	Bone Marrow, Cord Blood & Cord Tissue	Peripheral Blood Cord Blood
Cytokine Enriched Closed System GMP in a Box	✓	✓
CAR Insertion Potential	✓	✓
Current Status	Phase Ib	IND Planned Q1 2021
Clinical Indication	• COVID-19	• Solid & Liquid Tumors

F. Mesenchymal Stem Cell (MSC) Platform.

Bone marrow-derived allogeneic MSCs are considered to be a prominent cell type to treat degenerative diseases and autoimmune disorders. MSCs have been found to be capable of modulating immune responses, thereby reducing inflammation as well as immunopathology and protecting alveolar epithelial cells during acute respiratory distress syndrome, or ARDS, including that triggered by cytokine storm. More importantly, MSCs demonstrated promising activity in reducing the non-productive inflammation and in promoting lung generation in a phase II clinical trial, as well as in patients with ARDS in clinical practice. As a result, we believe MSCs have the potential to alleviate the SARS-CoV-2-derived cytokine storm and ARDS, and thereby have an effect on the treatment of subsequent chronic respiratory dysfunction and lung fibrosis.

We have developed and optimized procedures and proprietary protocols to generate multiple dose forms of MSC products from a single bone marrow or cord tissue sample, in a scalable format using our GMP-in-a-Box system.

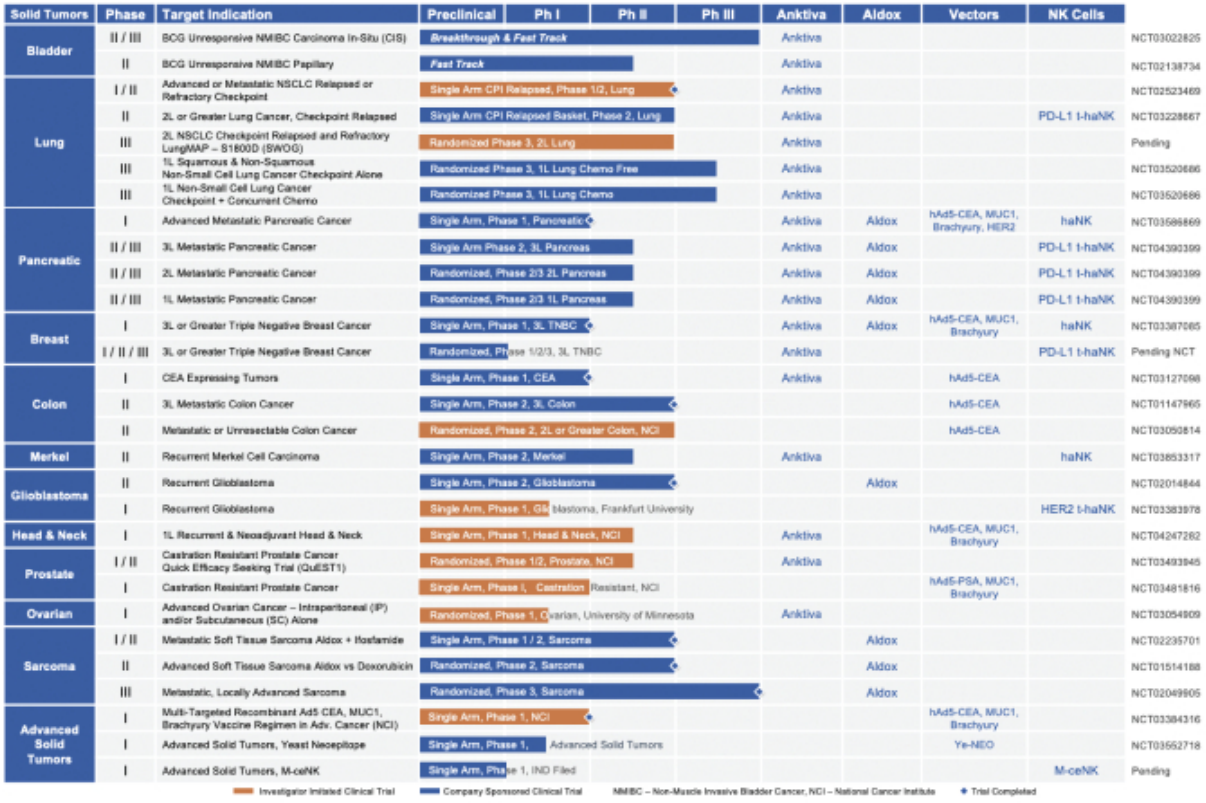
G. GMP-in-a-Box Approach

We believe we are a pioneer in allogeneic and autologous sourced NK and mesenchymal stem cell, or MSC, therapeutics. We utilize a scalable semi-automated GMP production process using GMP-in-a-Box that combines cytokine expansion and activation reagents such as Anktiva, and unique and simple processing methods, all of which are proprietary.

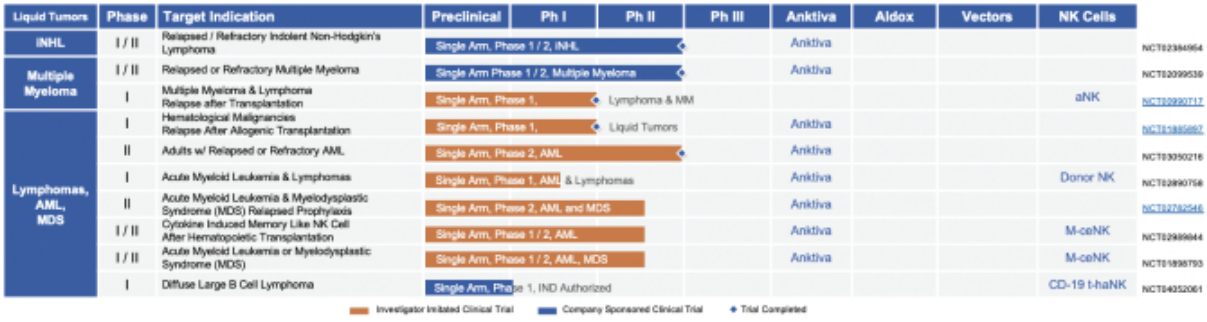
We have optimized processes for generating both fresh and cryopreserved clinical dose forms of memory-like NK cells with 100% purity (in the allogeneic setting) from a variety of sources, including cord blood and allogeneic and autologous peripheral blood. We have also optimized processes for generating fresh and cryopreserved clinical dose forms of MSCs from cord tissue and allogeneic bone marrow sources. We avoid the use of both feeder-layers for activation as well as other commonly applied additives that frequently create downstream issues in achieving a high-quality releasable final dose form and have been able to generate multiple dose forms from each donor product, both of which are critical features in achieving scalability.

VI. BROAD PIPELINE ACROSS ONCOLOGY AND INFECTIOUS DISEASE AT LATE-STAGE CLINICAL DEVELOPMENT

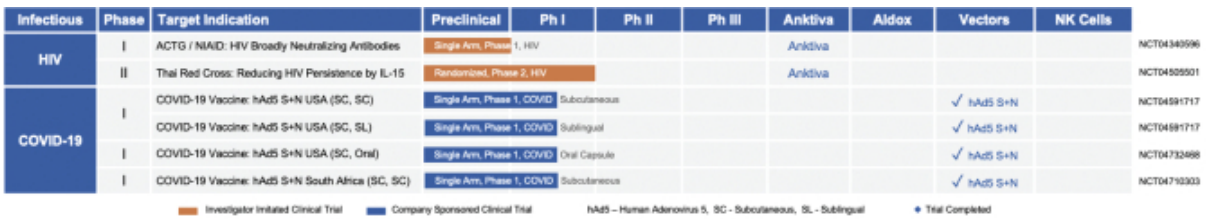
A. Solid Tumors: Late-Stage Clinical Pipeline



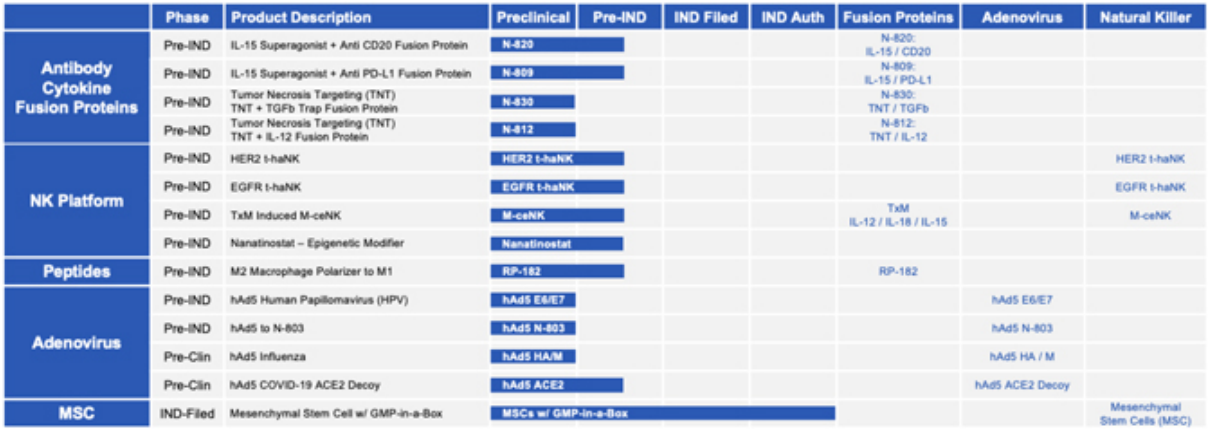
B. Liquid Tumors: Clinical Pipeline



C. Infectious Diseases: Clinical Pipeline



D. Pre-Clinical & Pre-IND Pipeline



VII. OUR SOLID TUMOR DEVELOPMENT PROGRAM

1. Bladder Cancer

CIS & Papillary Non-Muscle Invasive Bladder Cancer (NMIBC)

Opportunity

In the United States, bladder cancer is ranked the sixth most prevalent cancer and one of the most expensive (approximately $4 billion a year) cancers to treat. Bladder cancer is a common malignancy, with approximately 81,000 new patients diagnosed each year in the United States. The high recurrence rate and ongoing invasive monitoring requirement of bladder cancers are the key contributors to the economic and human toll of this disease. The median age at diagnosis is approximately 73 years. NMIBC makes up 75% of all bladder cancers in the United States. NMIBC is divided into two forms, papillary and CIS, of which approximately 10% of diagnoses are CIS disease. CIS disease is always classified as high-grade, whereas papillary tumors can range from low malignant potential to high-grade carcinoma. A substantial proportion of patients with intermediate and high-risk disease are at a significant risk for metastasis and death. Overall, 45% of all NMIBC incidence is classified as high-grade carcinoma.

Standard of Care

There is a significant unmet medical need in NMIBC, with one of the worst patient experiences among common cancers. A treatment approved in 1989, BCG immunotherapy, has been the primary standard of care for nearly 40 years. Intravesical administration of BCG causes the release of antigen presenting molecules and cytokines thereby inducing an immune response against the tumor cells.

After first line treatment with BCG, patients who progress (80-85% at one year) typically either undergo radical cystectomy (removal of the bladder) or face cancer progression. Radical cystectomy for bladder cancer is a high-risk procedure, with morbidity and mortality rates ranging from 28-64% and 3-6%, respectively. The high rates of morbidity and mortality reflect the fact that the majority of patients undergoing radical cystectomy are elderly patients with multiple comorbidities.

We are targeting patients with BCG unresponsive high-risk NMIBC. Patients with CIS NMIBC who recur within one year after receiving two courses of BCG are considered BCG unresponsive and patients with high-risk papillary disease who recur within nine months after receiving adequate BCG are considered BCG unresponsive. Anktiva is expected to enhance the immunostimulatory effects of BCG, by causing proliferation and activation of cytotoxic NK and T cells critical for killing bladder tumor cells. Our initial target market includes the approximately 17,000 of these patients diagnosed annually, including those patients who have previously failed BCG and have refused cystectomy.

We would expect that, if Anktiva for the treatment of high-risk NMIBC is approved by the FDA, patients would receive treatment until the earlier of up to two years or disease recurrence and would receive treatment in order to avoid cystectomy and delay disease recurrence.

Late-Stage Clinical Experience

Anktiva has been administered intravesically to more than 300 subjects across one Phase I clinical trial and one ongoing Phase II / III clinical trial, as well as several spINDs. The Phase I trial, completed in 2018, was a dose finding study of intravesical BCG in combination with Anktiva in patients with NMIBC in the BCG naïve setting. As can be seen in the table below, durable complete responses were noted in nine out of nine patients who also demonstrated durable responses at 24 months for both CIS and papillary disease. As a point of reference, the historical response rate for BCG naïve alone (standard of care) is 58-81% at 3-6 months post BCG alone. No serious adverse events or dose limiting toxicities were reported in any subjects and the maximum tolerated dose was not reached.

Anktiva + BCG in High-Risk NMIBC – Phase I Results

Durable Complete Responses (CR) or No Recurrence (NR) in 9 out of 9 Patients

Dose (intravesicular instillation)	Patient	Stage	Response Assessments							
			W12	6M	9M	12M	15M	18M	21M	24M
100 µg	1	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
	2	Pap Ta	CR*	CR	CR	CR	CR	CR	CR	CR
	3	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
200 µg	4	Pap T1	IC	CR*	CR	CR	CR	CR	CR	CR
	5	CIS	IC	IC	IC	CR	CR	CR	CR	CR
	6	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
400 µg	7	Pap T1	CR*	CR	CR	CR	CR	CR	CR	CR
	8	CIS	CR*	CR	CR	CR	CR	CR	CR	CR**
	9	Pap Ta	CR*	CR	CR	CR	CR	CR	CR	CR

*CR termed as No Recurrence (NR) in Papillary Disease **Negative Cystoscopy Inclusive Cytology IC: Inconclusive

A. BCG Unresponsive CIS NMIBC

Anktiva has achieved FDA Breakthrough Therapy designation (in addition to Fast Track designation) for the treatment of BCG unresponsive patients with CIS NMIBC, as well as Fast Track designation for BCG unresponsive papillary NMIBC and BCG naive CIS NMIBC.

In our Phase II / III, open-label multicenter trial of BCG unresponsive high grade CIS NMIBC patients, the patients are receiving BCG plus Anktiva weekly for six consecutive weeks during induction. The patients also receive additional treatment including three weekly maintenance instillations every three months for up to 12 months and then at month 18. Patients with no disease or low-grade Ta disease at months 24, 30, and 36 are eligible for continued BCG plus Anktiva (Cohorts A and B) or Anktiva alone (Cohort C) treatment (3 weekly instillations), by PI discretion.

The primary endpoint of the BCG unresponsive CIS NMIBC trial is complete response rate at any time equal to or greater than 30% and the lower bound of the 95% confidence interval must be greater than or equal to 20% for success. Complete response, or the disappearance of measurable disease in response to treatment, is evaluated at three months or nine months following initial administration of Anktiva plus BCG (and every three months thereafter until 24 months). This endpoint would be achieved once at least 24 of the 80 patients in the study achieve complete response.

In February 2021, we presented the following data at ASCO GU 2021 regarding our Phase II/III clinical results of IL-15RaFc superagonist Anktiva with BCG in BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS) patients: 80 patients have enrolled in cohort A of this phase II/III trial. Evaluable analysis at this time shows complete response (CR) rate at any time of 71% (N=51/72); for patients achieving CR, the probability of maintaining a CR for 12 months is 56%, with a median duration of complete response of 19.2 (7.6, 26.4) months. Low-grade treatment related adverse events (AE) include dysuria, hematuria, and pollakiuria (all £18%), urgency and fatigue (each 8%), chills (6%), and bladder spasm and pyrexia (each 5%), all other AEs were seen at 4% or less. The serious adverse event (SAE) rate is 1% for any given AE. No immune related SAEs have been observed. To date, 70/80 (87.5%) patients have avoided cystectomy in this BCG unresponsive population.

The investigator concluded that with a complete response rate of 71%, Anktiva has met its primary endpoint with a 56% probability of CR patients maintaining CR for at least 12 months. With the observed strong efficacy and an SAE rate of 1%, Anktiva represents a novel treatment option for BCG unresponsive CIS with a favorable benefit to risk ratio in a therapeutically challenging disease.

As of February 2021, our NMIBC CIS data as of Feb 2021 are as follows:

- QUILT 3.032 demonstrated excellent tolerability profile of Anktiva + BCG with no treatment related serious adverse events, 0% immune related AE, 0% treatment related discontinuation, and no grade 4 or 5 adverse events.
- CR rate at any time of 71% with median follow up 10.7 months, with cystectomy avoidance rate 88%.
- In responding patients, the estimated median duration of CR is 19.2 months based on Kaplan-Meier analysis methods, with probability of 56% maintaining CR at least 12 months
- Favorable and familiar administration profile to urologists.

All patients enrolled in the NMIBC BCG unresponsive CIS trial have been treated with the recommended number of full-strength doses of BCG on study during our trial. We have enrolled patients who have received a lower dosage of BCG therapy before enrollment in our trial as a result of BCG shortages. No less than 90% of patients enrolled in the trial as of December, 2020 have received the number of doses and amount of BCG recommended by the American Urological Association before enrolling in the trial. In the 51 patients with a complete response, 46 patients (90%) received a full dose of BCG prior to study entry. The FDA allowed our modification of the study design to allow enrollment of such patients, and definition of these patients may require further discussions with the FDA upon review. A published meta-analysis of six relevant randomized controlled trials and two quasi-randomized controlled trials in NMIBC concluded that low-dose BCG instillation significantly reduces the incidence of overall side effects, especially severe and systemic

symptoms in patients with NMIBC, while the oncological control efficacy of low-dose BCG is not inferior to standard-dose BCG. While there can be no assurance that the FDA will agree with this conclusion, we believe that this study may be relevant to the FDA's consideration for our label.

For BCG Unresponsive CIS NMIBC we expect an initial readout in the first half of 2021, a BLA filing in the second half of 2021 and a decision on our BLA filing by the FDA in 2022.

B. BCG Unresponsive Papillary NMIBC

As discussed, we are also pursuing approval in BCG unresponsive papillary NMIBC, for which we have also received Fast Track designation. In our Phase II, open-label multicenter trial of BCG unresponsive high grade papillary NMIBC patients, the patients are receiving BCG plus Anktiva weekly for six consecutive weeks during induction. The patients also receive additional treatment including three weekly maintenance instillations every three months for up to 12 months and then every nine months for up to 24 months. The primary endpoint of the trial is a 12-month disease free rate greater than or equal to 30% and the lower bound of the 95% confidence interval must be greater than or equal to 20% for success. To meet the primary endpoint, 24 out of 80 patients must be disease free at 12 months.

As of March 1, 2021, 26 sites are active in the United States, and 60 of the planned 80 patients with BCG unresponsive papillary NMIBC have been enrolled. We expect full accrual in Q1 2022 and an initial readout anticipated in Q2 2022.

2. Lung Cancer

Non-Small Cell Lung Cancer

Opportunity

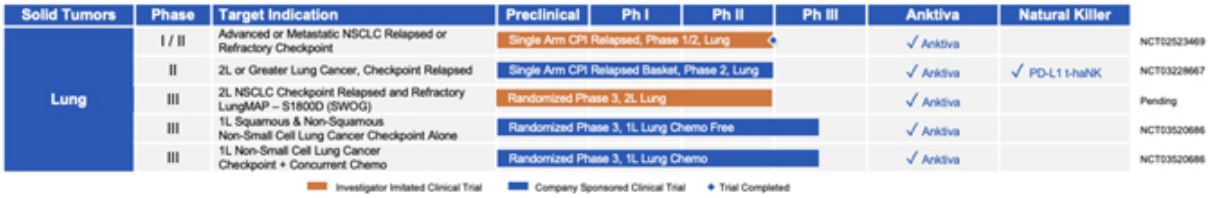
Lung cancer is the second most common cancer in the United States. In 2018, in the United States alone it is estimated that 228,820 new cases of lung cancer will be diagnosed, and 135,720 deaths will be attributed to the disease. Lung cancer is divided into two forms, NSCLC and SCLC, with NSCLC comprising 85-90% of lung cancer cases in the United States. Approximately 55% of NSCLC cases are metastatic, and we estimate that 20% of those metastatic cases involve relapsed or refractory cancers.

Standard of Care

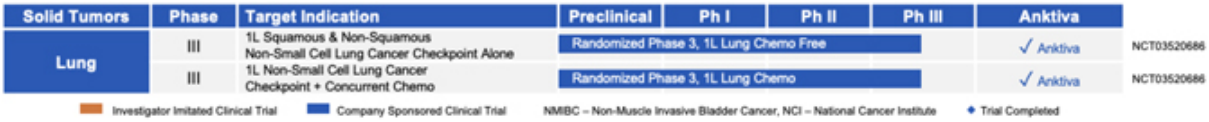
The development of checkpoint inhibitors, such as nivolumab, pembrolizumab and atezolizumab, targeting PD-1 and its ligand PD-L1, or PD-L1, have provided an improvement in the survival of treated patients. PD-1 and PD-L1 are proteins referred to as checkpoints that exist on the surface of cells and act to suppress the adaptive immune system. PD-1 and PD-L1 checkpoint inhibitor drugs bind to the proteins and interfere with their suppressive mechanisms. The aforementioned therapies are FDA-approved for patients with metastatic NSCLC. The application of these new therapies to NSCLC has been revolutionary, doubling the median overall survival in some settings; however, patient response may be short lived, due to late response and/or progression after achieving an initial response.

As with bladder cancer, Anktiva enhances the proliferation and activation of NK and T cells critical for targeting and killing of lung cancer cells. There is therefore a strong rationale to evaluate Anktiva in addition to an anti–PD-1 or anti–PD-L1 checkpoint inhibitor for patients with NSCLC who have relapsed after achieving an initial response to PD-1 or PD-L1 checkpoint inhibitor therapy.

Lung Cancer Program



1. Development in First Line Lung Cancer

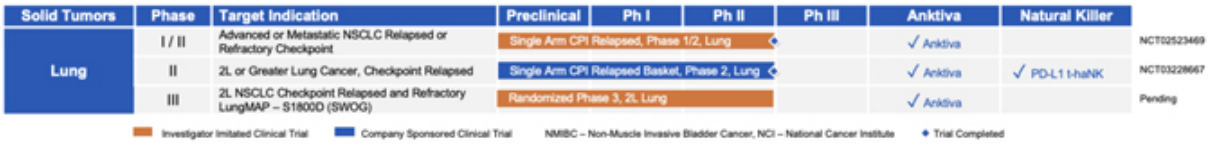


We are enrolling patients in a randomized Phase III trial (NCT03520686) to evaluate Anktiva plus checkpoint inhibitor combinations versus other checkpoint inhibitor combinations in the first line setting for NSCLC. Patients will be treated either in cohort A (immunotherapy for either squamous or nonsquamous NSCLC with PD-L1 TPS $\geq$1%), cohort B (chemoimmunotherapy for squamous NSCLC), or cohort C (chemoimmunotherapy for nonsquamous NSCLC).

Each study cohort will be analyzed separately:

- **Cohort A** stratifies patients based on squamous or non-squamous NSCLC types and PD-L1 expression. Patients are randomized 1:1 into a control arm where patients receive single agent pembrolizumab or an experimental arm where patients receive pembrolizumab plus Anktiva.
- **Cohort B** will randomize squamous NSCLC patients 1:1 into a control arm where patients receive an induction phase of carboplatin plus taxane plus pembrolizumab and a maintenance phase of pembrolizumab or into an experimental arm where patients receive the same treatment with the addition of Anktiva in both the induction and maintenance phases.
- **Cohort C** will randomize nonsquamous NSCLC patients 1:1 into a control arm where patients receive an induction phase of platinum-based chemotherapy plus pemetrexed plus pembrolizumab and a maintenance phase of pembrolizumab or into an experimental arm where patients receive the same treatment with the addition of Anktiva in both the induction and maintenance phases. Progression free survival is the primary outcome of all three cohorts.

2. Development in Second Line or Greater Lung Cancer



Analysis of the pooled data from a Phase I / II study (NCT02523469) conducted from January 2016 to June 2017 in 23 patients, and a subsequent investigator-initiated Phase II trial conducted by the Medical University of South Carolina yielded confirmation of efficacy of the combination of checkpoint and Anktiva in relapsed NSCLC. In 15 patients with PD-L1 greater than 50%, the overall response rate was 38% and the median

overall survival rate was 17.1 months (4.6, ongoing). These preliminary findings are favorable relative to the historical response rate seen in this patient population in the first line setting with checkpoint inhibitor therapy.

Phase II: Early Activity and Efficacy Signal of Anktiva + Checkpoint in Patients who Relapsed or were Refractory to CPI

Efficacy Endpoint	All Patients (n=56)	PD-L1 ≥ 50% (n=15)	CPI Relapsed refractory (n=35)	CPI relapsed (n=16)	CPI refractory (n=19)
Median PFS (months)	3.5 (2.7, 5.1)	4.5 (1.4, 8.5)	4.0 (2.8, 6.2)	4.9 (2.8, 7.0)	2.8 (2.1, 6.9)
Median OS (months)	13.4 (9.6, 19.5)	17.1 (4.6, NR)	12.9 (9.6, 19.6)	19.6 (6.2, NR)	11.2 (4.0, 18.5)
ORR	18%	38%	14%	25%	5%
SD	45%	38%	60%	56%	63%
DCR	63%	75%	74%	81%	68%

Data as of January 12, 2020 NR- Not Reached

N-803 plus nivolumab for advanced or metastatic non-small cell lung cancer: Update on phase II experience of combination PD1 blockade with an IL-15 superagonist"
John Wrangle, Medical University of South Carolina, Charleston, SC
AACR-IASLC (San Diego) Plenary Session

On the basis of these findings, we initiated a single-arm Phase IIb (NCT03228667) multicohort **basket** trial of Anktiva and checkpoint inhibitor combinations in patients who have previously received treatment with PD-1/PD-L1 immune checkpoint inhibitors per an FDA-approved indication. We are leveraging this trial to advance our program in second line or greater NSCLC. Enrollment is ongoing, and through March 1, 2021, 135 patients have been enrolled in the following cohorts:

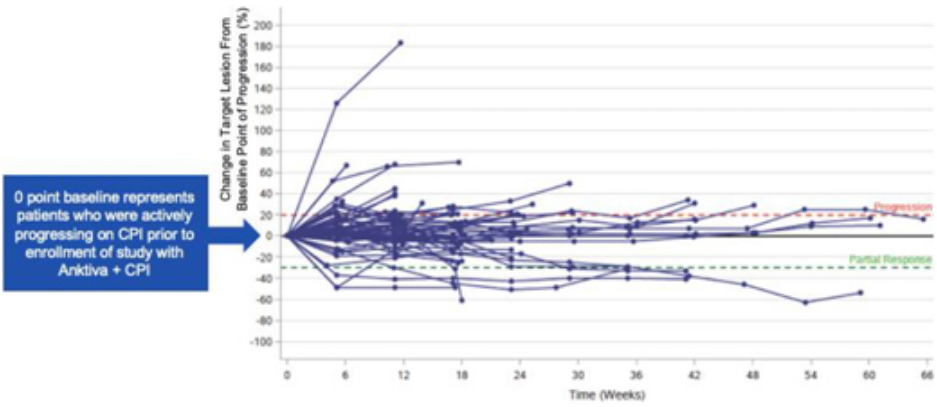
Phase IIb: Multi-Cohort Basket Trial of CPI Failures		**Enrolled Patients**
	Lung Cancer: Non-Small Cell	18 / 18 Enrolling
	Lung Cancer: Small Cell	10 / 10 Enrolled
Cohort 1	Head & Neck Squamous Cell Carcinoma	8 / 18 Enrolling
Third Line Patients	Melanoma	15 / 18 Enrolling
Checkpoint Failures Alone	Renal Cell Carcinoma	7 / 18 Enrolling
	Gastric	3 / 18 Enrolling
	Urothelial	1 / 18 Enrolling
	Cervical	2 / 18 Enrolling
Cohort 2 Second Line Checkpoint Failures Alone	High PD-L1 NSCLC	10 / 20 Enrolling
Cohort 3 Second Line Concurrent Chemo + CPI Failures	NSCLC	19 / 19 Completed Enrollment

Cohort 4 Second or Third Line Concurrent Chemo + CPI Stable Disease	NSCLC, Urothelial, HNSCC, RCC	(34 lung cancer patients) 42 / 41 Completed Enrollment

Preliminary Results for NSCLC from Ongoing Phase IIb Multi Cohort Trial

91 out of a total of 135 patients who have been enrolled and assigned to a cohort in the Phase IIb trial as of March 1 2021 are lung cancer patients, with 81 having NSCLC and 10 having SCLC.

Patients enrolling into this trial were eligible if actively progressing on checkpoint therapy. Upon enrollment (target lesion "0" in the following spider plot below, representing ongoing progression), patients continued on the same checkpoint but with the addition of Anktiva. Despite progressing on checkpoint therapy upon entry into the trial, the majority of patients reverted to stable disease and demonstrated durability of stable disease, some extending as long as nine months in this ongoing study as seen in the spider plot below. The spider plot below shows preliminary evidence of conversion from active progression (target lesion "0" baseline) to long-term stable disease and disease control in second- and third-line NSCLC patients who were actively progressing on checkpoint therapy upon study entry.



Based on the promising Phase II results of the Wrangle study and confirmatory basket trial data of Anktiva activity in rescuing patients who progressed on checkpoint therapy, a randomized registration trial in second and third line lung cancer patients is being planned. We expect complete data for the lung cancer cohorts in Q2 2021.

Based on the above data, Lung-MAP and ImmunityBio began discussions in July 2020 for inclusion in the multi-institutional Lung-MAP nationwide master protocol as a sub-study of NSCLC patients. We are currently working with Lung-MAP on the design of this Anktiva plus checkpoint inhibitor sub-study.

3. Pancreatic Cancer

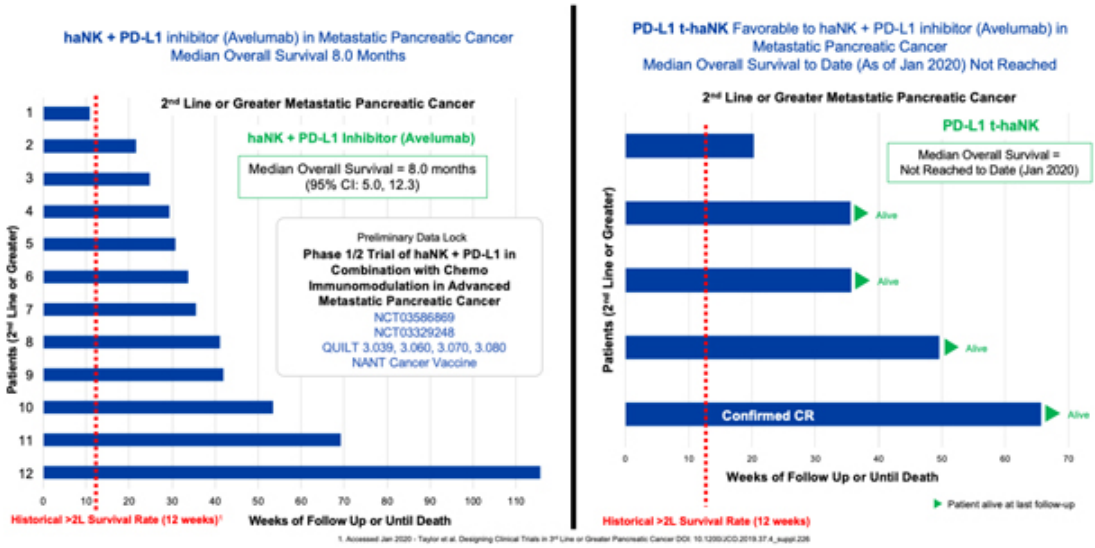
Metastatic Pancreatic Cancer

Pancreatic cancer is the third leading cause of cancer-related death in the United States, with an estimated 47,050 deaths and an estimated 57,600 new cases expected in 2020.

Surgery and subsequent adjuvant chemotherapy are the preferred treatment option for pancreatic cancer today. Approximately 82-89% of pancreatic cancer cases are recurrent or metastatic, and 80% of pancreatic cancer patients relapse. For the majority of patients who present with more advanced disease, treatment

typically consists of chemotherapy alone or supportive care for metastatic patients, and chemotherapy with or without radiation for those with locally advanced disease. Conventional immunotherapy is not part of the standard of care for these patients and the prognosis is not promising, with a five-year survival rate of 3%.

Exploratory Phase Ib/II trials and spINDs in patients with second line or greater metastatic pancreatic cancer in which Anktiva and aldoxorubicin were combined with off-the-shelf NK, or haNK, cells and other agents showed a durable complete remission in patients with advanced disease. The primary endpoints of the Phase Ib and II portions of the study were safety and objective response rate, respectively. In aggregate, 82% of patients (14 / 17) with advanced pancreatic cancer achieved disease control following combination therapy including Anktiva and aldoxorubicin. A single patient demonstrated an ongoing complete response, over nine months in duration through August 2020 with a significant and rapid decline of their cancer antigen 19-9, or CA19-9, levels. There were no Anktiva-related grade 3 or 4 adverse events reported.



On the basis of these exploratory studies in metastatic pancreatic cancer, together with the pre-clinical findings that PD-L1 t-haNK is as effective as haNK + anti-PD-L1 monoclonal antibody, the ongoing clinical development in first, second- and third-line pancreatic cancer utilizes PD-L1 t-haNK as described below.

Development in First, Second and Third Line Metastatic Pancreatic Cancer

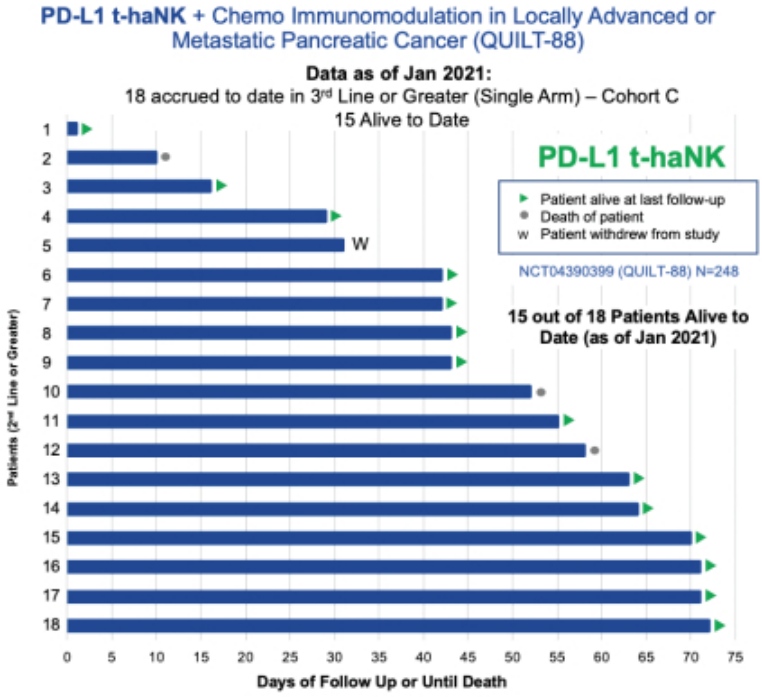
Solid Tumors	Phase	Target Indication	Preclinical	Ph I	Ph II	Ph III	Anktiva	Aldoxorubicin	Natural Killer	
Pancreatic	II / III	3L Metastatic Pancreatic Cancer	Single Arm Phase 2, 3L Pancreas				✓ Anktiva	✓ Aldox	✓ PD-L1 t-haNK	NCT04390399
	II / III	2L Metastatic Pancreatic Cancer	Randomized, Phase 2/3 2L Pancreas				✓ Anktiva	✓ Aldox	✓ PD-L1 t-haNK	NCT04390399
	II / III	1L Metastatic Pancreatic Cancer	Randomized, Phase 2/3 1L Pancreas				✓ Anktiva	✓ Aldox	✓ PD-L1 t-haNK	NCT04390399

Based on this encouraging data, we are enrolling patients in a Phase II trial.

- **First Line Advanced pancreatic cancer**. We are evaluating the combination of Anktiva with aldoxorubicin and low dose chemotherapy with or without PDL1 t-haNK versus Gemcitabine/Abraxane as the standard of care control arm in this randomized trial.
- **Second Line Advanced pancreatic cancer**. We are evaluating the combination of Anktiva with aldoxorubicin and low dose chemotherapy + PDL1 t-haNK versus 5FU/Onivyde as the standard of

care control arm in this randomized trial.

- **Third Line and Beyond,** we are evaluating the combination of Anktiva with aldoxorubicin and low dose chemotherapy + PDL1 t-haNK in a single arm cohort of this trial. The primary endpoint is overall survival and as of January 2021, 15 out of 18 (83%) of patients enrolled remain alive to date. We plan to meet with the FDA for an end of Phase II meeting and special protocol assessment during the second half of 2021 to discuss the adequacy of this trial design for the approval of combination therapies for pancreatic cancer.



4. Breast Cancer

Triple Negative Breast Cancer

Breast cancer is the fourth leading cause of cancer-related death in the United States, with an estimated 42,690 deaths from the disease and an estimated 279,100 new cases expected in 2020. TNBC is an aggressive subtype of breast cancer with limited treatment options and a poor prognosis that accounts for approximately 10-20% of all breast cancer types. 27% of cases are metastatic and recurrent. TNBC tumors frequently present at an advanced stage, are very heterogeneous (not all types and subgroups have been defined) and are associated with a higher risk of early relapse. They are characterized by a lack of hormonal receptor expression (estrogen receptor, or ER, and progesterone receptor, or PR), and an absence of human epidermal growth factor receptor 2, or HER2, protein expression or ERBB2 gene overexpression and/or amplification, which makes ER, PR and HER2 targeted therapies ineffective at treating TNBC. The checkpoint inhibitor atezolizumab has become the new standard of care for patients with advanced TNBC who are PD-L1 positive.

Additionally, the Merck-sponsored KEYNOTE-086 Phase II clinical trial that led to approval of the checkpoint inhibitor pembrolizumab in previously treated metastatic TNBC patients reported two out of 170 patients with a complete response and showed disease control in 13 of the 170 patients. Recently

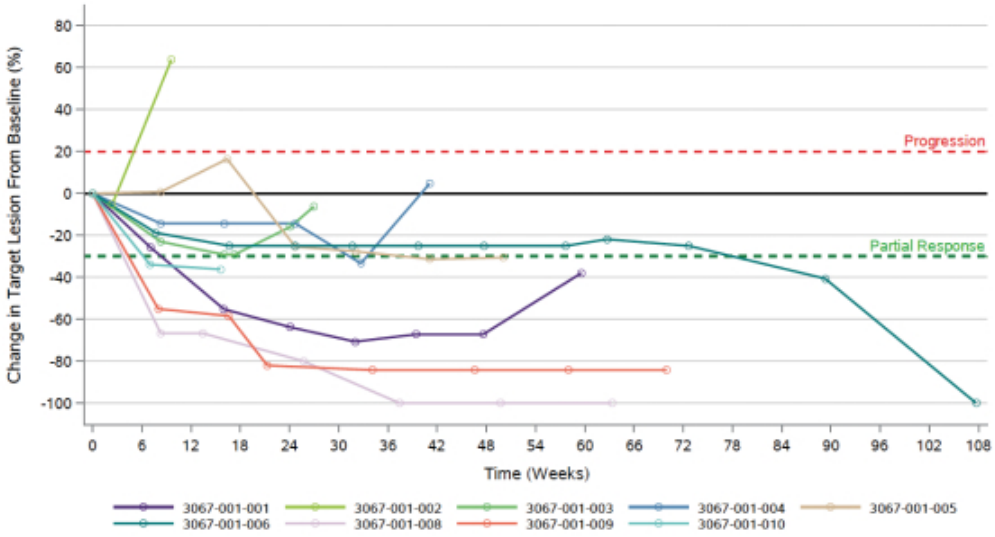
Immunomedics received approval for third line TNBC for their drug sacituzumab govitecan-hziy, in which the overall response rate was 33.3% and the median duration of response was 7.7 months.

We have treated nine patients in a Phase Ib / II trial of heavily pre-treated, metastatic TNBC with a combination immunotherapy that included Anktiva and aldoxorubicin, along with several other immunotherapy agents. Two out of the nine patients had complete responses to the combination therapy with eight of the nine patients having disease control. The primary endpoints of the Phase Ib and II portions of the study were safety and objective response rate, respectively. Serious adverse events reported in the trial included disease progression, pyrexia, mastitis, pneumonia, nausea, cholecystitis and pain in extremity, each of which was reported only once. The exploratory Phase Ib/II trial in the patients with advanced TNBC showed a disease control rate of 89% (n=9) with a complete or partial response of 67% (6 / 9). The median progression-free survival was 14.3 months with median overall survival of 20.2 months as of December 2020.

Exploratory Trial in Advanced TNBC: Aldox + Anktiva + haNK

Subjects with Complete or Partial Overall Response (immune-related response criteria, or irRC)	6 / 9 (67%)
Subjects with Complete Response (irRC)	2 / 9 (22%)
Subjects with Disease Control (irRC)	8 / 9 (89%)
Median Duration of Response (irRC)	12.7 months
Median Progression-Free Survival (irRC)	13.7 months
Average Overall Survival to date (median not yet reached)	19.2 months

The preliminary findings of our study in advanced metastatic (third-line or greater) TNBC where modalities 1, 2, and 3 were combined, showed 13.7 months progression-free survival and 19.2 months overall survival, as seen below. The Phase III IMpassion130 study of atezolizumab plus nab-paclitaxel in first line metastatic TNBC patients reported progression-free survival of 7.2 months and an overall survival of 21.3 months. We have not conducted a head-to-head clinical trial with atezolizumab.



Development in Third Line Triple Negative Breast Cancer

An open label Phase I, II and III randomized study comparing Sacituzumab Govitecan-Hziy versus Sacituzumab Plus Anktiva and PD-L1 t-haNK for the treatment of subjects with advanced Triple-Negative Breast Cancer after prior therapy, is being designed for submission in Q1 2021.

5. Colon Cancer

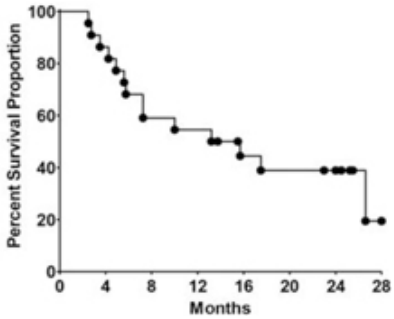
Colorectal cancer is the third leading cause of cancer-related deaths in the United States when men and women are considered separately, and the second leading cause when both sexes are combined. The American Cancer Society estimates that there will be over 104,000 new cases of colon cancer and 45,000 new cases of colorectal cancer in the United States in 2021.

ImmunityBio's colorectal cancer immunotherapy targets carcinoembryonic antigen, or CEA expressing colorectal cancer cells. CEA represents an attractive target antigen for immunotherapy since it is over-expressed in nearly all colorectal cancers and many pancreatic cancers, 70% of non-small cell lung cancers and approximately 50% of breast cancers. ImmunityBio's colorectal cancer immunotherapeutic product candidate has completed Phase I/II clinical trials at Duke University Medical Center in Durham, North Carolina and Medical Oncology Associates, in Spokane, Washington, funded by the National Cancer Institute (NCI).

Development in Metastatic Colon Cancer

A Phase I/II clinical trial evaluating dosing, safety, immunogenicity, and overall survival on metastatic colorectal cancer (mCRC) patients after immunotherapy with an advanced generation hAd5 [E1-, E2b-]-CEA(6D) vaccine candidate was performed (NCT01147965). Extended observations on long-term overall survival and further immune analyses on a subset of treated patients including assessment of cytolytic T cell responses, T-regulatory (Treg) to T-effector (Teff) cell ratios, flow cytometry on peripheral blood mononuclear cells (PBMC), and determination of HLA-A2 status was performed.

Overall median survival of 11 months was observed during long-term follow-up and no long-term adverse effects were reported. Cytolytic T cell responses increased after immunizations and cell-mediated immune (CMI) responses were induced whether or not patients were HLA-A2 positive or Ad5 immune. Preliminary results revealed that activated CD4+ and CD8+ T cells were detected in a post-immunization sample exhibiting high CMI activity.



Kaplan-Meier survival plot on long-term overall survival of metastatic colorectal cancer patients immunized 3 times with the highest doses of our vaccine candidate, demonstrating a median survival of 13 months, with 19% of patients surviving 28-months. While no head-to-head studies have been performed, this data compares favorably to historical controls of patients with late-stage metastatic colorectal cancer.

In light of these favorable results, we are exploring a trial in late-stage colorectal cancer patients

6. Merkel Cell Carcinoma

Merkel cell carcinoma, or MCC, is a rare and aggressive skin cancer that arises from uncontrolled growth of cells in the skin. Increasing in incidence, over 2,000 new cases are reported in the United States each year. Patients with metastatic or locally advanced MCC have an extremely poor prognosis, with less than 20% of patients surviving longer than five years. Typically, these patients are treated with a range of drugs, including chemotherapy, which can result in significant side effects. Although new immune therapies have the potential to improve survival, MCC is still fatal for a majority of patients who have progressed on or after treatment with a checkpoint inhibitor and represents an unmet medical need.

Development in Recurrent Merkel Cell Carcinoma

Solid Tumors	Phase	Target Indication	Preclinical	Ph I	Ph II	Ph III	Anktiva	Natural Killer	
Merkel	II	Recurrent Merkel Cell Carcinoma	Single Arm, Phase 2, Merkel				✓ Anktiva	✓ haNK	NCT03853317

QUILT 3.063 (NCT03853317) is our Phase II, open-label, single-arm trial evaluating the novel triple combination of “off-the-shelf” haNK cell therapy with Anktiva and avelumab, without chemotherapy in subjects that have progressed after treatment with a checkpoint inhibitor for MCC. This trial is currently open at multiple centers across the United States. As a rare disease, with approximately 2,000 patients being diagnosed in the United States each year, MCC patients often require regional referral and additional travel to a clinical trial site. The ongoing COVID-19 pandemic has continued to have an impact on enrollment due in part to limitations in travel and study accessibility as well as a significant reduction in patient referrals. In response to this, we will continue to implement measures to increase local community awareness of the trial as we add new sites. While we remain cautiously optimistic, it may require additional time to reach our interim data readout.

7. Glioblastoma

Recurrent Glioblastoma

Glioblastoma has an incidence of two to three per 100,000 adults per year, accounting for about 52% of all primary tumors to the brain and about 17% of all primary and metastatic brain tumors. It is an incurable disease based on current approved therapies. Relapsed patients usually receive bevacizumab with an objective response rate of approximately 20%, and overall survival of approximately 31 weeks. To date, clinical trials assessing novel therapies for recurrent glioblastoma have resulted in only modest increases in progression-free survival and minimal increases in overall survival.

Development in Recurrent Glioblastoma

We are developing a protocol to treat recurrent glioblastoma using aldoxorubicin. Unlike doxorubicin, aldoxorubicin appears to penetrate the blood-brain barrier in humans and is associated with objective tumor responses, stable disease and prolonged survival.

A single arm Phase II trial (NCT02014844) was completed in 2016 that assessed the preliminary efficacy and safety of aldoxorubicin administered to recurrent glioblastoma patients who progressed after first line therapy. The primary endpoint of the trial was objective response rate. Out of 28 subjects, investigator assessment of best overall tumor response reported one patient with a partial response and 11 patients with stable disease. Treatment-related grade 3 or 4 adverse events included: neutropenia; thrombocytopenia; febrile neutropenia; lymphopenia; anemia; decreased white blood cell count, neutrophil count or lymphocyte count; fatigue; mucosal inflammation; somnolence; hemiparesis; intestinal perforation; oral candidiasis; decreased appetite; and hypertension.

In addition, an investigator-initiated trial (NCT03383978) is ongoing exploring the safety and efficacy signals of HER2 t-haNK in patients with recurrent glioblastoma.

8. Head & Neck Cancer

Human papilloma virus, or HPV, is estimated to cause approximately 95% of cervical and 30-60% of oropharyngeal carcinoma cases. High-risk HPV type 16 is involved in more than 50% of cervical cancers worldwide and is the primary viral driver of esophageal, anal cancers, and head and neck squamous cell carcinomas, or HNSCC. HPV E6DD and E7DD genes expressed in squamous cell cancers are considered to be an attractive target for tumor specific immunotherapy because the cancer cells require E6 and E7 for progression.

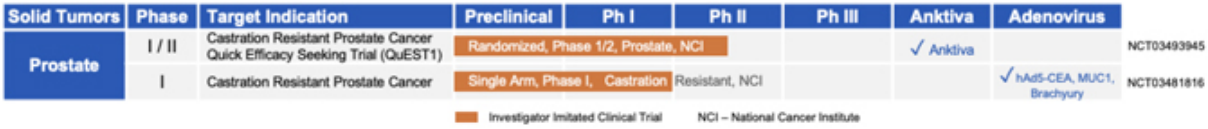
We have developed our proprietary hAd5 technology to deliver a proprietary modified/fused non-oncogenic HPV E6/E7 gene (E6D/E7D) to treat cancer patients with HPV-expressing cancer. The addition of a proprietary localization signal (ETSD) to the E6/E7 construct further distinguishes this vaccine by allowing for trafficking of the antigens to specific cellular compartments presentable and recognizable by CD4+ and CD8+ T cells, potentiating immunological memory against HPV-bearing tumor cells. This product candidate, in an earlier iteration, has been granted orphan-drug designation by the FDA for the treatment of HPV-associated HNSCC, and we intend to seek this designation for the ETSD modified product candidate.

Development in Head & Neck Cancer

9. Prostate Cancer

Prostate cancer is the second most common cancer in the United States in men with close to 200,000 new cases and over 34,000 deaths annually. One in eight men will be diagnosed with prostate cancer during their lifetime. Although localized or regional prostate cancer is highly treatable, the 5 year survival rate for distant metastatic prostate cancer is 30%.

Development in Castration Resistant Prostate Cancer



18 patients were enrolled in a Phase I/II trial to examine Ad-PSA, Ad-MUC1, and Ad-Brachyury as a therapy for patients with prostate cancer. The vaccine candidate was well tolerated with no dose limiting toxicities or grade three or higher treatment related adverse events. A Phase II trial in patients with castration resistant prostate cancer was initiated by the NCI.

10. Ovarian Cancer

There are over 20,000 new ovarian cancer cases diagnosed and approximately 14,000 deaths in the United States annually. Although ovarian cancer may occur at any age, it is more common in patients older than 50 years. Treatment often includes surgical debulking followed by chemotherapy. Prognosis is highly dependent on stage and grade and composition. Epithelial ovarian cancer is the most common type of ovarian cancer, and because 70 percent of cases are diagnosed at stage III or IV, it is associated with a poor prognosis

Allogeneic natural killer (NK) cell transfer is a potential immunotherapy to eliminate and control cancer. A promising source are CD34+hematopoietic progenitor cells (HPCs), since large numbers of cytotoxic NK cells can be generated. Effective boosting of NK cell function can be achieved by interleukin (IL)-15. However, its in vivo half-life is short and potent transpresentation by IL-15 receptor α (IL-15Rα) is absent.

ImmunityBio developed IL-15 superagonist N-803 (Anktiva), which combines IL-15 with an activating mutation, an IL-15Rα sushi domain for trans-presentation, and IgG1-Fc for increased half-life. Here, we investigated whether and how Anktiva improves HPC-NK cell functionality in leukemia and ovarian cancer (OC) models in vitro and in vivo in OC-bearing immunodeficient mice. We used flow cytometry-based assays, enzyme linked immunosorbent assay, microscopy-based serial killing assays, and bioluminescence imaging, for in vitro and in vivo experiments. Anktiva increased HPC-NK cell proliferation and interferon (IFN)g production. On leukemia cells, co-culture with HPC-NK cells and Anktiva increased ICAM-1 expression. Furthermore, Anktiva improved HPC-NK cell-mediated (serial) leukemia killing. Treating OC spheroids with HPC-NK cells and Anktiva increased IFNg-induced CXCL10 secretion, and target killing after prolonged exposure. In immunodeficient mice bearing human OC, Anktiva supported HPC-NK cell persistence in combination with total human immunoglobulins to prevent Fc-mediated HPC-NK cell depletion. Moreover, this combination treatment decreased tumor growth.

Anktiva is a promising IL-15-based compound that boosts HPC-NK cell expansion and functionality in vitro and in vivo. Adding Anktiva to HPC-NK cell therapy could improve cancer immunotherapy.

Development in Advanced Ovarian Cancer

An investigator at the University of Minnesota is also conducting a single site, Phase II trial (NCT03054909) to study patients with late-stage ovarian cancer with single agent Anktiva via subcutaneous or intraperitoneal administration. The data demonstrated intraperitoneal (IP) or subcutaneous administered Anktiva, increases NK cell cytotoxicity in ovarian cancer.

11. Sarcoma

Soft tissue sarcomas arise in any of the mesodermal tissues of the extremities, trunk, retroperitoneum, or head and neck. There will be an estimated 13,130 new cases of soft tissue sarcoma in the United States in 2020 and 5,350 deaths resulting from the disease. The five-year survival rate for localized soft tissue sarcoma is approximately 81%, which drops 57% and 16% for regional and distant metastatic disease, respectively. Treatment for Stage I-III soft tissue sarcoma includes surgery which can be followed by radiation and chemotherapy. Stage IV disease is rarely curable, with surgery, radiation and chemotherapy (with drugs doxorubicin and Ifosfamide) being the most common therapeutic approach.

Development in Sarcoma:

Aldoxorubicin Single Agent Studies

Aldoxorubicin has been extensively studied in Phase I, II and III as a single agent and in combination with Ifosfamide/Mesna (Phase Ib/II). The furthest development has been in soft tissue sarcomas where Phase I, II and III studies have been completed. There have also been Phase II trials in lung cancer, pancreatic cancer, glioblastoma and Kaposi's sarcoma in HIV positive patients.

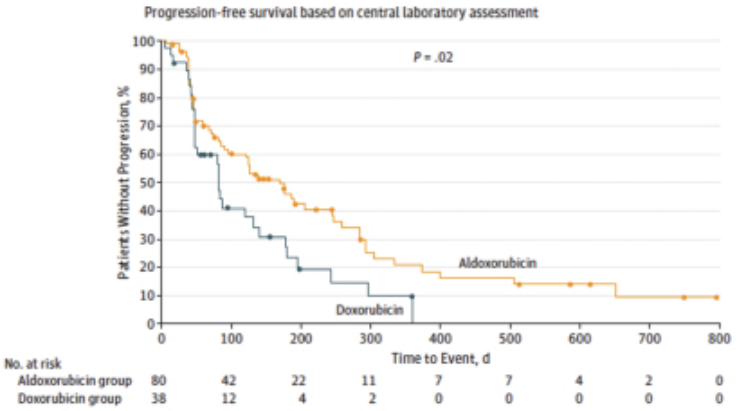
In 2014, a Phase II trial (NCT01514188) conducted by CytRx compared the safety and efficacy of aldoxorubicin to doxorubicin in patients with metastatic, locally advanced, unresectable soft tissue sarcoma. In this randomized study, patients received aldoxorubicin at 350 mg/m2 or doxorubicin at 75 mg/m2, with the lower dose of doxorubicin set due to the association between the cumulative dose of doxorubicin and cardiotoxicity. Aldoxorubicin showed lower rates of cardiac events than doxorubicin, measured as a drop in left ventricular ejection fraction, or LVEF. The rate of patients with ³10% drop in LVEF was 8% for aldoxorubicin versus 35% for doxorubicin after four cycles of treatment. The drop in LVEF persisted at two months after the end of treatment in 3.7% of patients treated with aldoxorubicin versus 33% of those treated with doxorubicin.

The Phase II trial results also showed that aldoxorubicin had a higher rate of response than doxorubicin. The median progression free survival, the primary efficacy endpoint, was significantly longer for aldoxorubicin versus doxorubicin. The results of the study are shown below.

	Assessment, No. (%)			
	Investigator		Central Laboratory	
Patients With Response	Aldoxorubicin Group (n = 83)	Doxorubicin Group (n = 40)	Aldoxorubicin Group (n = 80)[a]	Doxorubicin Group (n = 38)[a]
CR	2 (2)	0	0	0
PR	17 (20)	2 (5)	20 (25)	0
Overall response (CR+PR)	19 (23)	2 (5)	20 (25)	0
SD	45 (54)	25 (62)	30 (38)	17 (45)
Disease control (CR+PR+SD)	64 (77)	27 (68)	50 (62)	17 (45)
Progressive disease	13 (16)	11 (28)	24 (30)	17 (45)
Not evaluable	6 (7)	2 (5)	6 (8)	4 (11)

Abbreviations: CR – Complete Response, PR – Partial Response, SD – Stable Disease
* For 3 patients in the aldoxorubicin group and 2 patients in the doxorubicin group, the independent central laboratory did not identify a measurable lesion at screening.

The figure below shows the rates of progression-free survival for aldoxorubicin versus doxorubicin based on Central Radiology Review.



In addition, in 2017, a Phase III trial (NCT02049905) of aldoxorubicin versus physician's choice of treatment was completed. The trial was found to be underpowered to meet the primary efficacy endpoint, however, aldoxorubicin was shown to have a significantly lower cardiotoxicity compared to doxorubicin, even at nearly four times the cumulative dose of doxorubicin.

Cardiac Toxicity	Aldoxorubicin (N = 213)	Investigator's Choice Doxorubicin (N = 47)
Number of Cycles (Mean)	6.3	4.1
Mean Cumulative Dose	**2,190 mg** Total Cumulative Dose Achieved (Upper Limit)	578 mg Total Cumulative Dose Achieved (Upper Limit)
Subjects who received doxorubicin as compared to aldoxorubicin had a ≥ 20% decrease in LVEF from baseline at any postbaseline visit	**4.2%**	**10.6%**
Percentage of subjects with LVEF below 50% at any postbaseline visit was greater for the doxorubicin group as compared to the aldoxorubicin group	**7.0%**	**19.1%**

12. Advanced Solid Tumors

Clinical Development in Advanced Solid Tumors

A. Multi-Targeted Recombinant hAd5 CEA, MUC1, Brachyury Vaccine Regimen in Advanced Solid Tumors

In advanced solid tumors, ImmunityBio uses a second-generation human adenovirus (hAd5) to administer CEA, MUC1 and Brachyury concurrently to patients with advanced cancer. We performed an open-label, Phase I trial (NCT03384316) that evaluated concurrent administration of three therapeutic vaccines (ETBX-011 = CEA, ETBX-061 = MUC1 and ETBX-051 = brachyury). All three vaccines used the same modified adenovirus 5 (hAd5) vector backbone and were administered at a single dose level (DL) of 5×10^{11} viral particles (VP) per vector. The vaccine regimen consisting of all three vaccines was given every 3 weeks for three doses then every 8 weeks for up to 1 year. Clinical and immune responses were evaluated.

All patients developed $CD4^+$ and/or $CD8^+$ T-cell responses after vaccination to at least one tumor-associated antigen (TAA) encoded by the vaccine; 5/6 patients (83%) developed MUC1-specific T cells, 4/6 (67%) developed CEA-specific T cells, and 3/6 (50%) developed brachyury-specific T cells. The presence of adenovirus 5-neutralizing antibodies did not prevent the generation of TAA-specific T cells.

		Immune responses to MUC1								Immune responses to CEA								Immune responses to brachyury							
Patient no.	Post (vs. pre) no. of vaccines	CD4 CD107a	CD4 IFNg	CD4 IL-2	CD4 TNF	CD8 CD107a	CD8 IFNg	CD8 IL-2	CD8 TNF	CD4 CD107a	CD4 IFNg	CD4 IL-2	CD4 TNF	CD8 CD107a	CD8 IFNg	CD8 IL-2	CD8 TNF	CD4 CD107a	CD4 IFNg	CD4 IL-2	CD4 TNF	CD8 CD107a	CD8 IFNg	CD8 IL-2	CD8 TNF
PT3	1	0	185	0	0	0	543	3	0	0	0	0	0	0	0	43	0	0	0	0	44	0	362	0	0
	2	0	0	0	83	0	0	0	0	0	0	93	0	0	872	0	0	0	0	0	43	0	0	0	0
	3	97	7,331	3,866	12,531	133	425	49	2609	0	0	0	0	156	36	0	0	1,915	526	0	167	4,043	749	0	3,524
PT4	2	4,953	71,357	15,069	97,145	44,851	19,578	148	39,117	18	81	35	172	0	0	0	0	99	103	0	0	0	0	0	0
	9	9,439	178,943	22,691	223,919	22,480	10,343	0	16,598	0	0	0	0	0	0	0	0	192	25	146	0	0	0	0	0
PT5	1	0	0	2,057	1,435	0	0	140	0	13	0	1,881	1,300	0	0	30	0	0	0	0	0	0	0	172	0
	2	0	0	634	585	0	0	47	0	41	0	274	529	0	332	0	0	0	0	0	0	0	0	0	0
	3	134	0	0	0	0	228	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	810	381	1,603	4,002	1,219	0	0	0	0	0	0	0	3,962	781	0	0	0	0	0	0	0	0	0	0
PT8	2	0	0	0	0	620	0	0	390	0	2	0	0	166	0	0	86	0	112	0	0	281	0	0	216
	3	50	0	0	0	0	0	0	0	170	0	0	0	0	0	0	0	72	0	0	0	0	0	0	0
PT10	2	81	0	0	0	0	703	8	0	0	458	0	0	69	656	332	2,563	0	0	0	0	1,446	1,075	0	13,882
PT11	2	0	0	0	0	0	0	14	0	0	484	44	241	343	0	42	0	0	0	0	0	0	0	0	0

Table: *Tumor-associated antigen T cell responses developed after treatment with the TriAdeno vaccine regimen.* Immune responses reported in this table are calculated by comparing the absolute number of $CD4^+$ or $CD8^+$ T cells producing cytokine (IFN, IL-2, TNFα) or positive for CD107a per 1×10^6 PBMCs plated at the start of the in vitro stimulation at the specified time points after vaccine. Background (obtained with the negative control peptide pool, human leukocyte antigen [HLA]) and any response prior to vaccine are subtracted: [TAA after vaccine – HLA after vaccine] – [TAA before vaccine – HLA before vaccine]. Positive immune responses are defined as >250 (highlighted). Abbreviations: IFNg, interferon gamma; IL-2, interleukin-2; PT, patient; TNF, tumor necrosis factor.

Ten patients enrolled on trial (DL1 = 6 with 4 in the DL1 expansion cohort). All treatment-related adverse events were temporary, self-limiting, grade 1/2 and included injection site reactions and flu-like symptoms. Antigen-specific T cells to MUC1, CEA, and/or brachyury were generated in all patients. There was no evidence of antigenic competition. The administration of the vaccine regimen produced stable disease as the best clinical response.

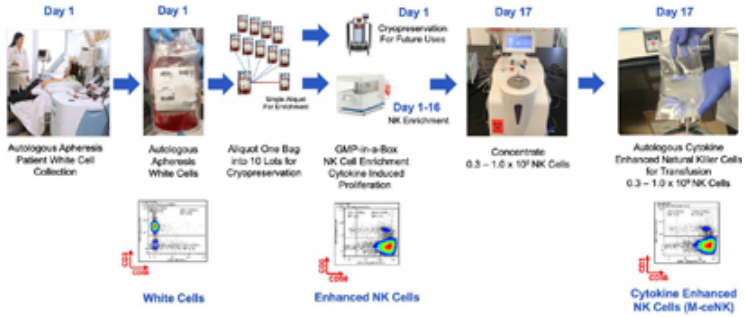
In conclusion, concurrent CEA, MUC1, and Brachyury can be administered to patients with advanced cancer with little to no risk of SAEs. Further studies of the vaccine regimen in combination with other agents, including immune checkpoint blockade, are planned.

B. Yeast Neoepitope

ImmunityBio's yeast vaccine platform, licensed from IB subsidiary GlobeImmune Inc., has been administered to over 800 patients with cancer or infectious diseases in FDA-regulated clinical trials with no SAEs. This platform technology consists of a heat-killed, recombinant *S. cerevisiae* yeast-based vaccine engineered to express immunogens such as tumor-associated antigens (TAA), pathogen antigens, and tumor-specific neoepitopes. Immunization with this platform elicits CD4+ and CD8+ T-cell responses capable of eliminating tumor cells or pathogen-infected cells. ImmunityBio recently conducted a first-in-human Phase I clinical trial of a yeast vaccine engineered to express patient and tumor-specific neoepitopes. Patients with cancer were administered yeast vaccines expressing multiple neoepitopes identified through a proprietary algorithm incorporating analysis of tumor vs normal DNA sequence, tumor RNA expression, and predicted human leukocyte antigen (HLA)-neoepitope binding. Since its licensure, ImmunityBio has improved the potency of the yeast vaccine by further processing the whole cell product into a lysate, thus directly exposing the immunogen and yeast immunogenic proteins to lymphocytes. This new product further accentuates a tumor-suppressive Th1 dominant response, while also potentially furthering the patent life cycle for this platform. Finally, ImmunityBio has developed a robust, scalable, and economical manufacturing process for the yeast platform, conducive to producing large scale products such as TAA or pathogen vaccines or rapid production of sufficient doses for N of 1 products such as the neoepitope vaccines.

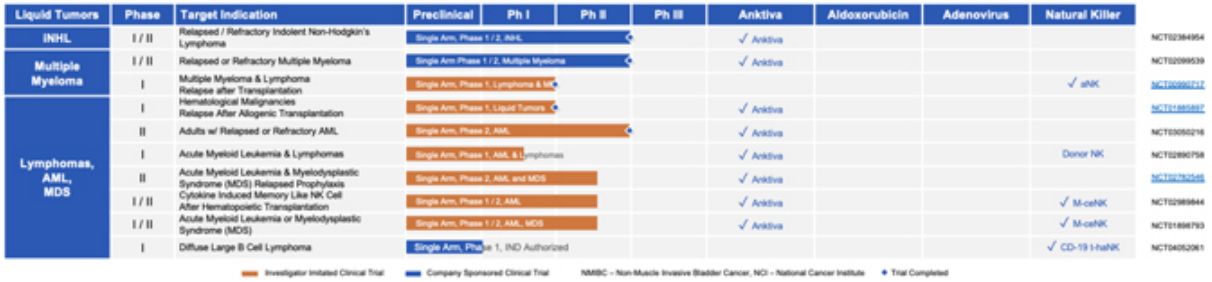
C. M-ceNK - *Memory Cytokine Enriched Natural Killer Cell Platform.*

Cytokine-induced memory-like NK cells are a unique set of lymphocytes that differentiate after a brief pre-activation with interleukin-12 (IL-12), IL-15, and IL-18 and exhibit enhanced responses to cytokine re-stimulation that include enhanced interferon-g production and cytotoxicity against leukemic cell lines. These cells have been isolated and characterized by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade. Published data so far has been limited to the acute myeloid leukemia patient population in the post-allogeneic, haploidentical stem cell transplantation setting.



Our cytokine enriched natural killer cell program is based on the ability to enrich and expand donor sourced NK cells in a GMP facility to a clinically relevant scale which allows for the production of a pure cytokine activated and expanded NK cell population that possesses the unique phenotype we call **M-CENK** cells. Phase I M-ceNK clinical trials in subjects with locally advanced or metastatic solid tumors is anticipated to begin in the second half of 2021.

VIII. OUR LIQUID TUMOR CLINICAL DEVELOPMENT PROGRAM



1. iNHL – Indolent Non-Hodgkin's Lymphoma

Incidence of iNHL

Over 80,000 adults and children will be diagnosed with Non-Hodgkin's Lymphoma, or NHL, and close to 20,000 with die each year in the United States. Slow-growing or indolent subtypes represent about 40 percent of all NHL cases annually. Indolent lymphomas commonly have fewer signs and symptoms when first diagnosed as they are slow growing and moving relative to aggressive lymphomas. Follicular lymphoma (FL) is the most common subtype of indolent NHL.

Immunotherapy is a rising modality in NHL cancer therapeutics, harnessing concepts from immunology to enhance, trigger, or rescue immune responses against malignant targets. Established immunotherapies include engineered therapeutic monoclonal antibodies (mAbs), such as the anti-CD20 mAb rituximab, which targets endogenous Fc-receptor bearing immune cells, including natural killer (NK) cells, to B cell malignancies.

IL-15 is a key cytokine for the development, survival, and function of NK cells. Recent in vitro and in vivo work demonstrated the ability of IL-15 to prime non-cytotoxic $CD56^{bright}$ NK cells to become anti-tumor effectors, a function previously believed to be largely restricted to the $CD56^{dim}$ NK cell subset. IL-15 also plays a key role in supporting memory CD8+ T cells, thus augmenting two types of anti-tumor effector lymphocytes. In vivo, IL-15 is trans-presented by IL-15Rα from accessory cells such as monocytes/macrophages and dendritic cells to ligate the IL-2/15Rgb heterodimer expressed on NK and T cells, resulting in activation of multiple signaling pathways, and hence multiple anti-tumor functions. Although IL-15 and IL-2 share signaling components, including the beta (CD122) and gamma chain (CD132), they have divergent effects, with IL-2 promoting Treg expansion. Initial pioneering studies tested *E. coli*-derived recombinant human (rh)-IL-15, which demonstrated immune modulation in patients. However, rhIL-15 has a short half-life and dose levels that modulated immune cells were limited by unacceptable adverse events (AE). N-803 (Anktiva) is an IL-15R super agonist complex with a prolonged in vivo half-life, physiologic trans-presentation, and accumulation in secondary lymphoid tissues.

Clinical Development in Relapsed / Refractory iNHL:

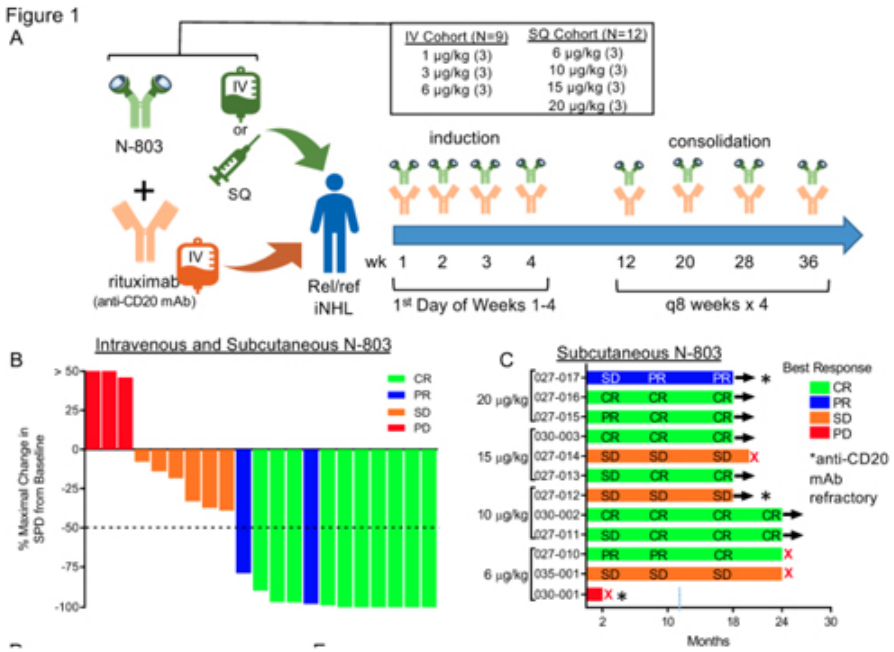
Liquid Tumors	Phase	Target Indication	Preclinical	Ph I	Ph II	Ph III	Anktiva	
iNHL	I / II	Relapsed / Refractory Indolent Non-Hodgkin's Lymphoma	Single Arm, Phase 1 / 2, iNHL				✓ Anktiva	NCT02384954

Company Sponsored Clinical Trial ◆ Trial Completed

In a multicenter Phase I study (NCT02384954), we tested the hypothesis that combining Anktiva with the lymphoma-targeting anti-CD20 mAb rituximab safely augments the immune system and response against indolent non-Hodgkin lymphoma (iNHL). This immunotherapy combination was well-tolerated, with no observed SAEs, and resulted in durable clinical responses including in rituximab-refractory patients. Subcutaneous Anktiva plus rituximab induced sustained proliferation, expansion, and activation of peripheral blood NK cells and CD8 T cells in vivo.

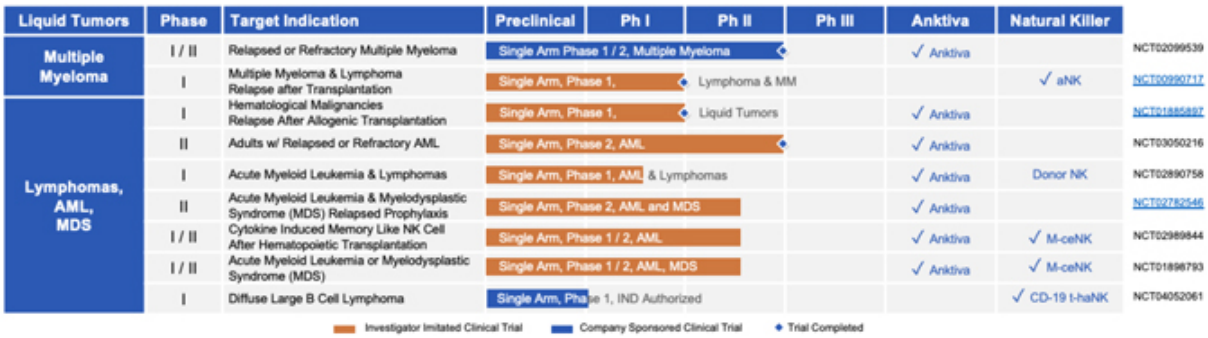
Overall response rate (ORR) was 67% (8 of 12) in the SQ cohort. The majority of patients experienced reductions in the size of their lymph nodes. For patients with anti-CD20 mAb sensitive disease, the ORR in the SQ cohort was 78% (7 of 9). In the SQ cohort, 7 of 7 (100%) responses were complete remissions (CR).

Patients in the SQ cohort had prolonged stable disease (SD) and conversion of SD and/or partial response (PR) to CR with a prolonged duration without progression (8 of 12 patients without progression at 18-24 months). In the SQ cohort, 6/7 CRs occurred at either the first (11 weeks) or second evaluation (40 weeks). In the IV cohort, CR responses occurred following the second evaluation and as late as 18 months follow-up. For the 5 patients with anti-CD20 mAb refractory disease in both IV and SQ cohorts, the ORR was 2 of 5 (40%) with 1 CR, 1 PR, 1 SD, and 2 PD. The PR and SD are ongoing in the SQ patients at > 18 months. The SQ cohort patient with PD was highly refractory, having received 5 prior lines of therapy.



Based on these encouraging findings of 100% complete remission (7 out of 7) in patients receiving subcutaneous Anktiva, ImmunityBio will explore the development of subcutaneous Anktiva in combination with rituximab +/- CD-19 t-haNK in this indication.

Liquid Tumors: Multiple Myeloma, Lymphomas, AML, MDS



Development in Multiple Myeloma, Lymphomas, AML and MDS:

Early in the development history of NK-92, we conducted a single-center, non-randomized, non-blinded, open-label, Phase I (NCT00990717) dose-escalation trial of irradiated NK-92 cells in adults with refractory hematological malignancies who relapsed after autologous hematopoietic cell transplantation (AHCT). The objectives were to determine safety, feasibility and evidence of activity. Patients were treated at one of three dose levels (1×10^9 cells/m2, 3×10^9 cells/m2 and 5×10^9 cells/m2), given on day 1, 3 and 5 for a planned total of six-monthly cycles.

Twelve (12) patients with lymphoma or multiple myeloma who relapsed after AHCT for relapsed/refractory disease were enrolled in this trial. The treatment was well tolerated, with minor toxicities restricted to acute infusion events, including fever, chills, nausea and fatigue. Two patients achieved a complete response (Hodgkin lymphoma and multiple myeloma), two patients had minor responses and one had clinical improvement on the trial.

Irradiated NK-92 cells can be administered at very high doses with minimal toxicity in patients with refractory blood cancers, who had relapsed after AHCT. We conclude that high dose NK-92 therapy shows some evidence of safety and efficacy in patients with refractory blood cancers and warrants further clinical investigation.

Since 2016, ImmunityBio has pursued two paths to develop natural killer cells for the treatment of liquid tumors:

- Off-the-shelf CD19 t-haNK
- Allogeneic and allogenic memory cytokine enhanced natural killer cells (M-ceNK)

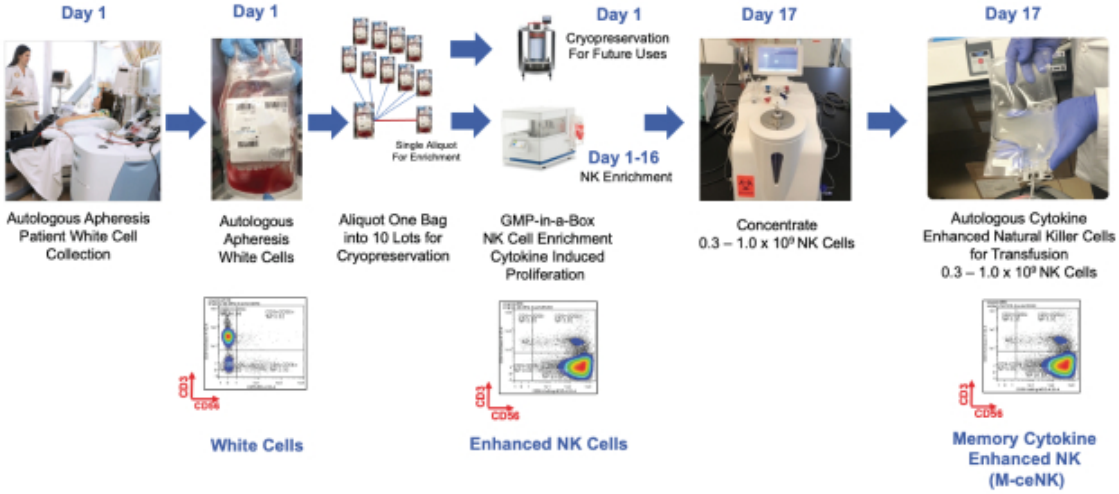
It is anticipated that these cellular therapies, combined with Anktiva which has been shown to enhance in-vivo NK and T cell proliferation, will provide next-generation approaches to liquid tumors.

A. Off-The-Shelf CD19 t-haNK

Our newest and one of our most promising platforms for the development of therapeutic product candidates is an innovative, bioengineered combination of our haNK and taNK platforms that incorporates all the features of our haNK platform together with a CAR. The resulting line of product candidates under this platform avails itself to all three modes of killing: innate, antibody-mediated and CAR-directed killing. These product candidates also include one or more additional expression elements such as functional cytokines, chemokines and trafficking factors, making them amongst the most versatile in our portfolio.

These product candidates are intended to be combined with commercially available therapeutic antibodies to effectively target either two different epitopes of the same cancer specific protein or two entirely different cancer specific proteins. In addition to our two t-haNK product candidates, PD-L1.t-haNK, recently cleared to commence Phase II trials, and CD19.t-haNK, cleared to commence Phase I trials. Based on the encouraging data of Anktiva in combination with rituximab, we anticipate combining CD19 t-haNK to this chemotherapy free protocol for the treatment of liquid tumors including diffuse large b-cell lymphoma and non-Hodgins's lymphoma.

B. M-ceNK - Memory Cytokine Enriched Natural Killer Cell Platform.



Cytokine-induced memory-like NK cells are a unique set of lymphocytes that differentiate after a brief pre-activation with interleukin-12 (IL-12), IL-15, and IL-18 and exhibit enhanced responses to cytokine re-stimulation that include enhanced interferon-g production and cytotoxicity against leukemic cell lines. These cells have been isolated and characterized by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade.

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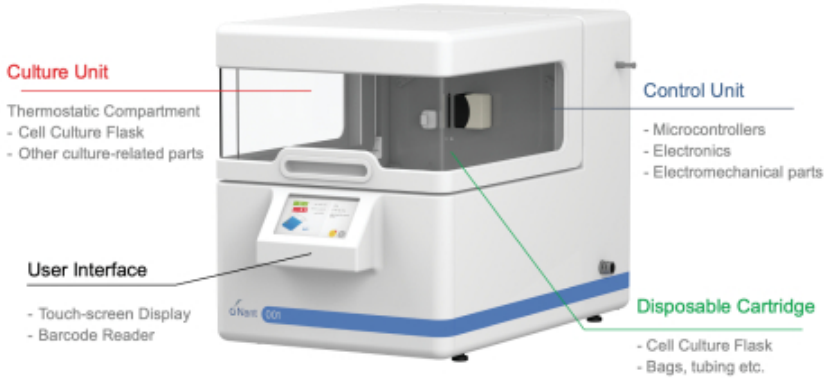
C. GMP-in-a-Box Approach



We are a leading company in the efforts to generate allogeneic and autologous sourced NK and mesenchymal stem cell, or MSC, therapeutics. We utilize a scalable GMP production process that combines the use of our semi-automated manufacturing equipment, cytokine expansion and activation reagents such as Anktiva and TxM, and unique and simple processing methods, all of which are proprietary. We have optimized processes for generating both fresh and cryopreserved clinical dose forms of memory-like NK cells with 100% purity (in the allogeneic setting) from a variety of sources, including cord blood and allogeneic and autologous peripheral blood. We avoid the use of both feeder-layers for activation as well as other commonly applied additives that frequently create downstream issues in achieving a high-quality releasable final dose form and have been able to generate multiple dose forms from each donor product, both of which are critical features in achieving scalability.

IX. OUR INFECTIOUS DISEASE CLINICAL DEVELOPMENT PROGRAM

1. HIV

Anktiva is being evaluated in subjects infected with HIV and multiple investigator-initiated Phase I clinical trials at the University of Minnesota and the University of California San Francisco, and a national multi-site trial with the AIDS Clinical Trial Group, or the ACTG, are in development.

The current strategy for curing HIV is known as the “kick and kill” approach. The “kick” is to induce HIV out of its latent resting state in T cells and the “kill” is to remove or kill the infected cells via an immune response or immunotherapy. Anktiva is a molecule capable of both kick and kill in this strategy because of its ability to activate viral transcription in CD4+ T cells (kick) while strongly activating CD8+ effector memory cells and NK cells important for recognizing and killing HIV infected cells (kill), as well as directing these cells to sites of viral reservoirs.

In multiple non-human primate experiments, Anktiva has been shown to activate CD8+ and NK cells and home these cells to lymphoid organs including normally T cell protected areas such as B cell follicles, reducing the amount of virus in these tissues at the same time. In these animal studies a significant reduction of plasma viremia was observed in NHPs infected with Simian Immunodeficiency Virus, or SIV, for over one year, who were given Anktiva weekly for four weeks.

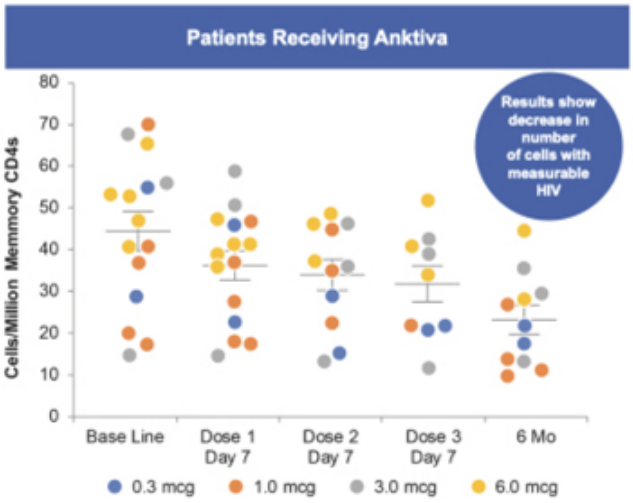
Recently, Anktiva has also shown strong activation of SIV from latency in NHP that are also CD8+-depleted, indicating an additional mechanism for shocking HIV out of hiding and perturbing the viral reservoir ultimately necessary in HIV cure strategies.

We have observed that Anktiva plus one or two anti-HIV broadly neutralizing antibodies, or bNAbs, has allowed long term suppression of simian/human immunodeficiency virus replication in the absence of anti-retroviral therapy in nine of the 13 animals.

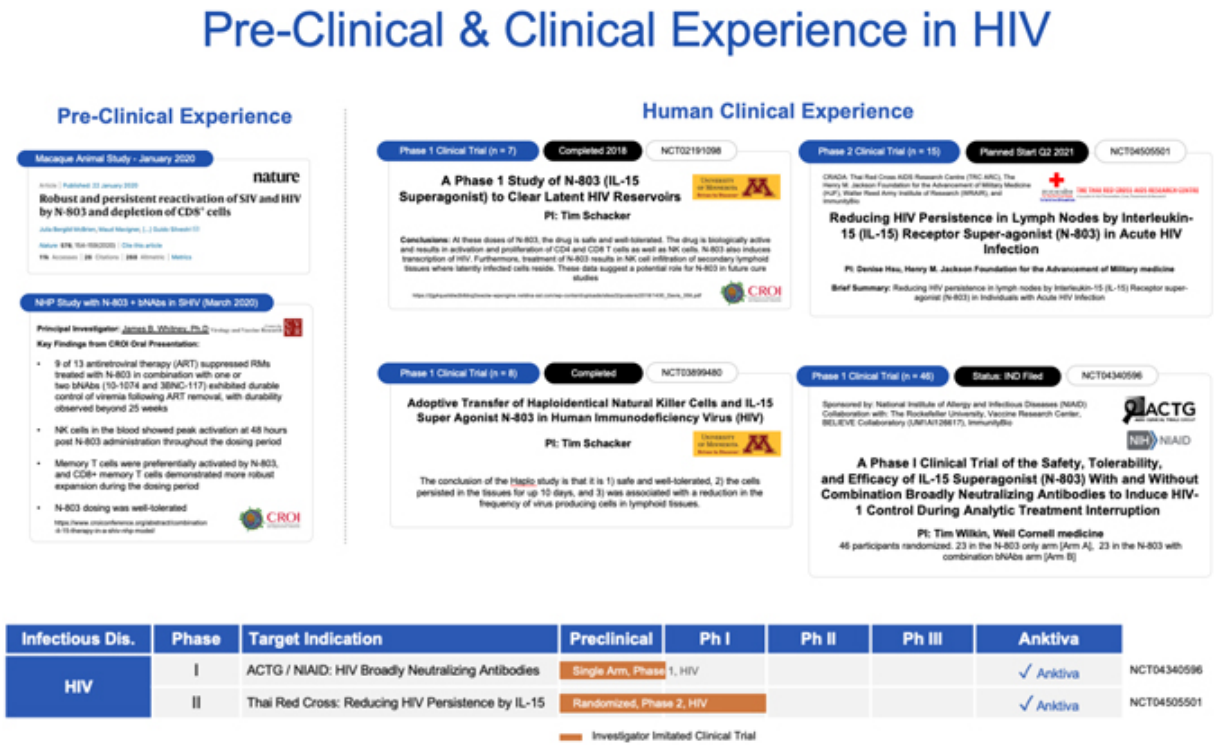
To follow on from these preclinical experiments, we filed an IND in December 2020 to conduct a Phase I clinical trial (N=46) of Anktiva plus two bNAbs sponsored by National Institute of Allergy and Infectious Diseases (NIAID) and conducted by the ACTG. This trial will explore whether Anktiva in combination with bNAbs can result in long term viral remission in the absence of anti-retroviral drugs, functionally curing patients from HIV infection.

Clinical Evidence of Viremia Control in HIV Patients

With respect to HIV, a Phase I clinical dose escalation study with the aim to determine the safety and tolerability of Anktiva in HIV-infected patients has been completed. The study has mirrored preclinical results in non-human primates in that Anktiva induces significant activation and proliferation of T and NK cells, shows evidence for activating virus transcription, suggests reservoir reduction in peripheral blood mononuclear cells, or PBMC, and produces no evidence of production of IL-15 antibodies or cytokine side effects, as shown in the figure below. The figure below shows a decrease over time in the number of cells with measurable HIV.



Clinical Development in HIV:



A second Phase I trial (NCT04340596) with total enrollment of eight patients is currently evaluating Anktiva in combination with adoptive transfer of haplo-identical NK cells. The primary and secondary objectives of this trial are to determine the safety of adoptive transfer of haploidentical NK cells when given with Anktiva therapy to HIV infected subjects who are on fully suppressive HIV therapy and to determine if adoptive transfer of haploidentical NK cells will decrease HIV virus reservoirs, respectively. HIV-infected individuals

who have been maintained on suppressive antiretroviral therapy for a minimum of 12 months with a CD4 count ≥500 cells/µl will be eligible for the therapy.

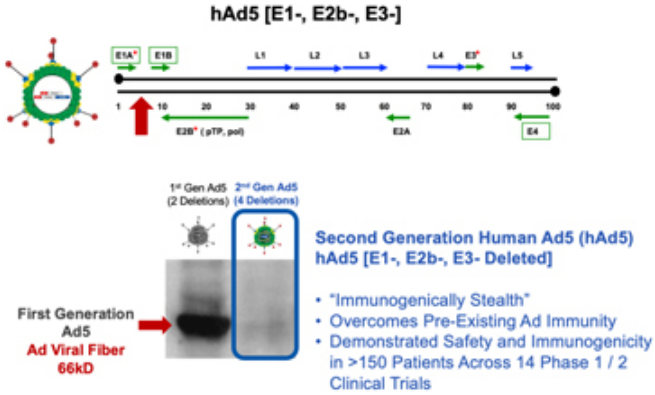
An additional Phase II (NCT04505501) protocol, anticipated to enroll 15 patients, in development with the Thai Red Cross and the United States Military HIV Research Program, is designed to investigate the safety, tolerability and immunostimulatory effects of administering Anktiva during acute HIV infection. Anktiva will be administered subcutaneously at weeks zero, three and six (for a total of three doses) and will be initiated together with antiretroviral therapy in order to determine if the immunostimulatory effects of Anktiva will reduce the amount of HIV present during acute infection. The study duration for individual participants will be approximately 12 weeks. It is hypothesized that Anktiva initiated with antiretroviral therapy during acute HIV infection will not result in complications or additional toxicities compared with anti-retroviral therapy alone, and may result in a reduced viral load in these subjects.

2. COVID-19

We have developed vaccine technologies to deliver tumor-associated antigens, or TAAs, and neoepitopes (expressed only by cancer cells), including hAd5, a second-generation adenovirus. Our vaccine technologies have the capability to induce T cell memory due to the activation of both CD4+ and CD8+ T cells along with antibody (or humoral) responses. Our hAd5 technology has produced several product candidates, which have been studied in multiple Phase I and Phase II clinical trials as potential vaccines for the treatment of certain cancers. Importantly, these product candidates have shown an ability to overcome previous adenovirus immunity in cancer patients and in preclinical models. The hAd5 technology has also been used with common TAAs to establish memory T cells in multiple clinical trials.

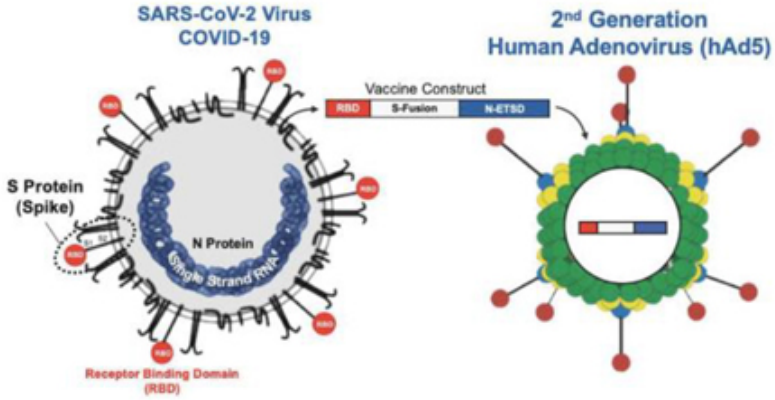
First-Generation Versus Second-Generation Adenovirus in a COVID-19 Context

First-generation adenovirus vectors feature the deletion of E1 and/or E3 genes normally responsible for producing viral structural proteins that generate anti-adenovirus-specific immune responses [E1- E3-]. Because adenoviruses are among the causes of the common cold, adenovirus immunity can be as high as 40-70% of the population. Therefore, using these first-generation adenovirus vectors as vaccines faces an immediate hurdle in needing to overcome this pre-existing immunity against the vector itself. Current developers of adenovirus-based COVID-19 vaccines and vaccine candidates appear to be challenged with reduced immunogenicity in patients with pre-existing adenovirus immunity. To address this issue, we have established a second-generation adenovirus vaccine candidate, leveraging our hAd5 technology, with the capability of being administered in the presence of this pre-existing adenovirus immunity for the delivery of tumor associated antigens or SARS-CoV-2 antigens in the fight against COVID-19, as a primary vaccine and/or as a booster to other vaccines.



Our advanced second-generation adenovirus technology, with two additional deletions in the E2b region [E1-, E2b-, E3-], confers advantageous immune properties to the vaccine candidate by eliciting potent immune responses to inserted viral (e.g. COVID-19) antigens while minimizing the immune responses to the adenovirus vector itself. Neutralizing antibodies and cytotoxic T cells recognizing adenovirus are directed to the adenovirus fiber protein and other “late” proteins whose expression is muted in our second-generation adenovirus technology. Thus, in individuals with pre-existing adenovirus immunity, we have demonstrated the generation of immunogenic responses to inserted antigens in multiple vaccinations over many months. Because of these modifications, we believe that our hAd5 [E1, E2b-, E3-] vectors have the potential to be superior to adenovirus [E1-] vectors in terms of immunogenicity and safety profile, and are a compelling technology to develop a COVID-19 vaccine in a rapid and efficient manner.

Our Next Generation COVID-19 Vaccine Candidate



The Differentiated Approach and Current Status of Our COVID-19 Vaccine Candidate Development

To address the ongoing COVID-19 pandemic, particularly in the face of mutations in Spike protein and the high efficiency of SARS-CoV-2 transmission that puts vulnerable persons and front-line workers at risk, we have developed a vaccine candidate to protect individuals from and prevent transmission of SARS-CoV-2 that elicits not only robust humoral responses but also activates T cells. This bivalent hAd5 S-Fusion + N-ETSD vaccine candidate expresses both an optimized viral spike (S) protein (S-Fusion) and a nucleocapsid protein with an Enhanced T-cell Stimulation Domain (N-ETSD) that directs N to the endo/lysosomal subcellular compartment to enhance MHC class II responses. The vaccine antigens are delivered by the second-generation adenovirus serotype 5 [E1-, E2b-, E3-] platform that appear to be safe and effective even in the presence of pre-existing adenovirus immunity. We previously developed this attenuated hAd5 viral vector platform that can be used to rapidly generate vaccines against multiple agents, allowing production of high numbers of doses in a minimal time frame. The hAd5 platform has unique deletions in the early 1 (E1), early 2 (E2b) and early 3 (E3) regions (hAd5 [E1-, E2b-, E3-]), which distinguishes it from other adenoviral vaccine platform technologies under development, and not only allows it to be effective in the presence of pre-existing adenovirus immunity but has a very low risk of generating de novo vector-directed immunity. Genes encoding target antigens are cloned into the viral genome, which once administered in vivo infect antigen presenting cells that express the inserted antigen gene and induce immune responses to the pathogenic target. The platform induces both antibodies and cell mediated immunity (CMI).

We have utilized this platform to produce vaccines candidates against viral antigens such as Influenza, HIV-1 and Lassa fever and COVID-19. In 2009, we employed the hAd5 [E1-, E2b-, E3-] vector platform to express hemagglutinin (HA) and neuraminidase (NA) genes from the H1N1 pandemic viruses (see Figure below). Inserts were consensus sequences designed from viral isolate sequences and the vaccine was rapidly constructed and

produced. Vaccination induced H1N1 immune responses in mice, which afforded protection from lethal virus challenge. In ferrets, vaccination protected from disease development and significantly reduced viral titers in nasal washes. H1N1 CMI as well as antibody induction correlated with the prevention of disease symptoms and reduction of viral replication.

The overwhelming majority of other SARS-CoV-2 vaccines and vaccine candidates in development target only the S antigen (see Figure below) and are expected to elicit SARS-CoV-2 neutralizing antibody responses. In the development of our vaccine candidate, we have paid specific attention to the generation of T cells which is predicted to enhance the breath and duration of the protective immune response against the two antigens; the addition of N in particular affords a greater opportunity for T cell responses. Importantly, we have previously shown that the hAd5 S-Fusion + N-ETSD vaccine candidate elicits T helper cell 1 (Th1) dominant antibody responses to both S and N as well as T-cell activation after vaccination of a murine (CD1) pre-clinical animal model. We have also shown that the SARSCoV-2 antigens expressed by the hAd5 S-Fusion + N-ETSD construct are recognized by T cells from previously SARS-CoV-2 infected individuals when expressed by autologous monocyte derived dendritic cells. These studies provide evidence that vaccination with the hAd5 S-Fusion + N-ETSD vaccine candidate (see Figure below) will re-capitulate natural infection that will then generate protective antibodies and memory T cells. As described in Canete and Venuesa's "COVID-19 makes B cells forget, but T cells remember", T cells provide protection even in the absence of antibody responses. This is supported by Sekine et al., who characterized T cell immunity in COVID-19 convalescent patients, finding SARS-CoV-2-specific T cells in most convalescent individuals (including asymptomatic cases) with undetectable antibody responses.

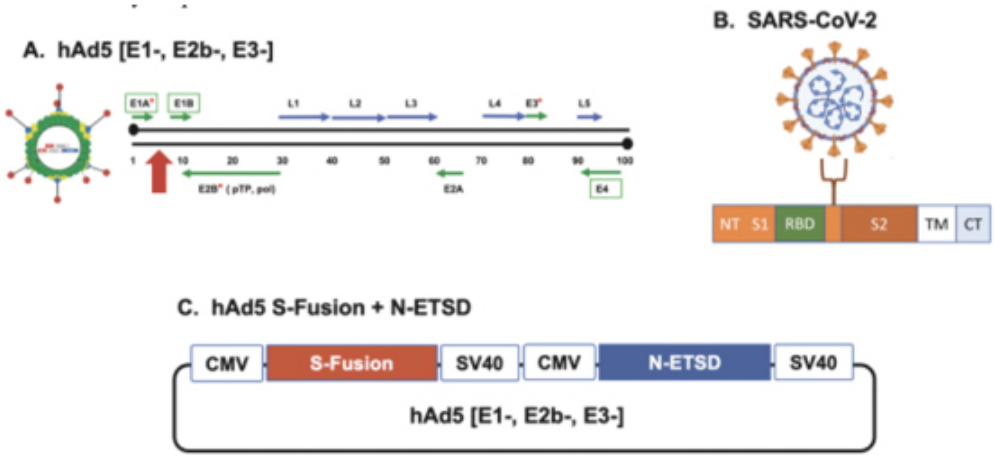


Figure: *The hAd5 platform, SARS-CoV-2, spike, and the hAd5 S-Fusion + N-ETSD vaccine.* (A) The human adenovirus serotype 5 vaccine platform with E1, E2b, and E3 regions deleted (hAd5 [E1-, E2b-, E3-]) is shown. (B) The SARS-CoV-2 virus displays spike (S) protein as a trimer on the viral surface. S protein comprises the N-terminal (NT), the S1 region including the Receptor Binding Domain (RBD), the S2 and transmembrane (TM) regions, and the C-terminal (CT); other function regions not labeled. (C) The bivalent vaccine comprises both S-Fusion and N-ETSD under control of cytomegalovirus (CMV) promoters delivered by the hAd5 [E1-, E2b-, E3-] platform.

Pre-Clinical & Non-Human Primate Challenge Studies to Date

Our preclinical studies have shown that the bivalent S-Fusion + N-ETSD hAd5 vaccine candidate resulted in robust T cell and humoral immune responses against SARS-CoV-2 S-Fusion and N-ETSD antigens. Immunogenicity in CD1 mice was assessed after two doses given 21 days apart (Day 0 and Day 21). Immune responses measured on Day 28 showed that the vaccinations elicited robust T cell responses to SARS-CoV-2. Importantly, a statistically significant CD4+ T cell response to N protein was generated in all five mice. This is consistent with studies in patients who have recovered from SARS-CoV who show memory T cells to N

protein. Four out of five mice generated an S-specific antibody response with evidence of Th1 dominance. Two of these mice demonstrated potent neutralizing antibodies against the spike protein. Analysis of both T cell cytokine responses and antibody isotypes demonstrated that the overall immune response was highly skewed towards T helper, or Th1, cell dominance important for potentially mitigating the risk of antibody-dependent enhancement of infection. In addition, we have shown that the vaccine antigens, when expressed in normal human dendritic cells, are recognized by COVID-19 patient antibodies in their convalescent plasma samples and that these dendritic cells can also activate the patients' S and N specific T cells. These results are summarized below:

- The S-Fusion and N-ETSD optimizations to S and N, respectively, generate antigen specific B cell, CD4+ and CD8+ T cell responses in mouse models.
- Characterization of this immune response demonstrated a Th1 bias in both T cell and antibody responses against S and N.
- The vaccine candidate induces neutralizing antibodies in these models verified by two independent SARS-CoV-2 neutralization assays.
- The vaccine antigens are expressed by normal donor dendritic cells and recognized by convalescent patient plasma via anti-SARS-CoV-2 antibodies.
- The vaccine antigens are processed and presented by patient dendritic cells to activate S and N specific T cells.

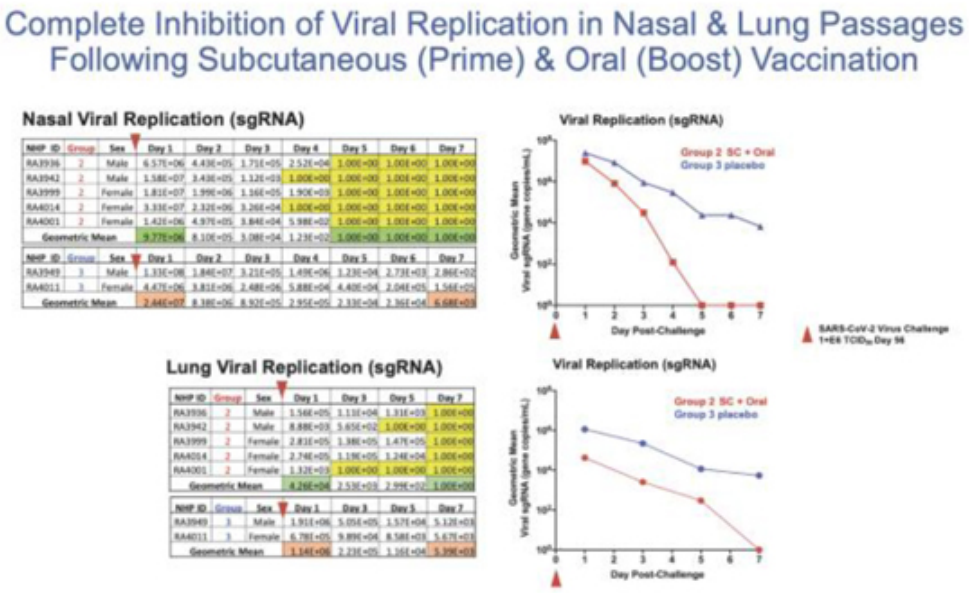
Complete Protection of Nasal and Lung Airways Against SARS-CoV-2 Challenge by Antibody Plus Th1 Dominant N- and S-Specific T-Cell Responses to Subcutaneous Prime and Thermally-Stable Oral Boost Bivalent hAd5 Vaccination in an NHP Study

In addition to the preclinical mouse data summarized above, preliminary findings from the non-human primate (NHP) COVID-19 challenge study conducted at Battelle Biomedical Research Center ("Battelle") and sponsored by Biomedical Advanced Research & Development Authority (BARDA, ASPR, DHHS) are noted below. The objective of this study was to evaluate the efficacy of novel SARS-CoV-2 vaccine candidates in NHPs. Vaccine-treated NHPs consisted of two groups (n=5/group) of male and female rhesus macaques that were administered three vaccinations of hAd5 S-Fusion + N-ETSD through a combination of subcutaneous injection (SC) and enteric-coated capsule delivery (Oral). Control NHP (n=4) were administered placebo equivalent of the treatment arm. Vaccinations occurred on study Days 0, 14 and 28. Twenty-eight days after the final vaccination (Day 56), all groups were administered virulent SARS-CoV-2 in the upper respiratory tract. Efficacy of the vaccine candidate was assessed by clinical monitoring, testing of sera in the cPass assay for inhibition of S RBD:angiotensin converting enzyme 2 (ACE2; the natural receptor for S during the initiation of infection) and viral burden reduction (genomic and sub-genomic RNA) in the NHP.

This study provided evidence for the efficacy of subcutaneous (prime) followed by oral (boost) of the hAd5 S+N vaccine candidate to provide protection against SARS-CoV-2 challenge. The results showed that immunization with the hAd5-COVID-19 vaccine candidate inhibited SARS-CoV-2 virus replication in 100% (10 of 10) of Rhesus macaques, with a drop in viral replication starting on the first day of vaccine administration, and undetectable viral levels as early as three to five days post-challenge in most of the animals. The vaccine candidate targeted both the inner nucleocapsid (N) and the outer spike (S) proteins of the virus to maximize the immune response. The goal of targeting both S and N was to both activate virus-specific T cells and generate anti-SARS-CoV-2-neutralizing antibodies. The study showed this broad immune response led to the complete clearance of the virus in a matter of days after infection of previously-vaccinated primates. This blocking of viral replication was observed in both the lung and nasal passages. By protecting the nasal passages (the primary point of entry for the virus), the vaccine candidate has the potential to reduce reinfection. Clearing replicating viruses from nasal passages is critical for reducing transmission of the virus from immunized recipients to others.

Rapid Clearance in Nasal Passages and Lung following Challenge

Viral Replication from Nasal Swab and Lung samples (sgRNA): Immunization with hAd5 S-Fusion+N-ETSD, both as subcutaneous and oral forms, successfully cleared the viruses from lung and nasal airways with zero viral replication detected within days after challenge. A comparison of the geometric means of the vaccinated and placebo-treated macaques revealed dramatic reduction of sub-genomic SARS-CoV-2 RNA (sgRNA), indicating vaccination dramatically reduced viral replication in the nasal and lung passages (Fig. 2) These results indicate protection of both the upper and lower respiratory tract by hAd5 S-Fusion + N-ETSD vaccination and suggest the vaccination could prevent transmission as well as COVID-related morbidity and mortality.



Group 2 viral replicating virus in the nasal and lung passages post-challenge.

Evidence of Memory B Cells Induced by Vaccination

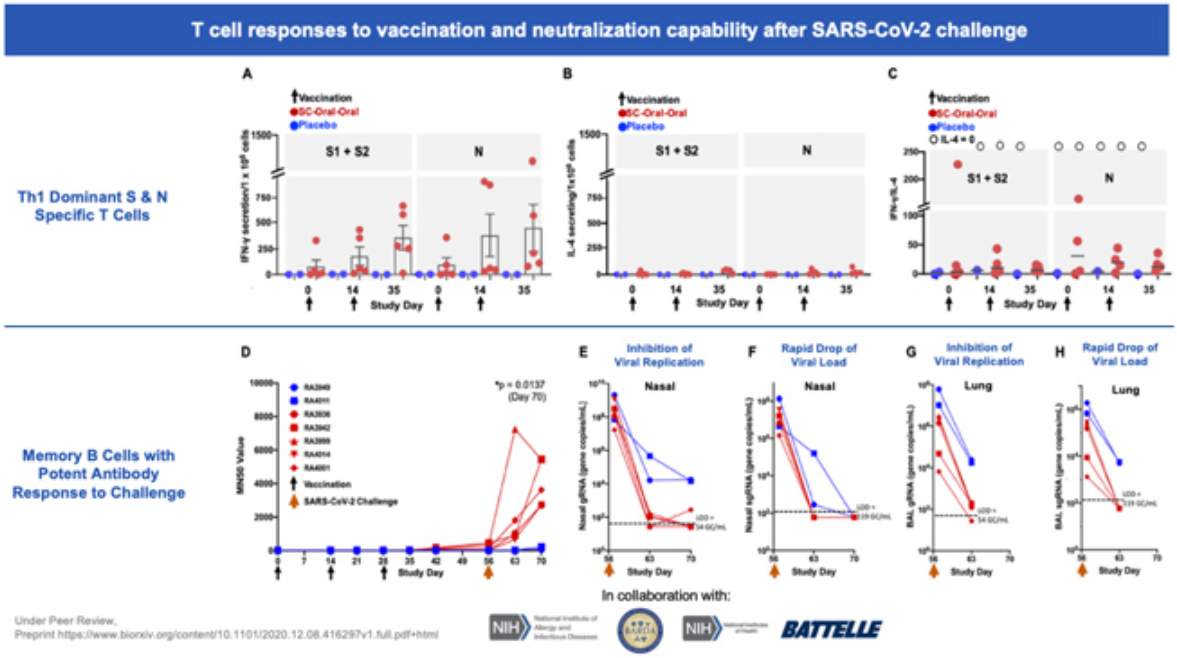
Results from a microneutralization assay demonstrated potent antibody response immediately following the virus challenge in both regimens of subcutaneous prime and boost followed by a single oral boost (group 1) as well as the regimen of subcutaneous prime with two subsequent oral boosts (group 2). Group 3 & 6 are placebo controls. As can be seen, neutralizing antibodies as high as 1:9000 dilution was achieved in the vaccinated animals.

Microneutralization Results (MN_{50} Value)

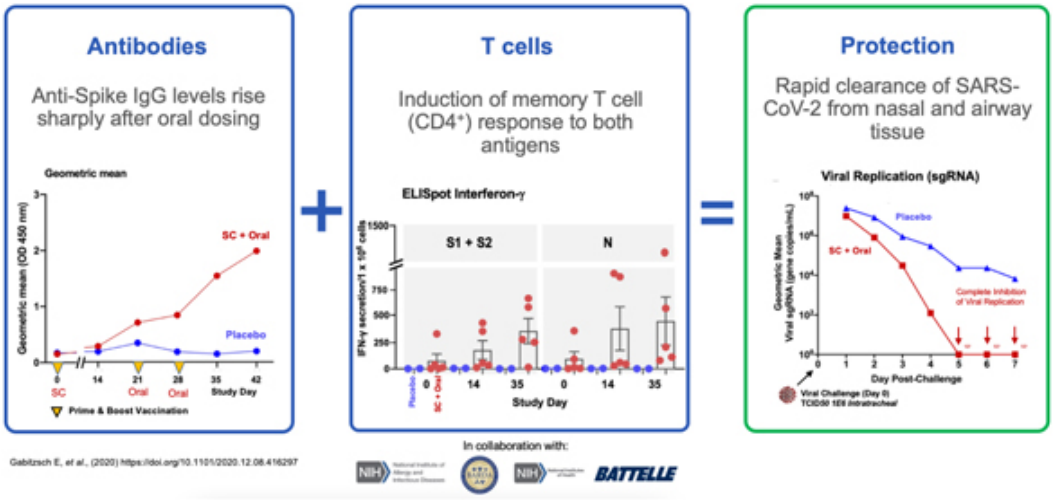
Animal ID	Group	Sex	Baseline	Day 14	Day 21	Day 28	Day 35	Day 42	Day 56	Day 63	Day 70
RA3938	1	Male	<20	<20	<20	<20	<20	<20	<20	2035	1354
RA3946	1	Male	<20	<20	<20	<20	214	339	509	2715	4978
RA3945	1	Male	<20	<20	<20	<20	<20	<20	198	1358	7241
RA4002	1	Female	<20	<20	129	<20	95	<20	566	2715	5431
RA4000	1	Female	<20	<20	<20	<20	36	<20	85	5431	9051
RA3936	2	Male	<20	<20	<20	<20	<20	<20	<20	1018	2715
RA3942	2	Male	<20	<20	<20	<20	28	170	453	905	5431
RA3999	2	Female	<20	<20	<20	<20	<20	113	339	7241	5431
RA4014	2	Female	<20	<20	<20	<20	<20	<20	<20	679	2715
RA4001	2	Female	<20	<20	<20	<20	<20	85	113	1810	3620
RA3949	3	Male	<20	<20	<20	<20	<20	<20	<20	<20	85
RA4011	3	Female	<20	<20	<20	<20	<20	<20	<20	<20	226
RA3950	6	Male	<20			<20	<20	<20	<20	<20	<20
RA4013	6	Female	<20			<20	<20	<20	<20	<20	679

SARS-CoV-2 Virus Challenge
1+E6 $TCID_{50}$
Day 56
(After Sample Collection)

Summary of Rapid Viral Clearance in NHP Challenge Based on T Cell & B Cell Activation Following Subcutaneous & Oral hAd5 S+N Vaccination



Based on these positive preclinical findings, we are advancing this next generation hAd5 COVID-19 vaccine candidate initially as a subcutaneous administration as our lead clinical candidate to test for its ability to potentially provide robust, durable cell-mediated and humoral immunity against SARS-CoV-2 infection. In addition to this route of administration, we are also developing our vaccine candidate into an oral and sublingual delivery formulation, which we refer to as AdenoCap. We believe AdenoCap can overcome the cold chain, global delivery and universal access challenges of an injectable vaccine and meet all the WHO preferred Target Product Profile requirements for a COVID-19 vaccine, including rapid scalability and low cost.



Current Clinical Status in COVID-19 Vaccine Candidate

While there are a number of vaccines with Emergency Use Authorization (EUA) and other candidates in development, we believe most are limited by their focus on antibody responses to the spike (S) protein. Our candidate uses a combination of S-Fusion and N-ETSD, our novel constructs of COVID-19 spike (S) and nucleocapsid (N) proteins, which has been shown to generate CD4+ and CD8+ T cell mediated immunity and

neutralizing antibodies in small animal models and inhibition of viral replication in nasal and lung passages in a non-human primate challenge study.

On October 13, 2020, the FDA authorized a Phase I, open-label, dose-finding study to examine the safety, reactogenicity and immunogenicity of the low-dose ($5x10^{10}$ VP) and intermediate-dose ($1x10^{11}$ VP) regimens of our vaccine candidate in healthy volunteers.

Notably, in our current cancer vaccine Phase I/II clinical trials, the doses of our hAd5 vaccine candidate were administered at ($5x10^{11}$ VP) and ($1.5x10^{12}$ VP) when administered for three tumor associated antigens simultaneously. The full dose for our hAD5 COVID-19 vaccine candidate is being determined and will be identified following the completion of the Phase I trials, including awaiting authorization from FDA to combine sublingual and oral formulation with a chosen subcutaneous dose. In the current Phase I study, the vaccine was given as a prime on day 1 and a boost on day 22, subcutaneously.

On Nov 10, 2020, enrollment was completed for both low and intermediate dose cohorts. Volunteers tolerated both doses remarkably well with no reports of any grade 3 or grade 4 adverse events in either group, and the grade 1 and grade 2 adverse events were mild in nature. On the basis of these preliminary findings, we filed an IND protocol amendment for a Phase II / III placebo-controlled, randomized, clinical trial observer-blind study to evaluate the safety, tolerability, immunogenicity, and efficacy of our hAd5 COVID-19 vaccine candidate to be administered subcutaneously at the intermediate dose.

In Q1 2021, the following clinical trials were authorized and initiated:

USA Phase I: The first two cohorts of the Phase I, open label, dose-ranging study (NCT04591717) of the vaccine candidate received two different dose levels (0.5 and 1.0ml). Participants received two subcutaneous injections 21 days apart. An additional group of 40 subjects will be enrolled to evaluate safety, reactogenicity, and immunogenicity of the combination of hAd5 in four different cohorts receiving **sublingual and subcutaneous** formulations to select an optimal combination dose for future studies.

USA Phase Ib: The second Phase 1b trial (NCT04732468) is designed to assess the safety, reactogenicity, and immunogenicity of the combination of hAd5 in **oral capsule and subcutaneous** formulations; and to select an optimal combination dose for future studies. Up to 40 subjects will be enrolled in the four-cohort study, which is anticipated to begin in Q1.

South Africa Phase I: Recruitment has begun in March 2021 in Cape Town, South Africa for a trial (NCT04710303) of subcutaneous administration to be followed by amendments using sublingual delivery and room temperature-stable oral capsules.

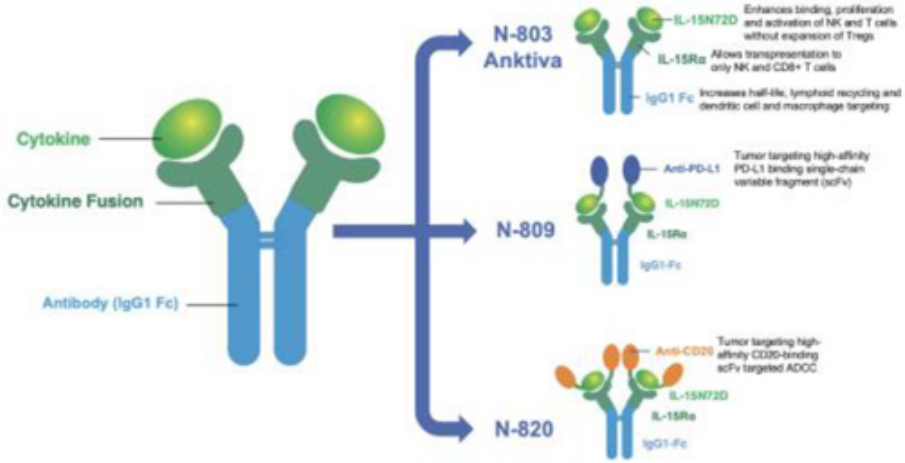
One Vaccine, Three Routes of Immune Protection

XI. Preclinical & Pre-IND Pipeline

	Phase	Product Description	Preclinical	Pre-IND	IND Filed	IND Auth	Fusion Proteins	Adenovirus	Natural Killer
Antibody Cytokine Fusion Proteins	Pre-IND	IL-15 Superagonist + Anti CD20 Fusion Protein	N-820				N-820: IL-15 / CD20		
	Pre-IND	IL-15 Superagonist + Anti PD-L1 Fusion Protein	N-809				N-809: IL-15 / PD-L1		
	Pre-IND	Tumor Necrosis Targeting (TNT) TNT + TGFb Trap Fusion Protein	N-830				N-830: TNT / TGFb		
	Pre-IND	Tumor Necrosis Targeting (TNT) TNT + IL-12 Fusion Protein	N-812				N-812: TNT / IL-12		
NK Platform	Pre-IND	HER2 t-haNK	HER2 t-haNK						HER2 t-haNK
	Pre-IND	EGFR t-haNK	EGFR t-haNK						EGFR t-haNK
	Pre-IND	TxM Induced M-ceNK	M-ceNK				TxM IL-12 / IL-18 / IL-15		M-ceNK
	Pre-IND	Nanatinostat – Epigenetic Modifier	Nanatinostat						
Peptides	Pre-IND	M2 Macrophage Polarizer to M1	RP-182				RP-182		
Adenovirus	Pre-IND	hAd5 Human Papillomavirus (HPV)	hAd5 E6/E7					hAd5 E6/E7	
	Pre-IND	hAd5 to N-803	hAd5 N-803					hAd5 N-803	
	Pre-Clin	hAd5 Influenza	hAd5 HA/M					hAd5 HA / M	
	Pre-Clin	hAd5 COVID-19 ACE2 Decoy	hAd5 ACE2					hAd5 ACE2 Decoy	
MSC	IND-Filed	Mesenchymal Stem Cell w/ GMP-in-a-Box	MSCs w/ GMP-in-a-Box						Mesenchymal Stem Cells (MSC)

1. Antibody Cytokine Fusion Proteins

Antibody Cytokine Fusion Proteins in Development



In addition to Anktiva, we are developing novel cytokine fusion proteins to further enhance NK and T cell activation directed to the tumor microenvironment and modulate the systemic and local immune response to further amplify tumor destruction.

A. N-820: IL-15 / CD20

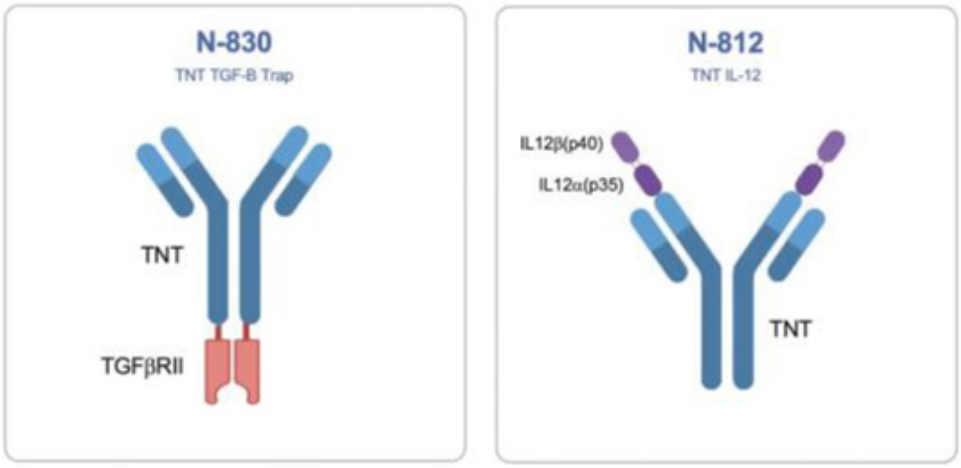
N-820 is a novel bifunctional protein, fusing Anktiva with anti-CD20. The N-820 molecule allows for CD20-targeted antibody-dependent cellular cytotoxicity, or ADCC, while targeting IL-15 activity to areas expressing CD20, such as B cells, lymphomas and leukemias, particularly non-Hodgkin lymphoma and chronic lymphocytic leukemia, respectively.

In preclinical studies, N-820 depleted B cells in the blood, lymph nodes and spleen of non-human primates, and directly targeted CD20-expressing B cell lymphoma cells akin to rituximab. N-820 was selectively targeted to the lymph nodes and other organs such as the liver, whereas rituximab persisted in blood, and simultaneously activated NK cells to enhance ADCC to induce cell death of B-lymphoma cells. This directed localization of IL-15 activity to the targeted tumor cells may allow for precise induction of a local immunological response and a robust cell death outcome within a lesion or cancerous tissue (e.g., a cancerous lymph node).

B. N-809: IL-15 / Anti-PDL1

N-809 is a fusion of Anktiva with a proprietary anti-PD-L1. In collaborative *in vivo* studies with the NCI, we observed that N-809 has the same ability to bind PD-L1 as an anti-PD-L1 monoclonal antibody, N-809 tripled proliferation and doubled activation of T cells in tumor-bearing mice, and effected clearance of human bladder cancer cells that express PD-L1 in which localization of N-809 to the tumor site was witnessed for 24 hours. Accumulation to the site of PD-L1 expressing tumor cells was specific to N-809, which cured six out of ten tumor-bearing mice. N-809 also increased the cytotoxic potential of NK cells, effecting lysis of several tumor cell types. Similarly, the highest level of ADCC was seen when N-809 was added to patient-derived NK cells. In a subsequent study, N-809 enhanced NK and CD8+ T-cell activation and function when compared with an Anktiva and anti-PD-L1 combination. Overall, N-809 increased survival rate in preclinical animal cancer models when compared to the combination of Anktiva and anti-PD-L1.

Necrotic Tumor Cell Targeting



C. N-830: TNT / TGF-ß Trap

Necrotic areas appear in cancer lesions when rapidly dividing cancer cells die (known as necrosis) due to insufficiencies in available nutrients, growth factors, and/or oxygen supply or due to patient treatment with radiation or other cancer therapies. Necrosing cells in these areas lyse and reveal their intracellular DNA to extracellular factors. Using exposed DNA as a target, we are developing an antibody-based fusion protein, N-830, which recognizes single and double-stranded DNA through the tumor necrosis targeting, or TNT, antibody and serves as a decoy receptor, or trap, for secreted TGF-ß. An earlier version of the TNT antibody that was radiolabeled and used as a diagnostic demonstrated selective targeting to and prolonged retention in tumors of clinical trial patients. TNT antibody administration following cytoreductive therapies demonstrated increased localization of the antibody to tumors in animal models and enhanced median survival in patients.

TGF-ß plays a pivotal role in fibrosis in a variety of clinical diseases including cancer, autoimmunity, and infectious disease. By creating the TNT-TGFß trap fusion protein, N-830, we are developing this potential therapeutic to decrease fibrosis in naturally fibrotic cancers (e.g. pancreatic cancer, hepatocellular carcinoma, breast cancer, etc.) or for coupling with radio- or chemotherapy regimens which are known to induce large populations of necrotic cell bodies at the tumor site.

D. N-812: TNT / IL-12

In addition to using the TNT antibody as a means of targeting tumors for the removal of cytokines like TGF-ß using the “trap” mechanism, the TNT strategy also enables tumor-specific delivery of other fusion partners, such as immune-activating cytokines. IL-12 stimulates the cytotoxic activity of CD8+ T and NK cells against cancer cells and diminishes the activity of inhibitory cytokines like IL-4. However, due to its potency, IL-12 is particularly toxic when administered systemically, which has significantly limited its clinical development. Here, by fusing IL-12 to TNT, we have developed a potential therapeutic to direct the localization of IL-12 to the necrotic tumor cells via TNT, thus activating cytotoxic immunity at the tumor microenvironment, while avoiding potential systemic toxicity. In collaborative *in vivo* studies with the NCI, six out of ten tumor-bearing mice had complete responses by the combination of an IL-12 fused to a different tumor necrosis targeting antibody with Anktiva and our hAd5 vaccine candidate immunizing for mutations expressed only by tumor cells (neoepitopes). Further analysis of these experiments demonstrated that this treatment regimen effected cytotoxic T cell infiltration into the tumor microenvironment and the formation of immunological memory in cured animals. Our lead TNT / IL-12 fusion product (N-812) candidate is entering pre-IND development.

2. t-haNK Platform: CAR-Directed and Antibody-Mediated Killing

Our newest and most promising platform for the development of therapeutic product candidates is an innovative, bioengineered combination of our haNK and taNK platforms that incorporates all the features of our haNK platform together with a CAR. The resulting line of product candidates under this platform avails itself to all three modes of killing: innate, antibody-mediated and CAR-directed killing. These product candidates also include one or more additional expression elements such as functional cytokines, chemokines and trafficking factors, making them amongst the most versatile in our portfolio. These product candidates are intended to be combined with commercially available therapeutic antibodies to effectively target either two different epitopes of the same cancer specific protein or two entirely different cancer specific proteins.

In addition to our two t-haNK product candidates, PD-L1.t-haNK, recently cleared to commence Phase II testing, and CD19.t-haNK, cleared to commence Phase I testing, we believe a pipeline of prominent CARs for t-haNK, including HER2, which is nearing IND submission, and EGFR, which is advancing through clinical enabling studies, among others, will enable us to potentially address an even broader range of cancers as part of a chemotherapy-free combination regimen.

- EGFR t-haNK: Advancing through clinical enabling studies
- HER2 t-haNK: IND submission

3. Peptides & Immunomodulators

A. RP-182

Under the tumoricidal macrophage modality, we are developing the small, easy-to-manufacture synthetic peptide RP-182, to induce tumor-associated macrophages, or TAM, to become phagocytic in the tumor microenvironment and facilitate therapeutic activity.

Various TAM subpopulations can co-exist within tumor microenvironment facilitating angiogenesis, metabolism and immune suppression/evasion.

RP-182, an activator of tumoricidal macrophages, effects tumor suppression, induces anti-tumor immunity and extends the survival of preclinical pancreatic animal models. We believe that in orchestration with our other immunomodulatory agents, such as our adenovirus and yeast vaccine technologies and engineered cytokines, it will produce positive tumoricidal and immunological responses in tough-to-treat cancers, especially those prone to fibrosis.

B. Cynviloq

Cynviloq, an alternative to nab-paclitaxel (AbraxaneTM, a standard of care for pancreatic cancer) and a co-polymer nanoparticle micelle paclitaxel with certain rights owned by NANTibody, a joint venture between Sorrento and us, in which we have majority ownership, will continue Phase Ib/II trials for advanced metastatic pancreatic carcinoma to evaluate safety upon receipt of additional manufacturing, drug product and safety information from the drug's manufacturer, Samyang Biopharmaceuticals. Cynviloq is approved in South Korea for metastatic breast cancer, NSCLC and ovarian cancer.

4. Adenovirus

A. hAd5 Human Papillomavirus (HPV)

In April 2017, we entered into a license agreement with Sanford Health pursuant to which we obtained a worldwide, exclusive license under Sanford's applicable patent and know-how rights to use, make, have made, sell, offer to sell, export and import products for all uses and applications of polynucleotides encoding mutant E16 antigen (mutant HPV16 E6 antigen + mutant HPV16 E7 antigen) and the encoded mutant E16 antigen

Head & Neck Cancer

Human papilloma virus, or HPV, is known to cause approximately 95% of cervical and 30-60% of oropharyngeal carcinoma cases. High-risk HPV type 16 is involved in more than 50% of cervical cancers worldwide and is the primary viral driver of esophageal, anal cancers, and head and neck squamous cell carcinomas, or HNSCC. HPV E6 and E7 genes expressed in squamous cell cancers are considered to be an attractive target for tumor specific immunotherapy because the cancer cells require E6 and E7 for progression.

We have developed our proprietary hAd5 technology to deliver a proprietary modified/fused non-oncogenic HPV E6/E7 gene (E6D/E7D) to treat cancer patients with HPV-expressing cancer. The addition of a proprietary localization signal (ETSD) to the E6/E7 construct further distinguishes this vaccine by allowing for trafficking of the antigens to specific cellular compartments presentable and recognizable by CD4+ and CD8+ T cells, potentiating immunological memory against HPV-bearing tumor cells. This product candidate,

in an earlier iteration, has been granted orphan-drug designation by the FDA for the treatment of HPV-associated HNSCC, and we intend to seek this designation for the ETSD modified product candidate.

B. hAd5 Influenza

Conventional influenza vaccines take at least 12 to 18 months to prepare and distribute, due to their production using the 1950s technology of chicken eggs and complicated cell lines. The inability to quickly respond to an outbreak, as exemplified during the 2009 H1N1 pandemic, has accelerated the need to develop novel technologies that minimize vaccine creation, preparation, testing, manufacturing, regulatory approval and distribution time. In response to the pandemic H1N1 of 2009, we utilized the hAd5 [E1, E2b-, E3-] platform to quickly create a vaccine against the disease that could induce both humoral immunity and cell mediated responses.

Vaccination with hAd5 [E1-, E2b-,E3]-H1N1 induced robust CMI and humoral immune responses to H1N1, which translated into significant protection from disease development and death following H1N1 challenge in mice. In challenge studies, mice and ferrets were protected from intranasal challenge with virulent H1N1 influenza virus following immunization with hAd5 [E1, E2b-, E3-] platform expressing HA and NA. Vaccinated ferrets had minimal or no clinical symptoms of H1N1 infection and nasal washes revealed a complete blockade of the virus production in the upper respiratory tract. Reducing the clinical symptoms of influenza such as coughing and sneezing as well as potentially blocking H1N1 virus shedding can greatly reduce horizontal transmission, an important aspect in containing pandemic infectious diseases.

Conventional influenza vaccines function by inducing antibodies (Abs) against the highly variable surface glycoprotein hemagglutinin (HA). Humoral responses against influenza viruses are important, but increasing data indicate that induction of a potent cell-mediated immune response will increase the protective effects. ImmunityBio has constructed and evaluated several new Influenza vaccines containing conserved and consensus influenza proteins. To develop complete immunologic memory against influenza, especially heterosubtypic immunity, it has been reported that the vaccination must induce both B-cell and CD4 immunity.[9] Thus, vaccines inducing both humoral and cellular immune responses would be of greater benefit than current vaccines. To this end and to address the critical need, IB has developed a rapidly amenable, multiple use vaccine delivery platform in a single backbone. The capacity of CMI to respond to heterologous influenza viruses holds tremendous potential in the development of a universal influenza vaccine. We have utilized our hAd5 [E1-, E2b-, E3-] as a platform for a universal vaccine.

We are evaluating and continue to develop “Universal” Influenza vaccine candidates that will induce broad immune responses against influenza resulting a wide breadth of protection against various strains of influenza viruses.

C. hAd5 COVID-19 ACE2 Decoy

The highly-transmissible SARS-CoV-2 variants now replacing the first wave strain pose an increased threat to human health by their ability, in some instances, to escape existing humoral protection conferred by previous infection, neutralizing antibodies, and possibly vaccination. Thus, other therapeutic options are necessary. One such therapeutic option that leverages SARS-CoV-2 initiation of infection by binding of its spike receptor binding domain (S RBD) to surface expressed host cell angiotensin-converting enzyme 2 (ACE2) is an ACE2 ‘decoy’ that would trap the virus by competitive binding and thus inhibit propagation of infection. Here, we used Molecular Dynamic (MD) simulations to predict ACE2 mutations that might increase its affinity for S RBD and screened these candidates for binding affinity in vitro. A double mutant ACE2(T27Y/H34A)-IgG1FC fusion protein was found to have very high affinity for S RBD and to show greater neutralization of SARS-CoV-2 in a live virus assay as compared to wild type ACE2.

We further modified the double mutant ACE2 decoy by addition of an H374N mutation to inhibit ACE2 enzymatic activity while maintaining high S RBD affinity. We then confirmed the potential efficacy of our ACE2(T27Y/H34A/H374N)-IgG1FC Triple Decoy against S RBD expressing variant-associated E484K, K417N, N501Y, and L452R mutations and found that our ACE2 Triple Decoy not only maintains its high affinity for S RBD expressing these mutations, but shows enhanced affinity for S RBD expressing the N501Y or L452R mutations and the highest affinity for S RBD expressing both the E484K and N501Y mutations. The ACE2 Triple Decoy also demonstrates the ability to compete with wild type ACE2 in the cPass™ surrogate virus neutralization in the presence of S RBD with these mutations. Additional MD simulation of ACE2 interactions using mutated S RBD provides some insight into the enhanced affinity of our ACE2 Triple Decoy for mutated S RBD. The ACE2 Triple Decoy is now undergoing continued assessment, including expression by a human adenovirus serotype 5 (hAd5) construct to facilitate delivery in vivo.

SARS-CoV-2 variants have rapidly swept the globe and very recent investigations reveal that several of these variants have shown the ability to escape neutralization by convalescent antibodies in recovered COVID-19 patients and recombinant neutralizing antibodies (nAbs) developed as therapeutics. There are also fears that current vaccines may not be as effective against some of the variants and early evidence suggests that for some vaccines, this risk may exist. The latter is a particular concern, as the massive vaccine efforts currently underway employ vaccines designed to elicit immune responses against first-wave sequence SARS-CoV-2 spike (S) protein and specifically the S receptor binding domain (S RBD) that binds to angiotensin converting enzyme 2 (ACE2) on the surface of human cells in the airway and gut that initiates viral entry and infection. While one response to the threat of loss of vaccine efficacy might be to continually re-design vaccines to target specific new variants, this would be an ongoing game of catch-up because it can be expected that further novel variants will emerge, particularly since several recent reports have shown that antibodies elicited by infection and vaccination act as evolutionary forces that result in the predominance of viral variants that escape these immune defenses. While efforts to adapt vaccines should be encouraged, in parallel, new therapeutic approaches to neutralize viral infection that are not undermined by the presence of mutations should be advanced.

To address the need for a therapeutic and potentially prophylactic approach that has a low likelihood of being adversely affected by variant mutations, we have designed and tested ACE2 ‘decoys’ that leverage the binding of the S RBD to ACE2. This is an approach that is also being pursued by others using a variety of fusion proteins and delivery methods. Our ACE2 decoys under development are recombinant ACE2-IgG1FC or -IgAFC fusion proteins, with the ACE2 sequence optimized for binding affinity to S RBD. The ACE2 decoy would be given to a patient infected with SARS-CoV-2 to prevent binding of virus to host cell ACE2 by competing with endogenous ACE2 for spike binding, and allow clearance of the virus. To successfully compete, an efficacious ACE2 decoy would ideally have significantly higher affinity for S RBD than endogenous, host-cell expressed ACE2. To identify ACE2 mutations with a high probability of increasing affinity, we utilized our in silico Molecular Dynamic (MD) simulation capabilities.

Because the ACE2 decoy concept is based on interaction of ACE2 with S RBD, its binding affinity and thus efficacy may also be vulnerable to changes in the SARS-CoV-2 S RBD sequence. We therefore assessed the affinity of our ACE2 decoy, as compared to wild type (WT) ACE2, for S RBD with a variety of single or multiple mutations associated with the currently predominant variants, including the B.1.351 variant expressing E484K, K417N, and N501Y mutations, the B.1.1.7 variant (N501Y), and the Cal.20.C L452R variant.

Our findings show that the N27Y and H34A mutations of ACE2 conferred the greatest increase in affinity for S RBD of the ACE2 variants tested. Our final ACE2 Triple Decoy also included an H374N mutation to

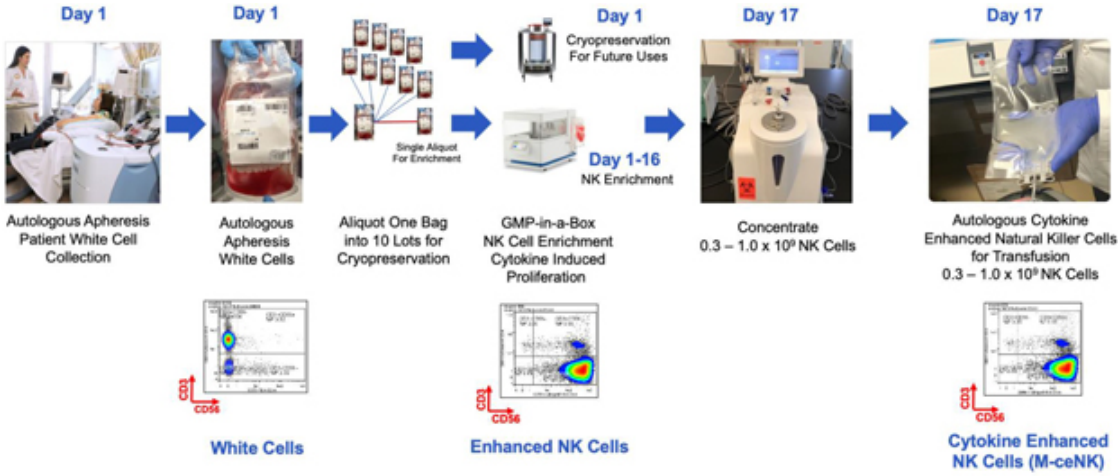
abrogate ACE2 enzymatic activity. This ACE2 Triple Decoy not only maintained affinity for variant S RBD, it showed an increased affinity for S RBD expressing N501Y or L452R mutations.

5. Mesenchymal Stem Cells (MSCs) Platform

Bone marrow-derived allogeneic MSCs are considered to be a prominent cell type to treat degenerative diseases and autoimmune disorders. MSCs are reported to be immunoprivileged, allowing for transplantation of allogeneic MSCs without the risk of being rejected by the host immune system. MSCs have been found to be capable of modulating immune responses, thereby reducing inflammation as well as immunopathology and protecting alveolar epithelial cells during acute respiratory distress syndrome, or ARDS, including that triggered by cytokine storm. More importantly, MSCs demonstrated promising activity in reducing the non-productive inflammation and in promoting lung generation in a phase II clinical trial, as well as in patients with ARDS in clinical practice. As a result, we believe MSCs have the potential to alleviate the SARS-CoV-2-derived cytokine storm and ARDS, and thereby have an effect on the treatment of subsequent chronic respiratory dysfunction and lung fibrosis.

We have developed and optimized procedures and proprietary protocols to generate multiple dose forms of MSC products from a single bone marrow or cord tissue sample, in a scalable format using our GMP-in-a-Box system.

6. Memory Cytokine Enriched Natural Killers (M-ceNK)



Cytokine-induced memory-like NK cells are a unique set of lymphocytes that differentiate after a brief pre-activation with interleukin-12 (IL-12), IL-15, and IL-18 and exhibit enhanced responses to cytokine re-stimulation that include enhanced interferon-g production and cytotoxicity against leukemic cell lines. These cells have been isolated and characterized by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade.

Published data so far has been limited to the acute myeloid leukemia patient population in the post-allogeneic, haploidentical stem cell transplantation setting.

Our cytokine enriched natural killer cell program is based on the ability to enrich and expand donor sourced NK cells in a GMP facility to a clinically relevant scale which allows for the production of a pure cytokine

activated and expanded NK cell population that possesses the unique phenotype we call M-CENK cells. Phase I M-ceNK clinical trials in subjects with locally advanced or metastatic solid tumors is anticipated to begin in the second half of 2021.

CAR-T cell therapy requires isolating and modifying a patient's own cells, which requires time and which may not be feasible if rapid treatment is required. In addition, some patients may have already endured multiple rounds of therapy, depleting their own supplies of CAR-T cells and preventing generation of a useful dose. CAR-T therapies have shown high remission rates in patients with B-cell precursor ALL and B-cell lymphomas; however, approximately 30% to 50% of patients who achieve disease remission at one month with CD19 CAR-T eventually relapse, usually within one year of treatment. Practical limitations of CAR-T therapy include cost barriers (including the difficulty of applicable insurance coverage), challenges in manufacturing high-quality, effective CAR-T therapies, and toxicity.

7. GMP-in-a-Box: A Next Generation CAR-T Therapy

In response to the limitations currently faced by CAR-T cell therapies, we have developed a novel automated closed system bioreactor for T cell proliferation called GMP-in-a-Box, which is less expensive, labor intensive and cumbersome than current methods of manufacturing. This bioreactor has received CE marking in the European Economic Area, which allows products to be sold that have met high health, safety and environmental requirements. GMP-in-a-Box has demonstrated the capability to manufacture multiple cell types from cord blood, bone marrow, adipose tissue, and peripherical blood from both allogenic and autologous sources. We have established proprietary manufacturing techniques utilizing fusion-proteins, including Anktiva, to generate cytokine enriched T cells, or M-ceNK. We believe autologous and allogeneic M-ceNK cells will serve as the basis for next generation CAR-T cells.

GMP-in-a-Box, a proprietary closed system advanced cell manufacturing bioreactor, as shown below, provides just-in-time and repeat dosing if needed, while avoiding complex logistics associated with current CAR-T cell generation. The manufacturing process is automated, scalable and efficient, reducing costs and increasing speed and reliability. There is also the potential to provide multiple doses of cryopreserved cytokine enriched CAR-T cells from a single apheresis.

RISK FACTORS

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

Risk Factor Summary

Risks Related to Our Financial Condition and Capital Requirements

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

Risks Related to Our Business and Industry Regulation

- We may develop product candidates in combination with other therapies, which exposes us to additional risks.
- It may take longer and cost more to complete our clinical trials than we project, or we may not be able to complete them at all.
- Our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.
- Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We have limited experience conducting clinical trials and have relied and will rely on third parties and related parties to conduct many of our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practice ("GCP") regulations, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.
- Our clinical trials may not be initiated or completed when we expect, and we may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.
- We use Immuno-Oncology Clinic, Inc., a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or required to contract with other clinical trial sites, and our clinical development plans will be significantly delayed, and we will incur additional costs.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of necessary marketing approvals could be delayed or otherwise adversely affected.
- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Risks Related to Government Regulation

- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- Results for any patient who receives compassionate use access to our product candidates should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial, and cannot be used to establish safety or efficacy for regulatory approval.
- The clinical and commercial utility of our product candidates are uncertain and may never be realized.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.
- We have never commercialized a product candidate before, and we may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- We are, and if we receive regulatory approval of our product candidates, will continue to be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- Our GMP-in-a-Box will be regulated by the FDA as a medical device, and regulatory compliance for medical devices is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

Risks Related to Intellectual Property

- If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our product candidates and technologies, we may not be able to compete effectively or operate profitably.
- If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.
- We may be involved in lawsuits to protect or enforce our patents or other intellectual property or the patents or other intellectual property of our licensors, which could be expensive, time-consuming and unsuccessful.
- Issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.
- The use of our technology and product candidates could potentially conflict with the rights of others, and third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product candidates and technologies.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Risks Related to Our Common Stock

- Dr. Soon-Shiong, our executive chairman and our principal stockholder, has significant interests in other companies which may conflict with our interests.
- Dr. Patrick Soon-Shiong, through his voting control of the combined company, will be in a position to control actions that require stockholder approval.
- The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.
- We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

Risks Related to Our Financial Condition and Capital Requirements

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

Our operations have consumed substantial amounts of cash since inception. As of December 31, 2020, NantKwest, prior to the merger with ImmunityBio had an accumulated deficit of $754.6 million, and as of September 30, 2020, ImmunityBio, prior to the merger, had an accumulated deficit of $822.7 million. In addition, research and development and operating costs have also been substantial and are expected to increase. A significant portion of our funding had been in the form of promissory notes representing $254.6 million in indebtedness as of December 31, 2020 held by entities affiliated with Dr. Soon-Shiong with a maturity date of September 30, 2025.

As of December 31, 2020, NantKwest, prior to the merger, had cash, cash equivalents and marketable securities of $66.2 million and as of September 30, 2020 ImmunityBio had cash, cash equivalents and marketable securities of $61.7 million. In order to complete the development of our current product candidates, and in order to implement our business plan, we anticipate that we will have to spend more than the funds currently available to us. Furthermore, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Moreover, our fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

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

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

Unless and until we can generate a sufficient amount of revenues, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. In that connection, we intend to issue additional shares in connection with one or more future capital raising transactions. Additional funds may not be available when we seek to raise capital or need funds on terms that are acceptable to us, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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

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

We have a significant amount of debt and may need to incur additional debt to support our growth. As of December 31, 2020, the total indebtedness of ImmunityBio was $254.6 million consisting of related party promissory notes, all held by entities affiliated with Dr. Soon-Shiong with a maturity date of September 30, 2025. During the first quarter of 2021, prior to the closing of the merger, ImmunityBio to incurred an additional $40 million in principal amount of debt. In connection with the closing of the merger, we assumed all of ImmunityBio’s debt.

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 competitive disadvantage compared with our competitors; and
- limit our ability to borrow additional funds, even when necessary to maintain adequate liquidity, which would also limit our ability to further expand our business.

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

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

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

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

Our businesses may not be integrated successfully or such integration may be more difficult, time consuming or costly than expected. Operating costs, customer loss and business disruption, including difficulties in maintaining relationships with employees, customers, suppliers or vendors, may be greater than expected following the merger. Revenues following the merger may be lower 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. The overall combination of our businesses may also result in material unanticipated problems, expenses, liabilities, competitive responses, and loss of customer and other business relationships. The difficulties of combining the operations of the companies include, among others:

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

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

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

We are a biopharmaceutical company, and now that the merger with ImmunityBio has been completed, we have a much broader portfolio of product candidates at various stages of development. None of our products have been approved for commercial sale or for which marketing approval has been sought, although we have generated limited revenues from license agreements and grant programs as well as from product sales of our proprietary GMP-in-a-Box bioreactors and related consumables associated with such equipment.

We expect to incur significant expenses as we seek to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals and, upon successful receipt of FDA approval, commercializing our products. We will also incur costs as we hire additional personnel and increase our manufacturing capabilities, including the lease or purchase of a facility for the manufacturing of our product candidates for ongoing and future clinical trials and, upon potential receipt of FDA approval, for our initial commercialization activities. Moreover, we do not expect to have any significant product sales or revenue for a number of years. These losses have had an adverse impact on our stockholders' equity and working capital and, as these operating losses continue to increase significantly in the future due to such expenditures, will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when the combined company may become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

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

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

We have only a limited operating history on which a decision to invest in us can be based and against which we can test the plans and assumptions in our business plan. Our future is dependent upon our ability to implement our business plan, as that business plan may

be modified from time to time by our new management and board of directors. Investors therefore cannot evaluate the likelihood of our success.

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

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

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

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

We will not be permitted to market or promote any of our product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates or regulatory approval that will allow us to successfully commercialize our product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow successful commercialization, and then successfully commercialize our product candidates, we will not be able to generate revenues from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

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

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

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

- price our product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our product;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;

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

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

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

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have limited experience conducting clinical trials and have relied and will rely on third parties and related parties to conduct many of our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practice ("GCP") regulations, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

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

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

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

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

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

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

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

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

If any of our relationships with these third or related parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result,

delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. In addition, we have entered into agreements with the Immuno-Oncology Clinic Inc. (the "Clinic"), a related party, to continue to conduct and oversee certain of our clinical trials. Large-scale clinical trials will require significant additional resources and reliance on CROs, clinical investigators or consultants. Consequently, our reliance on outside parties may introduce delays beyond our control. Our CROs, the Clinic and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs, the Clinic and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs, the Clinic or other third parties conducting our clinical trials do not perform their contractual duties or regulatory obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP or other regulatory requirements or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

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

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

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. In addition, in the past, the Clinic has conducted clinical trials involving our product candidates, and in the future the Clinic may conduct, clinical trials involving our product candidates. NantWorks, which is controlled by, and a majority of which is owned by, the Executive Chairman of the combined company, Dr. Soon-Shiong, provides certain administrative services (and has loaned money) to the Clinic. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us, the Clinic and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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

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

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

- regulators or Institutional Review Boards ("IRBs") may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or regulators or IRBs may require that we modify or amend our clinical trial protocols;
- delays in reaching a consensus or inability to obtain agreement with the FDA or comparable foreign regulatory authorities on trial design or eligibility criteria for patient enrollment;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications, trial design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from trials with clinical trial sites in foreign countries;
- the FDA may not allow us to use the clinical trial data from a research institution to support an investigational new drug ("IND") if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical trials;
- delays in or failure to reach an agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- imposition of a temporary or permanent clinical hold, such as the clinical hold on the Phase II/III clinical trial for our hAd5 COVID-19 vaccine candidate pending modifications to the protocol and FDA's review of additional information, including of immunogenicity and safety data from the Phase I portion of the study, or the temporary hold previously experienced in our 2014 clinical study relating to aldoxorubicin; although this temporary clinical hold involved a single death of a compassionate use patient, since that time, aldoxorubicin has been administered in multiple Phase II clinical trials and a Phase III clinical trial with no further clinical holds;
- suspensions or terminations by regulatory agencies, IRBs, or us for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a biologically or mechanistically similar therapeutic or therapeutic candidate;
- delays in adding new investigators or clinical trial sites, or withdrawal of clinical trial sites from a trial;
- failure by our CROs, clinical trial sites or patients, or other third parties, or us to adhere to clinical trial requirements, including regulatory, contractual or protocol requirements;
- failure to perform in accordance with the GCP requirements, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols to regulatory authorities and IRBs, and which may cause delays in our development programs, or changes to regulatory review times;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a BLA or NDA;
- clinical trials of our product candidates producing negative or inconclusive results may fail to provide sufficient data and information to support product approval, or our trials may fail to reach the necessary level of statistical or clinical significance, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials, or preclinical studies, or abandon product development programs;
- interruption of, or delays in receiving, supplies of our product candidates or other drugs or components of our therapies due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- early results from our clinical trials of our product candidates may be negatively affected by changes in efficacy measures such as overall response rate and duration of response as more patients are enrolled in our clinical trials or as new cohorts of our clinical trials are tested, and overall response rate and duration of response may be negatively affected by the inclusion of unconfirmed responses in preliminary results that we report if such responses are not later confirmed;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- there may be changes to the therapeutics or their regulatory status which we are administering in combination with our product candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the FDA or comparable regulatory authorities may take longer than we anticipate making a decision on our product candidates;
- transfer of our manufacturing processes to our CMOs or other larger-scale facilities operated by a CMO or by us and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;

- our use of different manufacturing processes within our clinical trials, and any effects that may result from the use of different processes on the clinical data that we have reported and will report in the future;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing, including as a result of any quality issues associated with the contract manufacturer;
- delays and additional costs associated with business disruptions, new regulatory requirements, social distancing and other restrictions imposed by governmental or regulatory agencies and clinical trial sites due to the COVID-19 pandemic, which may include enrollment delays or failures to follow trial protocols; and
- obtaining sufficient supply of therapies that may be used in combination with our molecular agents or as comparative agents in clinical trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Strategy ("REMS") to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates.

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

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

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

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

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

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

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

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

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

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

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

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

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

Even 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 an adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

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

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

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

Even if our product candidate, Anktiva, is approved and commercialized, we may not become profitable.

One of our leading product candidate, Anktiva, is initially targeting a small population of patients that suffer from bladder cancer, lung cancer and metastatic pancreatic cancer, when used as a combination therapy. Even if the FDA approves this candidate for these indications, and even if the combined company obtains significant market share for it, because the potential target population may be

small, we may never achieve profitability without obtaining regulatory approval for additional indications. The FDA often approves new therapies initially only for use in patients with relapsed or refractory metastatic disease, which may limit our patient population.

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

In addition to our own research and process development efforts, we will seek to collaborate with government, academic research institutions and corporate partners, including our affiliates, to improve manufacturing of our existing product candidates, including Anktiva, hAd5 and yeast technologies, and to develop Anktiva and other therapies for new indications.

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

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

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

- collaborators may own or co-own intellectual property covering our product candidates or technology that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. Additionally, exclusive rights that we may grant in connection with collaboration agreements may limit our ability to enter into new or additional collaboration agreements or strategic partnerships if we experience issues with existing collaborations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our efforts to develop, manufacture and market COVID-19 therapeutics will require additional personnel who will require training, which may cause some of our employees to reallocate their time from other duties which could in turn cause delays in clinical supply of our other product candidates or trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including refusal to approve pending applications, license suspension or revocation, withdrawal of an

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

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

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

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

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

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

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

therapies may be provided to patients in combination with other agents provided by third parties or our affiliates. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

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

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

- decreased demand for our products, if approved;
- injury to our reputation;
- withdrawal of clinical trial participants or sites and potential termination of clinical trial sites or entire clinical programs;
- initiation of investigations by regulators, refusal to approve marketing applications or supplements, and withdrawal or limitation of product approvals;
- costs to defend litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- significant negative media attention;
- decrease in the price of our stock and overall value of our company;
- exhaustion of our available insurance coverage and our capital resources; or
- the inability to commercialize our product candidates.

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

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

The combined company will not have sufficient resources to pursue development of all or even a substantial portion of the potential opportunities that we believe will be afforded to us by our product candidates. Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions as to which product candidates and indications to pursue and how much of our resources to allocate to each. Our management must also evaluate the benefits of developing in-licensed or jointly owned technologies, which in some circumstances we may be contractually obligated to pursue, relative to developing other product candidates, indications or programs. Our management has broad discretion to suspend, scale down, or discontinue any or all of these development efforts, or to initiate new programs to treat other diseases. If we select and commit resources to opportunities that we are unable to successfully develop, or we forego more promising opportunities, our business, financial condition and results of operations will be adversely affected.

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

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

development capabilities and approval, manufacturing, marketing, financial and managerial resources and experience than we do. Our competitors may:

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

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

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

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

In the T cell memory modality, we also compete with cell therapy and chimeric antigen receptor T-cell, or CAR-T cell, based companies including Allogene Therapeutics Inc., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Forty Seven, Inc., or Forty Seven (which was acquired by Gilead Sciences, Inc. in April 2020), Intellia Therapeutics, Inc., Iovance Biotherapeutics, Inc. and Legend Biotech Corporation.

From an infectious disease perspective, we will compete with Abbott Laboratories Inc., or Abbott Laboratories, BMS, Gilead Sciences, Inc., or Gilead and GSK, in the field of human immunodeficiency virus, or HIV. In the field of COVID-19, we will compete with Altimmune, Inc., AstraZeneca, BioNTech SE/Pfizer, CanSinoBio Biologics Inc., or CanSinoBio, GSK, Johnson & Johnson, Merck, Moderna, Inc., Novavax, Inc., Vaxart, Inc., or Vaxart and with many other new competitors that are emerging frequently.

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

In addition, a very large number of companies, government agencies and academic centers around the world are developing COVID-19 vaccines, and many of these entities are in more advanced stages of development than we are, including some that have started Phase II and/or III clinical trials or already have emergency regulatory approval in some regions. Even if our COVID-19 vaccine candidate is ultimately approved for marketing, the value of our opportunity would be adversely impacted if other COVID-19 vaccines are approved earlier or show better efficacy or safety than our COVID-19 vaccine candidate.

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

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

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

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

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

We use relatively novel technologies involving the Anktiva, aldoxorubicin, hAd5 and yeast technologies and cell-based therapies and our natural killer cell platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals. Public perception may be influenced by claims, such as claims that our technologies are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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

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

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

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

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

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

to ensure that our product candidates are safe, pure and potent. To the extent that we are required to establish and implement any post-approval requirements, we will likely need to invest a significant amount of time, effort and money. Such post-approval requirements may also limit the commercial prospects of our product candidates.

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

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

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

- if the COVID-19 pandemic continues or reoccurs it may negatively impact our ability to establish commercial operations, educate and interact with healthcare professionals, and successfully launch our product on a timely basis;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

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

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

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

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

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

Our product candidates may face competition sooner than anticipated.

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

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

For our small molecular product candidates, if qualified, the regulatory exclusivity period is less than for our biologic product candidates. The Federal Food, Drug, and Cosmetic Act ("FDCA") provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if

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

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

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

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

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

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

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

Outbreaks of epidemic, pandemic or contagious diseases, such as the COVID-19 pandemic, may significantly disrupt our operations and adversely affect our business, financial condition and results of operations. In March 2020, the World Health Organization ("WHO") declared the outbreak of the COVID-19 pandemic as the novel coronavirus continues to spread throughout the world. The spread of this pandemic has caused significant volatility and uncertainty in the United States and international markets and has resulted in increased risks to our operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters and at our manufacturing facilities, which are currently subject to state executive orders and shelter-in-place orders, and at our clinical trial sites, as well as the business or operations of our other manufacturers, CROs, CMOs, clinical sites or other third parties with whom we conduct business.

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

- *Financial*: While to date, the financial impact to our businesses has not been material, we anticipate that the pandemic could have an adverse financial impact in the short-term and potentially beyond. As a result of slower patient enrollment, we may not be able to complete our clinical trials as planned or in a timely manner. We expect to continue spending on research and development during the year-ended December 31, 2021 and beyond, and we could also have unexpected expenses related to the pandemic. The short-term continued expenses, as well as the overall uncertainty and disruption caused by the pandemic, will likely cause a delay in our ability to commercialize a product and adversely impact our financial results.
- *Supply Chain*: While to date we have not experienced significant disruptions in their respective supply chains and distribution channels, an extended duration of this pandemic could result in disruptions in the future. For example, quarantines, shelter-in-place and similar government orders, travel restrictions and health impacts of the COVID-19 pandemic, could impact the availability or productivity of personnel at third-party laboratory supply manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in disruptions in our supply chain and adversely affect our ability to have manufactured certain product candidates for clinical supply.
- *Clinical Trials*: This pandemic has not significantly impacted our business or financial results, however, it is likely to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. Due to site and participant availability during the pandemic, new subject enrollment is expected to slow, at least in the short-term, for most of our clinical trials. For ongoing trials, we have seen an increasing number of clinical trial sites imposing restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID-19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies. As a result, our anticipated filing and marketing timelines may be adversely impacted.
- *Overall Economic and Capital Markets Environment*: The impact of the COVID-19 pandemic could result in a prolonged recession or depression in the United States or globally that could harm the banking system, limit demand for all products and services and cause other seen and unforeseen events and circumstances, all of which could negatively impact us. The continued spread of COVID-19 has led to and could continue to lead to severe disruption and volatility in the United States and global capital markets, which could result in a decline in stock price, increase our cost of capital and adversely affect our ability to access the capital markets in the future. In addition, trading prices on the public stock market have been highly volatile as a result of the COVID-19 pandemic.
- *Regulatory Reviews*: The operations of the FDA or other regulatory agencies may be adversely affected. In response to COVID-19, federal, state and local governments are issuing new rules, regulations, orders and advisories on a regular basis. These government actions can impact us, our members and our suppliers. There is also the possibility that we may experience delays with obtaining approvals for our IND applications, BLAs, and/or NDAs.

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

We have formed, and may in the future form or seek, strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third and related parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. For example, we have entered into an agreement whereby Viracta granted to us exclusive world-wide rights to Viracta's phase II drug candidate, VRx-3996, for use in combination with our platform of NK cell therapies. However, if Viracta fails to raise sufficient capital to complete their pivotal phase II trial, if their trial is unsuccessful, or if our future clinical trial of NK cell therapy in combination with VRx-3996 fails, the value of the Viracta license would be adversely affected.

Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our manufacturing facilities may be negatively impacted by the ongoing coronavirus pandemic.

The coronavirus pandemic, including any actions we have taken in response, may disrupt our internal operations, including by heightening the risk that a significant portion of our workforce could suffer illness or otherwise not be permitted or be unable to work, and required that certain of our employees work remotely, which has heightened certain risks, including those related to cybersecurity and internal controls. Additionally the coronavirus pandemic has impacted, and may continue to impact, our office and manufacturing locations, as well as our analytical, process development, and transitional research teams, including through the effects of facility closures, reductions in operating hours and other social distancing efforts. For example, if even a small number of our employees in our working clusters related to manufacturing, analytical, process development, or translational research, tested positive for COVID-19, it would require us to temporarily close a number of our offices or manufacturing facilities and temporarily suspend operations in order to conduct a deep clean of the facilities in order to ensure the safety of our employees. Additionally, we cannot predict whether these conditions and concerns will continue or whether we will experience more significant or frequent disruptions in the future, including the complete closure of one or more of our facilities. In addition, in the event demand for our products is significantly reduced as a result of the coronavirus pandemic and related economic impacts, we may need to assess different corporate actions and cost-cutting measures, including reducing our workforce or closing one or more facilities, and these actions could cause us to incur costs and expose us to other risks and inefficiencies, including whether we would be able to rehire our workforce or recommence operations at a given facility if our business experiences a subsequent recovery.

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

There are numerous laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy laws apply more broadly than the Health Insurance Portability and Accountability Act (“HIPAA”) and associated regulations. For example, California recently enacted legislation—the California Consumer Privacy Act (“CCPA”)—

which went into effect on January 1, 2020. The CCPA, among other things, creates new data privacy and security obligations for covered companies and provides new privacy rights to California consumers, including the right to opt out of certain disclosures of their information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. The California Attorney General has not yet issued final regulations implementing the CCPA, and it remains unclear what language such regulations will contain, or how the statute and regulations will be interpreted.

There are also various laws and regulations in other jurisdictions relating to privacy and security. For example, European Union ("EU") member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. Moreover, the EU Data Protection Directive, which formerly governed the collection, processing and other use of personal health or other data in the EU, was replaced with the EU General Data Protection Regulation ("GDPR") in May 2018. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to such individuals, the security and confidentiality of the personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant entity, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information.

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

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

We will be heavily dependent on our senior management, particularly Dr. Soon-Shiong, our Executive Chairman, and a loss of a member of our senior management team in the future, even if only temporary, could harm our business.

If we lose members of our senior management for a short or an extended time, we may not be able to find appropriate replacements on a timely basis, and our business could be adversely affected. Our existing operations and our future development depend to a significant extent upon the performance and active participation of certain key individuals, particularly Dr. Soon-Shiong, our Executive Chairman. Although Dr. Soon-Shiong focuses heavily on our matters and is highly active in their management, he does devote a significant amount of his time to a number of different endeavors and companies, including NantHealth, Inc., NantMedia Holdings, LLC (which operates the Los Angeles Times and the San Diego Union-Tribune) and NantWorks, which is a collection of multiple companies in the healthcare and technology space. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, the commercial and other relationships that we have with entities affiliated with him, his role in our company and his public reputation. We may also be dependent on additional funding from Dr. Soon-Shiong and his affiliates, which may not be available when needed and which he is under no obligation to provide. If we were to lose the services of Dr. Soon-Shiong for a short or an extended time, for any reason, including, for example, due to the contraction of COVID-19, we may not be able to find appropriate replacements on a timely basis and our financial condition and results of operations could be materially adversely affected.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We face significant competition for employees, particularly scientific personnel, from other biopharmaceutical companies, which include both publicly traded and privately held companies, and we may not be able to hire new employees quickly enough to meet our needs. We do not have employment agreements with our key employees and all of our employees are hired on an "at-will" basis, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

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

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

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

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

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

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

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

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company or product, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

could result in significant delays to our currently anticipated timeline for development and approval of our product candidates or prevent their approval entirely.

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

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable contract terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB or central IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of qualified materials under cGMP and applying them on a subject by subject basis for use in clinical trials; or
- timely implementing or validating changes to our manufacturing or quality control processes and methods needed to address FDA feedback.

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

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

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

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

Our current product candidates are in the early stages of development. We currently have ongoing clinical trials to evaluate their respective product candidates. Success in early clinical trials does not ensure that large-scale clinical trials will be successful nor does it predict final results. In addition, we will not be able to treat patients if we cannot manufacture a sufficient quantity of Anktiva or therapies that meet our minimum specifications. In addition, Anktiva and many of our other product candidates have only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our product candidates as we expand into larger clinical trials.

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

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

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

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

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

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

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

and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

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

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

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

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

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

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

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

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

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

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

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, for any medical device products we develop, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals for any medical device products, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. The FDA also regulates the advertising and promotion of medical devices to ensure that the claims are consistent with their regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Any medical device products we develop will be subject to extensive regulation by the FDA and non- U.S. regulatory agencies. Further, all of our potential medical device products and material modifications will be subject to extensive regulation and clearance or approval

from the FDA and non- U.S. regulatory agencies prior to commercial sale and distribution as well as after clearance or approval. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing, or labeling our medical device products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. If any of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

We will be subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

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

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

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

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

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

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

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

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

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

If we or any of our third-party manufacturers that we may engage use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and any third-party manufacturers that we may use in the future. We and any of our third party manufacturers that we may engage are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our procedures for using, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In response to the COVID-19 pandemic, the FDA recently announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. While the FDA indicated that it will consider alternative methods for inspections and could exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

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

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

In particular, if we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. We, and any of our collaborators, must comply with requirements concerning advertising and

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

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

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

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

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

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

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

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

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

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our product candidates. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

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

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

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

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

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical

outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

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

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

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

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

Since enactment of the ACA in 2010, in both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates profitably. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and were to remain in effect until 2029 unless additional Congressional action is taken. The CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. In January 2013, the American Taxpayer Relief Act of 2012, or ATRA, was approved which, among other things, reduced Medicare payments to several providers, with primary focus on the hospital outpatient setting and ancillary services, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On January 20, 2017, the new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices, and, for that reason, some final regulations have yet to take effect. In December 2017, Congress repealed the individual mandate for health insurance required by the ACA and could consider further legislation to repeal other elements of the ACA. At the end of 2017, CMS promulgated regulations that reduce the amount paid to hospitals for outpatient drugs purchased under the 340B program, and some states have enacted transparency laws requiring manufacturers to report information on drug prices and price increases. On December 14, 2018, the U.S. District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter. On December 18, 2019, the Fifth Circuit ruled that the ACA's individual mandate is unconstitutional given that the Tax Act eliminated the tax penalty associated with the individual mandate. In

concluding that the individual mandate is unconstitutional, the question remains whether, or how much of, the rest of the ACA is severable from that constitutional defect. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when or how the U.S. Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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

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

In addition, there have been a number of other policy, legislative and regulatory proposals aimed at changing the pharmaceutical industry. For instance, on May 11, 2018, the current administration presented its "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. Although some proposals related to the administration's Blueprint may require additional authorization to become effective, may ultimately be withdrawn, or may face challenges in the courts, Congress and the administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those product candidates in the United States, our potential exposure under such laws will increase significantly, and

our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Some of our competitors may be better able to sustain the costs of such litigation or other proceeding because they have substantially greater resources. Such proceedings could result in revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our product candidates or technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensor, our or our licensor's patent counsel and the patent examiner were unaware during prosecution. If a

third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and growth prospects.

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

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

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

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

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

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

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

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

An element of our intellectual property strategy is to license intellectual property rights and technologies from third parties and/or our affiliates. Other parties, including our competitors or our affiliates, may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. In addition, with respect to any patents we co-own with other parties—including our affiliates—we may require licenses to such co-owners' interest to such patents. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us

due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties and/or our affiliates. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future additional product candidates and could increase the cost, and extend the timelines associated with our development, of such other products, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

We seek to protect these trade secrets and other proprietary technology, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or

unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

One of NantKwest's ten issued U.S. patents is subject to a claim challenging the inventorship.

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

Risks Related to Our Common Stock

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

Our executive chairman, Dr. Soon-Shiong, is the founder of NantWorks, LLC ("NantWorks"). The various NantWorks companies are currently exploring opportunities in the immunotherapy, oncology, infectious disease and inflammatory disease fields. In particular, we have agreements with a number of related parties that provide services, technology and equipment for use in their efforts to develop their product pipelines. Dr. Soon-Shiong holds a controlling interest, either directly or indirectly, in these entities. Consequently, Dr. Soon-Shiong's interests may not be aligned with our other stockholders and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do not view as being in their interest as investors in our company. In addition, other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in other therapeutic fields which we

may target in the future). Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us.

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

We have entered into shared services agreements with NantWorks, pursuant to which NantWorks and its affiliates provide corporate, general and administrative and other support services to us. If Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, we may be unable to establish or maintain this relationship with NantWorks on a commercially reasonable basis, if at all. As a result, we could experience a lack of business continuity due to loss of historical and institutional knowledge and a lack of familiarity of new employees and/or new service providers with business processes, operating requirements, policies and procedures, and we may incur additional costs as new employees and/or service providers gain necessary experience. In addition, the loss of the services of NantWorks might significantly delay or prevent the development of our product candidates or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business and results of operations.

Dr. Patrick Soon-Shiong, through his voting control of the combined company, will be in a position to control actions that require stockholder approval.

Dr. Soon-Shiong, through his direct and indirect ownership of the combined company's common stock, will have voting control of the combined company. Immediately following the closing, Dr. Soon-Shiong and certain of his affiliates are expected to beneficially own approximately 82% of the shares of the combined company's common stock outstanding. Additionally, an affiliate of Dr. Soon-Shiong will hold a warrant to purchase an additional 1,638,000 shares of combined company common stock that will become exercisable if certain performance conditions are satisfied. Dr. Soon-Shiong also indirectly holds 139,768,338 contingent value rights ("CVRs") issued to the former stockholders of Altor BioScience Corporation (succeeded by Altor BioScience LLC) ("Altor") in connection with ImmunityBio's acquisition of Altor. After the completion of the merger, if the underlying conditions for payment are met, the CVRs become payable in cash or shares of our common stock or any combination as the holder elects. Dr. Soon-Shiong has elected to receive shares of our common stock for all of the CVRs. Dr. Soon-Shiong will serve as Executive Chairman of the board of directors of the combined company following the closing.

Dr. Soon-Shiong will be 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 combined company, the election or removal of directors and transactions involving a change of control. Dr. Soon-Shiong's concentrated ownership could limit the ability of the remaining stockholders of the combined company to influence corporate matters, and the interests of Dr. Soon-Shiong may not coincide with the combined company's interests or the interests of its remaining stockholders. In addition, entities affiliated with Dr. Soon-Shiong held promissory notes representing $254.6 million in indebtedness of ImmunityBio as of December 31, 2020, which debt will remain outstanding in accordance with its terms following the closing of the merger.

In addition, pursuant to the Nominating Agreement between us and Cambridge Equities, LP, or Cambridge, an entity that Dr. Soon-Shiong controls, Cambridge has the ability to designate one director to be nominated for election to our board of directors for as long as Cambridge continues to hold at least 20% of the issued and outstanding shares of our common stock. Dr. Soon-Shiong was selected by Cambridge to hold this board seat. Dr. Soon-Shiong and his affiliates will therefore have significant influence over management and significant control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, for the foreseeable future. This concentrated control will limit stockholders' ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

The market price of our 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 cash 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;
- investors' perceptions regarding the viability, timing, and availability of COVID-19 vaccines; and
- the other factors described in this "*Risk Factors*" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. In addition, our Executive Chairman, Dr. Patrick Soon-Shiong, and his affiliates currently beneficially own approximately 82% of our outstanding shares of common stock. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

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

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

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

As a public company listed in the U.S., and increasingly after we no longer qualify as a "smaller reporting company," we have incurred and will continue to incur significant additional legal, accounting and other expenses as a result of operating as a public company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to create a larger finance function with additional personnel to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the U.S., we may be required, pursuant to Section 404 of Sarbanes-Oxley, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. In addition, we are required to disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we no longer qualify as a "smaller reporting company," we will be required to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. To date, we have not engaged our independent registered public accounting firm to perform an audit of, and give an opinion on, our internal control over financial reporting. There can be no assurance that we will not discover deficiencies or a material weakness in our internal control over financial reporting or that our auditor will agree with management's assessment of our internal control over financial reporting if or when our auditor conducts such audit and delivers an opinion.

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

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

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

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

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce

accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

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

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

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

Our Executive Chairman, Dr. Patrick Soon-Shiong, and entities affiliated with him, control a majority of our common stock. As a result, we are a "controlled company" within the meaning of the Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and may elect not to comply with certain Nasdaq corporate governance requirements, including (1) the requirement that a majority of the board of directors consist of independent directors, and (2) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements. However, our board of directors is currently comprised of a majority of independent directors. In addition, although not required by the rules of Nasdaq, in August 2019, our board of directors established a nominating and corporate governance committee comprised of two directors, which are independent.

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

Although we no longer qualify as an emerging growth company, we qualify as a "smaller reporting company" during fiscal year 2021, which allows us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; and
- reduced disclosure obligations regarding executive compensation.

Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

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

We could be subject to additional income tax liabilities.

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

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

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, which was approved by Congress on December 20, 2017 significantly changed the U.S. Internal Revenue Code. Such changes include a reduction in the corporate tax rate and limitations on certain corporate deductions and credits, among other changes. We have generally accounted for such changes in accordance with our understanding of the TCJA and guidance available as of the date of this filing as described in more detail in our financial statements. The CARES Act, which was signed into law on March 27, 2020, further modified the TCJA and we will continue to monitor and assess the impact of the federal legislation on our business and the extent to which various states conform to the newly enacted federal tax law. In addition, adverse changes in the financial outlook of our operations or further changes in tax laws or regulations could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations.

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

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

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

We elected in our amended and restated certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. Our decision not to be subject to Section 203 will allow, for example, our Executive Chairman (who with members of his immediate family and entities affiliated with him owned approximately 64.4% of our common stock as of December 31, 2020) to transfer shares in excess of 15% of our voting stock to a third-party free of the restrictions imposed by Section 203. This may make us more vulnerable to takeovers that are completed without the approval of our board of directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

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

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

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

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

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

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

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

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