
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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):
December 17, 2021**

ImmunityBio, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37507
(Commission
File Number)

43-1979754
(IRS Employer
Identification No.)

**3530 John Hopkins Court
San Diego, California 92121**
(Address of principal executive offices, including zip code)

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

Not Applicable
(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 (see General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	IBRX	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

Item 1.01 Entry into a Material Definitive Agreement.

On December 17, 2021, ImmunityBio, Inc. (the “Company”) received gross proceeds of \$300,000,000 and entered into a Promissory Note (the “Note”) with Nant Capital, LLC on the following terms:

- principal of Three Hundred Million dollars (\$300,000,000);
- maturity date of December 17, 2022 (the “Maturity Date”);
- origination fee of 0.5%;
- interest rate of the Term Secured Overnight Financing Rate (SOFR) plus 5.4%;
- interest paid quarterly in arrears; and
- if the Note is not paid by the Maturity Date and is in default, then the Company may choose to pay off the Note by converting the then outstanding principal and interest into shares of Company common stock at a conversion price of \$5.67 per share.

The foregoing description of the Note does not purport to be complete and is qualified in its entirety by reference to the full text of the Note, a copy of which is attached hereto as Exhibit 10.1 and is 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.

To the extent relevant, the information set forth in Item 1.01 above is incorporated by reference into this Item 2.03.

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

The Board of Directors previously approved an amendment to the Company’s Certificate of Incorporation to increase the number of authorized shares of Common Stock to Nine Hundred Million (900,000,000) shares. On December 19, 2021, such amendment was approved by the written consent of stockholders holding approximately 79% of the Company’s issued and outstanding shares of Common Stock. An information statement will be mailed to all stockholders of record on December 17, 2021 and the increase in the number of authorized shares of Common Stock will be effective 21 days after the mailing of the Information Statement.

Item 7.01 Regulation FD Disclosure.

As previously disclosed, the Company had filed a registration statement regarding, and had been pursuing, an ATM offering to finance its ongoing operations. With the receipt of \$300,000,000 of gross proceeds from the debt financing described above, the Company plans to pause its efforts to raise capital via the ATM offering for the near foreseeable future although it may decide to continue its ATM offering at any time.

On December 20, 2021, the Company issued a press release regarding the matters described above as well as additional information regarding its ongoing business initiatives and year in review. A copy of the press release is filed as Exhibit 99.1 and incorporated by reference.

The information in this Item 7.01 of this report is being furnished and shall not be deemed filed for purposes of Section 18 of the Exchange Act of 1934, as amended (the “Exchange Act”), nor will it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K (“Report”) contains forward-looking statements which include statements regarding plans regarding our ATM offering. These statements are based upon information available to us as of the date of this Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. In particular, the Company’s utilization of its ATM will depend upon future market conditions and other factors. Given these uncertainties, you should not place undue reliance on these forward-looking statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame.

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

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
10.1	Promissory Note by and between the Company and Nant Capital, LLC dated as of December 17, 2021.
99.1	Press Release dated December 20, 2021
104	Cover page interactive data file (embedded within the Inline XBRL document)

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 hereunto duly authorized.

IMMUNITYBIO, INC.

Date: December 20, 2021

By: /s/ David Sachs

David Sachs

Chief Financial Officer

THIS NOTE AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “**ACT**”), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT AS PERMITTED UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT OR AN EXEMPTION THEREFROM. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER, PLEDGE OR HYPOTHECATION OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

IMMUNITYBIO, INC.

PROMISSORY NOTE

\$300,000,000

December 17, 2021

FOR VALUE RECEIVED, ImmunityBio, Inc., a Delaware corporation (the “**Company**”) promises to pay to Nant Capital, LLC or its registered assigns (“**Investor**”), in lawful money of the United States of America the principal sum of Three Hundred Million Dollars (\$300,000,000), or such lesser amount as shall equal the outstanding principal amount hereof, together with interest from the date of this Promissory Note (this “**Note**”) on the unpaid principal balance at a rate equal to the Term SOFR Rate (as defined below) plus 5.4% per annum which shall be adjusted to the then current SOFR on each Interest Payment Date, computed on the basis of the actual number of days elapsed and a year of 365 days. All unpaid principal, together with any then unpaid and accrued interest and other amounts payable hereunder, shall be due and payable on the earlier of (i) December 17, 2022 (the “**Maturity Date**”), or (ii) when, upon the occurrence and during the continuance of an Event of Default, such amounts are declared due and payable by Investor or made automatically due and payable, in each case, in accordance with the terms hereof.

The following is a statement of the rights of Investor and the conditions to which this Note is subject, and to which Investor, by the acceptance of this Note, agrees:

1. Payments.

(a) *Interest.* Accrued interest on this Note shall be payable quarterly, in arrears, on each Interest Payment Date.

(b) *Voluntary Prepayment.* Upon five business days’ prior written notice to Investor, the Company may prepay this Note in whole or in part, *provided* that any such prepayment will be applied first to the payment of accrued but unpaid interest on this Note and second, if the amount of prepayment exceeds the amount of all such interest, to the payment of outstanding principal of this Note.

2. Events of Default. The occurrence of any of the following shall constitute an “**Event of Default**” under this Note.

(a) *Failure to Pay.* The Company shall fail to pay the principal payment, plus any accrued and unpaid interest, on the Maturity Date;

(b) *Voluntary Bankruptcy or Insolvency Proceedings.* The Company shall (i) apply for or consent to the appointment of a receiver, trustee, liquidator or custodian of itself or of all or a substantial part of its property, (ii) admit in writing its inability to pay its debts generally as they mature, (iii) make a general assignment for the benefit of its or any of its creditors, (iv) be dissolved or liquidated, (v) commence a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now or hereafter in effect or consent to any such relief or to the appointment of or taking possession of its property by any official in an involuntary case or other proceeding commenced against it, or (vi) take any action for the purpose of effecting any of the foregoing; or

(c) *Involuntary Bankruptcy or Insolvency Proceedings.* Proceedings for the appointment of a receiver, trustee, liquidator or custodian of the Company, or of all or a substantial part of the property thereof, or an involuntary case or other proceedings seeking liquidation, reorganization or other relief with respect to the Company or any of its subsidiaries, if any, or the debts thereof under any bankruptcy, insolvency or other similar law now or hereafter in effect shall be commenced and an order for relief entered or such proceeding shall not be dismissed or discharged within 45 days of commencement.

3. Rights of Investor upon Default. Upon the occurrence of any Event of Default (other than an Event of Default described in **Section 2(b)** or **2(c)**) and at any time thereafter during the continuance of such Event of Default, Investor may, by written notice to the Company, declare all outstanding Obligations payable by the Company hereunder to be immediately due and payable without presentment, demand, protest or any other notice of any kind, all of which are hereby expressly waived, anything contained herein to the contrary notwithstanding. Upon the occurrence of any Event of Default described in **Section 2(b)** or **2(c)**, immediately and without notice, all outstanding Obligations payable by the Company hereunder shall automatically become immediately due and payable, without presentment, demand, protest or any other notice of any kind, all of which are hereby expressly waived, anything contained herein to the contrary notwithstanding. In addition to the foregoing remedies, upon the occurrence and during the continuance of any Event of Default, Investor may exercise any other right, power or remedy otherwise permitted to it by law, either by suit in equity or by action at law, or both.

4. Conversion.

(a) Common Stock. Subject to the Company increasing its number of authorized shares of Common Stock, on or after the Maturity Date, if there is an Event of Default as described in Section 2(a) the Company has the right, at its sole option, to convert the outstanding principal amount of this Note and all accrued and unpaid interest on this Note into fully paid and nonassessable shares of the Company's common stock at a price per share equal to \$5.67 (subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event).

(b) Fractional Shares; Interest; Effect of Conversion. No fractional shares shall be issued upon conversion of this Note. In lieu of the Company issuing any fractional shares to the Investor upon the conversion of this Note, the Company shall pay to Investor an amount equal to the product obtained by multiplying the applicable conversion price by the fraction of a share not issued pursuant to the previous sentence. In addition, to the extent not converted into shares of capital stock, the Company shall pay to Investor any interest accrued on the amount converted and on the amount to be paid by the Company pursuant to the previous sentence. Upon conversion of this Note in full and the payment of the amounts specified in this paragraph, the Company shall be forever released from all its obligations and liabilities under this Note and this Note shall be deemed of no further force or effect, whether or not the original of this Note has been delivered to the Company for cancellation.

5. **Representations and Warranties of Investor.** By acceptance of this Note, Investor represents and warrants to the Company that Investor has full legal capacity, power and authority to execute and deliver this Note and to perform its obligations hereunder. This Note constitutes valid and binding obligations of Investor, enforceable in accordance with its terms, except as limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors' rights generally and general principles of equity.

6. **Origination Fee.** In connection with, and upon the funding of the Note, the Company shall pay to Investor an origination fee of one-half of one percent (0.5%) of Three Hundred Million Dollars (\$300,000,000).

7. **Definitions.** As used in this Note, the following capitalized terms have the following meanings:

“**Event of Default**” has the meaning given in **Section 2** hereof.

“**Investor**” shall mean the Person specified in the introductory paragraph of this Note or any Person who shall at the time be the registered holder of this Note.

“**Interest Payment Date**” means the 17th day of each March, June, September and December, commencing with March 17, 2022.

“**Obligations**” shall mean and include all loans, advances, debts, liabilities and obligations, howsoever arising, owed by the Company to Investor of every kind and description, now existing or hereafter arising under or pursuant to the terms of this Note, including, all interest, fees, charges, expenses, attorneys' fees and costs and accountants' fees and costs chargeable to and payable by the Company hereunder and thereunder, in each case, whether direct or indirect, absolute or contingent, due or to become due, and whether or not arising after the commencement of a proceeding under Title 11 of the United States Code (11 U. S. C. Section 101 *et seq.*), as amended from time to time (including post-petition interest) and whether or not allowed or allowable as a claim in any such proceeding.

“**Person**” shall mean and include an individual, a partnership, a corporation (including a business trust), a joint stock company, a limited liability company, an unincorporated association, a joint venture or other entity or a governmental authority.

“**CME Term SOFR Administrator**” means CME Group Benchmark Administration Limited as administrator of the forward-looking term Secured Overnight Financing Rate (SOFR) (or a successor administrator).

“**Interest Period**” means (a) the period commencing on the date of this Note and ending on the numerically corresponding day in the calendar month that is three months thereafter and (b) each three-month period thereafter ending on an Interest Payment Date; *provided*, that (i) if any Interest Period would end on a day other than a Business Day, such Interest Period shall be extended to the next succeeding Business Day unless such next succeeding Business Day would fall in the next calendar month, in which case such Interest Period shall end on the next preceding Business Day, and (ii) any Interest Period that commences on the last Business Day of a calendar month (or on a day for which there is no numerically corresponding day in the last calendar month of such Interest Period) shall end on the last Business Day of the last calendar month of such Interest Period.

“**Term SOFR Determination Day**” has the meaning assigned to it under the definition of Term SOFR Reference Rate.

“**Term SOFR Rate**” means, for any tenor comparable to the applicable Interest Period, the Term SOFR Reference Rate at approximately 5:00 a.m., Chicago time, two U.S. Securities Business Days prior to the commencement of such tenor comparable to the applicable Interest Period, as such rate is published by the CME Term SOFR Administrator.

“**Term SOFR Reference Rate**” means, for any day and time (such day, the “**Term SOFR Determination Day**”), for any tenor comparable to the applicable Interest Period, the rate per annum reasonably determined by the Company as the forward-looking term rate based on SOFR. If by 5:00 pm (New York City time) on the fifth (5th) U.S. Government Securities Business Day immediately following any Term SOFR Determination Day, the “Term SOFR Reference Rate” for the applicable tenor has not been published by the CME Term SOFR Administrator, then the Term SOFR Reference Rate for such Term SOFR Determination Day will be the Term SOFR Reference Rate as published in respect of the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate was published by the CME Term SOFR Administrator.

“**U.S. Government Securities Business Day**” means any day except for (i) a Saturday, (ii) a Sunday or (iii) a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

8. Miscellaneous.

(a) *Waiver and Amendment.* Any provision of this Note may be amended, waived or modified upon the written consent of the Company and Investor.

(b) *Notices.* All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail (if to Investor) or otherwise delivered by hand, messenger or courier service addressed:

(i) if to Investor, to Investor’s address, facsimile number or electronic mail address as shown in the Company’s records, as may be updated in accordance with the provisions hereof, or, until such holder so furnishes an address, facsimile number or electronic mail address to the Company, then to the address, facsimile number or electronic mail address of the last holder of this Note for which the Company has contact information in its records; or

(ii) if to the Company, to the attention of the Chief Executive Officer or Chief Financial Officer of the Company at 3530 John Hopkins Court San Diego, CA 92121, or at such other current address as the Company shall have furnished to Investor, with a copy (which shall not constitute notice) to Martin J. Waters, Wilson Sonsini Goodrich & Rosati, P.C., 12235 El Camino Real, Suite 200, San Diego, CA 92130-3002.

Each such notice or other communication shall for all purposes of this Note be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent via a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent via mail, at the earlier of its receipt or five days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent via facsimile, upon confirmation of facsimile transfer or, if sent via electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient’s next business day. In the event of any conflict between the Company’s books and records and this Note or any notice delivered hereunder, the Company’s books and records will control absent fraud or error.

(c) *Payment.* Unless converted into the Company's equity securities pursuant to the terms hereof, payment shall be made in lawful tender of the United States.

(d) *Default Rate; Usury.* During any period prior to the Maturity Date in which a non-payment by the Company of the interest earned on the Note has occurred and is continuing, or an Event of Default has occurred and is continuing, the Company shall pay interest on the unpaid principal balance hereof at a rate per annum equal to the rate otherwise applicable hereunder of eight percent (8%). 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.

(e) *Waivers.* The Company hereby waives notice of default, presentment or demand for payment, protest or notice of nonpayment or dishonor and all other notices or demands relative to this instrument.

(f) *Governing Law.* This 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 regard to the conflicts of law provisions of the State of California, or of any other state.

(g) *Restriction on Transferability.* This Note and the rights and obligations hereunder may not be assigned by either the Investor or the Company without the prior written consent of the other party.

(h) *Registration.* The Company or its agent will keep books for the registration and registration of transfer of the Note. Subject to this section and any other restrictions on or conditions to transfer set forth in the Note, the Note may be transferred only upon its surrender to the Company for registration of transfer, duly endorsed, or accompanied by a duly executed written instrument of transfer in form satisfactory to the Company. Prior to registration of any such transfer, the Company shall treat the person in whose name the Note is registered as the owner and holder of the Note for all purposes, including payment of principal and interest, and the Company shall not be affected by notice to the contrary.

(signature page follows)

The Company has caused this Note to be issued as of the date first written above.

IMMUNITYBIO, INC.,
a Delaware corporation

By: /s/ Richard Adcock

Name: Richard Adcock

Title: Chief Executive Officer and President

(Signature page for Note)

IMMUNITYBIO ANNOUNCES COMPLETION OF \$470 MILLION POST-MERGER FINANCING TO FUND LATE-STAGE CANCER CLINICAL TRIALS, PHASE 3 OF COVID T-CELL UNIVERSAL BOOST VACCINE TRIAL AND PROVIDES UPDATE ON BLADDER CANCER BLA FILING

Year-End Review:

- SISONKE Universal Boost COVID T-Cell vaccine trial initiates Phase 3 enrollment in South Africa in previously vaccinated participants
- Increased GMP manufacturing capacity for RNA, DNA, Subunit Proteins, and Adjuvants vaccine platforms in U.S., South Africa, and Botswana
- Non-Muscle Invasive Bladder Cancer (NMIBC) planned data cutoff in January 2022 with median follow-up exceeding 24-months for carcinoma in situ (CIS) cohort; Biologics License Application (BLA) filing planned for Q1, 2022
- Thirteen (13) Phase 2 / 3 clinical trials in progress for the treatment of multiple tumor types, COVID, and HIV
- Seminal immunotherapy patents issued with terms extended to 2038

CULVER CITY, Calif., December 20, 2021 - ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, has successfully raised an aggregate \$470 million of equity and debt financing in 2021, with \$300 million in new debt financing from Nant Capital, LLC. With this new financing from ImmunityBio's founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Patrick Soon-Shiong, on December 17, 2021, the company is now well positioned to pursue its late-stage clinical portfolio, expand large-scale GMP manufacturing capacity, and advance recruitment of a commercial organization in the urology market.

"In just a short nine months since the formation of ImmunityBio following the merger with NantKwest in March 2021, the progress made in advancing the late-stage clinical platforms in cancer and infectious diseases has been quite remarkable," said Soon-Shiong. "In less than one year, the company has accomplished several important milestones: advanced our Universal Boost COVID T-Cell Vaccine to Phase 3; acquired, developed, and scaled multiple vaccine platforms including DNA to RNA to Subunit proteins; expanded our GMP manufacturing capacity across NK cells, fusion proteins, and RNA vaccines; advanced clinical trial enrollment across pancreatic, breast, and bladder cancers; was selected by the NCI and national cooperative groups for a large Lung-MAP trial; advanced our HIV clinical program globally; and received issuance of seminal cancer vaccine and bladder cancer patents with terms up to 2038."

"With \$470 million of financing achieved since the merger, we now have the resources to rapidly advance our late-stage pipeline, build upon our 400,000 sq. feet of GMP biologic, vaccine, and NK manufacturing facilities for 2022 and expand our commercial operations in anticipation of our bladder cancer BLA filing in Q1, 2022," continued Soon-Shiong. "I am proud of the tireless efforts of management and of the entire organization who dedicated their efforts to accomplish these ambitious milestones and I am pleased to support the recently completed financing round."

ImmunityBio now has 21 active clinical trials, 13 of which are in Phase II or III development. In addition, the company has held discussions with the FDA to file a biologics license application (BLA) for Anktiva™ (to be branded VesAnktiva™ for intravesical administration) plus BCG for BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ (CIS) with a planned data cutoff date of January 2022, under discussions with the FDA. By that date, the median follow-up of patients with high risk CIS BCG responsive disease will exceed 24 months.

ImmunityBio and its scientists published over twenty scientific papers on its immunotherapy portfolio in 2021 and the company has over 750 granted patents for its immunotherapy technologies, including the Nant Cancer Vaccine.

“During the year, management and the clinical, regulatory, scientific, and manufacturing teams made tremendous progress across the board at ImmunityBio. We are advancing our clinical development at an increasing rate with the goal of positioning ourselves to apply for regulatory approval in 2022,” said Richard Adcock, President and CEO of ImmunityBio. “With the \$300 million financing from Nant Capital combined with the equity raised over the last nine months, we have made the decision to pause the At-the-Market offering and we are well positioned to further accelerate development of our oncology and COVID-19 trials— with the goal of bringing these promising technologies to more people in need globally.”

Clinical Year-End Review of Strategic Milestones:

1. BCG-Unresponsive Non-Muscle Invasive Bladder Cancer CIS (QUILT 3.032)

The company reported that the primary end points were met for both CIS and Papillary BCG-unresponsive non-muscle invasive bladder cancer in October 2021 with a complete remission rate of 72% and a 12-month disease-free rate of 57%, respectively.

At the end of November 2021, the company provided briefing books and updates to the FDA with November cutoff data showing a 72% complete response rate in the CIS cohort and a median duration of complete response of 24 months. Of note, in those patients who responded to the investigational therapeutic, the probability of avoiding both progression of bladder cancer and cystectomy for over 24 months exceeded 90 percent. The data to the FDA included findings that the combination of Anktiva and BCG had a high safety profile with zero percent treatment-related serious adverse events, zero percent immune related adverse events, and 100 percent bladder cancer-specific overall survival at 24 months. The company plans on a data cutoff in January 2022, which would provide a median follow up in this CIS cohort in excess of 24 months, and anticipates a BLA filing with this final analysis in Q1, 2022.

The papillary cohort continues to accrue and updates will be provided as part of an oral presentation at the ASCO Genitourinary Cancers Symposium in February 2022.

Seminal patents covering intravesical administration of BCG and Anktiva were issued (US 11,173,191 B2 and US 9,925,247 B2) providing term coverage until 2035.

2. Pancreatic Cancer (QUILT 88):

In October 2021, ImmunityBio announced that the study's third cohort, which includes patients with third-line or greater disease, is fully enrolled and of the evaluable patients, 90% (43/48) have exceeded the historical survival rates of approximately two months with standard-of-care chemotherapy. Based on the strength of this early data and the significant unmet medical need, ImmunityBio submitted an amendment to the FDA to increase enrollment in the third cohort ("Cohort C"), and enrollment is actively ongoing. The interim results of Cohort C in the QUILT 88 study have been selected for presentation at the ASCO Gastrointestinal Cancers Symposium, January 2022 in San Francisco and the data to date continues to show that the historical overall survival in patients who have enrolled with 3rd, 4th, 5th and even 6th line metastatic pancreatic cancer exceeds any historical overall survival rate for this advanced stage of disease for which there is no further treatment options available.

3. Natural Killer Cell Platform Advances

A. PD-L1 T-haNK

- **Manufacturing Scale:** The company has significantly advanced the manufacturing scale of PD-L1 t-haNK in 2021 and has now achieved 200-liter scale in the last nine months. At this scale, a single manufacturing campaign yields approximately 700 billion PD-L1 t-haNK cells, sufficient for 350 doses. The company has successfully manufactured and cryopreserved trillions of PD-L1 t-haNK cells and is advancing to 500-liter scale in 2022. The company believes it is the first to achieve this large-scale manufacturing capability and capacity in the field of natural killer cells.
- **Clinical Trials with PD-L1 T-haNK:**
 - **TNBC:** The company continues to study this engineered NK-92 cell line in Phase 1 / 2 trials in Triple Negative Breast Cancer to increase effectiveness of Trodelvy (sacituzumab govitecn-hziy) (CT.gov [NCT04927884](#))
 - **Metastatic pancreatic cancer** to prolong survival rate (CT.gov [NCT04390399](#))
 - **Head & Neck Cancer** to increase the effectiveness of Keytruda (pembrolizumab) plus N-803 (CT.gov [NCT04847466](#))
- **Mechanism of Action:** On March 2021, in collaboration with National Cancer Institute (NCI), ImmunityBio's PD-L1 t-haNK was reported to be a potent cell therapy agent against myeloid-derived suppressor cells (MDSC) and overcome T cell escape in multiple types of resistant tumors.

B. M-ceNK

- **Manufacturing Scale:** The company has achieved a first-in-class manufacturing scale of highly potent natural killer cells isolated from autologous or allogeneic peripheral blood retrieved by an outpatient process of blood withdrawal and separating out white cells, termed apheresis. Over 3,000 percent M-ceNK (memory cytokine enhanced natural killer cells) cell expansion was achieved from a single apheresis. The company has successfully established proprietary proliferation and cryopreservation techniques and this first-generation manufacturing method enables as many as twenty (20) doses of 1 billion M-ceNK cells from a single apheresis. The second-generation manufacturing process has advanced the yield from 20 billion to ~100 billion M-ceNK cells, translating into ~100 doses from a single autologous or allogeneic apheresis sample.
- **Clinical Trials with M-ceNK in Solid Tumors:** In May 2021, the company announced that the FDA authorized ImmunityBio to conduct a first-in-human trial to study the cryopreserved memory cytokine-enhanced NK cell (M-ceNK) platform in solid tumors. An initial study involving 20 subjects (15 healthy donors and 5 cancer patients) showed that healthy and patient-derived M-ceNK cells killed NK-resistant tumor cells with equal potency as shown in pre-clinical models.
- **Mechanism of Action:** In an initial, proof-of-concept clinical study, memory-like NK cells with freshly isolated cytokine-stimulated NK cells demonstrated encouraging results in patients with liquid tumors. These m-ceNK cells, or memory-cytokine enriched NK cells, have been designed for autologous cell therapy, but have also been generated as an allogeneic product from cord blood. The m-ceNK product is characterized as CD56+ cells that are armed with NK cell activating surface receptors required for proliferation, homing and tumor recognition and binding. Both the healthy- and cancer patient-derived m-ceNK cells killed NK-resistant tumor cells with equal potency when tested against tumor cells of different origins, including breast, Merkel, ovarian, adenocarcinoma, and lymphoma.

C. CD-19 t-haNK

- **Manufacturing Scale:** Since the June 2019 announcement of FDA authorization to launch the first engineered GMP-grade cryopreserved bi-specific NK cell therapy targeting CD-16 and CD-19 in patients with lymphoma, the merged company undertook manufacturing improvements to scale the product prior to initiation of clinical trials. These advances have been successfully completed and the amended manufacturing process has been submitted to the FDA. CD-19 T-haNK has been manufactured at 200-liter scale and the GMP product is now ready for clinical trials.
- **Clinical Trials:** A clinical trial in advanced B cell lymphoma is anticipated to begin in the first half of 2022.

4. N-803 (Anktiva) and Aldoxorubicin Clinical Development in Cancer & HIV

- A. **Lung Cancer:** In October 2021, ImmunityBio announced that N-803 has been chosen by Lung Cancer Master Protocol (Lung-MAP), a public-private partnership—which includes the National Cancer Institute (NCI), the National Clinical Trials Network (NCTN) Cooperative Groups (SWOG, ECOG-ACRIN, Alliance, and NRG), Friends of Cancer Research, and the Foundation for the National Institutes of Health (FNIH)—to study N-803 (Anktiva) in the Lung-MAP trial.

ImmunityBio’s study will test N-803 (Anktiva) in combination with Merck’s Keytruda (pembrolizumab) in up to 478 second-line patients with tumors that are not targetable with a drug, which accounts for the majority of NSCLC cases.

In Q4 2021, ImmunityBio received approval from the Institutional Review Board (IRB) overseeing the Lung-Map study to proceed with the trial—one of the National Cancer Institute’s largest lung cancer clinical trials with more than 700 sites.

- B. **Pancreatic Cancer, Triple Negative Breast Cancer, Head & Neck Cancer:** N-803 and Aldoxorubicin are used in combination with PD-L1 t-haNK in Phase 1 / 2 clinical trials described above.
- C. **Glioblastoma:** A Phase 1 / 2 trial has been submitted for the study of N-803 and Aldoxorubicin in Glioblastoma. Further progress will be provided in 2022.
- D. **HIV with N-803:** In June 2021, ImmunityBio announced the opening of a Phase 1 ‘HIV Cure Study’ in patients off therapy and a Phase 2 study in acutely infected patients. Sponsored by the NIAID and AIDS Clinical Trials Group, an “HIV cure study” will evaluate whether Anktiva (N-803) alone or together with broadly neutralizing antibodies can control HIV following interruption of antiretroviral therapy (ART). The Phase 1 open-label, randomized study will enroll 46 people living with HIV whose virus has been suppressed by ART for approximately two years, including at least 30 percent cisgender women or transgender men. A second clinical trial studying Anktiva in HIV is being conducted by the U.S. Military HIV Research Program in Thailand. The Phase 2 study is evaluating Anktiva in combination with antiretroviral therapy (ART) during acute HIV infection as an experimental therapy to target and inhibit early establishment of HIV reservoirs in infected individuals.

Both studies have opened and patients are actively enrolling. Preliminary data will be reported in 2022.

5. COVID Program to Overcome Spike Variants and Induce T Cell Immunity

Since the inception of the pandemic, ImmunityBio and its scientists have hypothesized that antibody-based vaccines alone are insufficient to prevent transmission and will not overcome viral evolution, resulting in loss of efficacy of antibody-based vaccines with the inevitable development of variants. The company from the onset believed strongly that an immune response generating a combination of antibodies, T cells, and memory B cells is critical to prevent infection, reduce viral load, prevent transmission, provide durable protection and overcome this pandemic.

In order to reduce viral load, T cells are necessary to kill virally infected cells in the nasal and lung passages and thereby prevent transmission even from highly transmissible variants. The non-human primate COVID virus challenge study performed by ImmunityBio in September 2020, supported by BARDA confirmed that ImmunityBio's second-generation hAd5 S+N vaccine accomplished the goal of reducing viral load following a COVID virus challenge, to non-detectable levels. The study was published on September 2021 in *Frontiers in Immunology* entitled, "Dual-Antigen COVID-19 Vaccine Subcutaneous Prime Delivery with Oral Boosts Protects NHP Against SARS-CoV-2 Challenge", showing the presence of memory B cells and a rapid antibody response post-challenge with killing of infected cells resulting in no detectable COVID viruses in the nasal and lung passages.

On the basis of these findings, the ImmunityBio program was designed to pursue this strategy of driving T cell and antibody protection, and to develop a second-generation vaccine with broad depth of antigenic coverage. Furthermore, the company pursued a strategy to develop a vaccine that could be manufactured at scale, at low cost, overcome cold-chain distribution issues and provide long-lasting durable protection for the global population. The programs, initiated as early as March 2020, are described below and the initial findings have shown that hAd5 S+N vaccination as a single prime alone induces a 10-fold increase in mean T cell responses in Phase 1 participants and are sustained against spike variants.

Since initiating the initial homologous prime boost trial in October 2020 in the United States, it has become apparent that a "mix-and-match" strategy could provide maximal immune protection. The company has followed this path and the homologous and heterologous portfolio of vaccine platforms are at various stages of clinical development.

A. Homologous Platform

Homologous hAd5 S + N Platform Prime & Boost:

In October 2020, the FDA authorized a Phase 1 trial of ImmunityBio's dual construct Spike + Nucleocapsid (hAd5 S+N) COVID-19 vaccine, designed to drive both T cell and antibody immunity. The company undertook a rigorous development strategy to explore multiple methods of administration (oral, intranasal, subcutaneous, and combinations of each) to determine the best site of delivery to achieve maximum antibody, T cell and mucosal immunity. In February 2021, this trial was expanded to South Africa (The ProVIVA-SA1 Trial). To date, 74 participants have enrolled in the U.S. and South African Phase 1 studies. Data acquisition and analysis from both trials is ongoing. Preliminary analysis has shown that subcutaneous dosing of hAd5 S+N provides strong T cell responses to both Spike and Nucleocapsid antigens with no serious adverse events reported to date. These studies formed the basis of the Universal T Cell Boost Trial (SISONKE Boost Trial) activated in South Africa in July 2021.

United States Studies: In April 2021, we reported on the preliminary data from the United States trial showing that just a single prime subcutaneous vaccination with our COVID-19 vaccine candidate induced a 10-fold increase in T cell response—equivalent to T cell responses from patients previously infected with SARS-CoV-2. We have also shown that the T-cell responses are maintained against variants, which is critical to providing protection against this ever-changing virus. In light of the FDA Guidance to the industry regarding risks of thrombosis with thrombocytopenia syndrome (TTS) that were observed with other adenoviral vectored COVID-19 vaccines, the FDA requested that ImmunityBio provide multiple risk mitigations and management measures, which ImmunityBio did and incorporated into all new COVID-19 study protocols, lifting all clinical holds. The immunogenicity assays from the U.S. trials are being validated and this process is expected to be completed in Q1 2022. The ongoing U.S. trials will be completed as planned with the subjects who have been enrolled.

B. Heterologous Mix-and-Match Program

ImmunityBio has acquired the rights to multiple platforms and initiated a consortium including the Baylor College of Medicine, Infectious Disease Research Institute (IDRI), Amyris, Inc. and EnGeneIC to develop, manufacture and scale second-generation vaccines that combine different advanced DNA, RNA, protein constructs, and adjuvants. The company has adopted a long-term approach to addressing COVID and future pandemics and believes these mix-and-match components are critical to providing accessible, broad, and durable protection against current and future variants such as Delta and Omicron variants.

“Developing a novel vaccine candidate during a global pandemic has been challenging for a number of reasons, which have affected all drug developers,” said Soon-Shiong. “When we first announced our intent to develop a COVID-19 vaccine in April 2020, we indicated a vaccine that generates long-lasting, cell-mediated T cell immunity would require the use of genomics, molecular dynamics, and new vectors. We also hypothesized that a heterologous approach (mix-and-match) would strengthen immune response. Almost two years into the pandemic and dozens of virus mutations later, these predictions are proving more accurate than ever, which is why we are partnering with IDRI, Amyris, Inc., EnGeneIC, and the Baylor College of Medicine to develop next generation mRNA, recombinant protein vaccine candidates and first-in-class invariant NK-T Cell (iNK-T) COVID vaccines. We anticipate being able to move quickly to enroll participants in our COVID-19 trials in South Africa and Botswana and, ideally, bringing a highly effective vaccine to market in the next 12-18 months.”

ImmunityBio has undertaken the strategy that a mix-and-match approach of different vaccine platforms (DNA, RNA and subunit proteins) would provide the strongest durable immunity and allow large-scale manufacturing, mitigating supply chain limitations of any single platform. To execute on this strategy, the company announced in [November 2021](#), expansion of its vaccine program.

1. Heterologous SISONKE Universal Boost T Cell Trial (South Africa):

J&J Ad26 Prime + hAd5 S + N Boost Enters Phase 3

The SISONKE Universal Boost T Cell Trial was the first DNA / DNA heterologous mix and match trial of Ad26 and hAd5. The [Phase 1 / 2 / 3 trial](#) was designed to study the efficacy, safety, and immunogenicity of ImmunityBio's T-Cell COVID-19 vaccine as a boost in participants who have already received a spike-only antibody-based vaccine. The study is designed to explore whether the T-cell-based vaccine could prevent breakthrough infections from the Delta variant in health care workers who are already vaccinated. The goal of the hAd5 S+N vaccine is to potentially provide increased protection and long-term immunity against the multiple variants and multiple waves affecting South Africa and other countries. Phase 1 studies of subcutaneous dosing in the U.S. have demonstrated no serious adverse events and potent T-cell responses after a single prime dose.

The SISONKE Universal Boost Phase 2 trial is fully enrolled with 60 participants with no serious adverse events. The Phase 3 trial is now open and enrollment will begin in January 2022.

2. Heterologous THEMBA Trial (South Africa):

SASA RNA Prime + hAd5 S+N Boost

The [THEMBA trial](#) is the first heterologous RNA / DNA prime boost study of self-amplifying self-adjuvating RNA (SASA-RNA), next-generation nano-lipid carriers with hAd5 S+N. The trial is under regulatory review at SAHPRA and the company is awaiting authorization to begin the study in South Africa.

3. Heterologous PULA Trial (Botswana):

SASA RNA Prime + Nabisome EDV or RBD Subunit Protein Boost

Nabisome (EDV) Platform: In [November 2021](#), EnGeneIC and ImmunityBio signed an exclusive, worldwide license agreement to develop the first invariant NK – T (iNK-T) cell vaccine for the treatment of COVID. This nano cell technology, termed Nabisome EDV, is now in Phase 1 clinical trials in Australia. To date, the initial dose of 2x10⁹ EDV IM dose has been shown to be safe with promising antibody, memory B cell and T-cell activity. ImmunityBio plans to expand this trial in Australia and the U.S. and use Nabisome in combination with SASA RNA in the PULA trial in Botswana. The PULA Mix-and-Match Trial will be submitted in Q4 2021 for regulatory review.

RBD Recombinant Protein Subunit + Adjuvant Platform: In November 2021, ImmunityBio announced it had licensed a recombinant protein COVID-19 vaccine (RBD Subunit) candidate from Baylor College of Medicine, which was developed at the Texas Children’s Hospital Center for Vaccine Development. Protein-based vaccines have long been used to confer immunity against hepatitis B and human papillomavirus (HPV), as immune responses often target proteins that are part of viruses and bacteria. This recombinant protein vaccine technology is proven and well-established. Production of these vaccines can be easily scaled up in low-resource countries. Paired with powerful adjuvant formulations developed by IDRI and partners, protein-based vaccines can provide broad protection against multiple coronavirus variants and are stable at room temperatures. ImmunityBio will lead development, manufacture scale up and commercialization of the recombinant protein vaccine candidate in South Africa.

C. Vaccine Manufacturing Capacity

ImmunityBio has expanded manufacturing capacity for each of these platforms (hAd5, SASA RNA, Adjuvants, and RBD subunit) in the U.S., as well as secured manufacturing sites in [South Africa](#) and [Botswana](#) with strategic collaborators. The SASA RNA manufacturing capacity will support the ImmunityBio/Amyris COVID-19 joint venture.

About ImmunityBio

ImmunityBio is a leading 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 clinical pipeline consists of 21 clinical trials—13 of which are in Phase II or III development—across 12 indications in solid and liquid cancers (including bladder, pancreatic, and lung cancers) and infectious diseases (including SARS-CoV-2 and HIV). Currently 17 first-in-human immunotherapy agents are in clinical testing and, to date, over 1,800 patients have been studied with our antibody cytokine fusion proteins, albumin chemo immunomodulators, Adeno and yeast vaccines and our off-the-shelf natural killer cell products. 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).

The company's platforms are 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. ImmunityBio is currently developing a dual construct COVID-19 vaccine candidate using its hAd5 platform. The company has established GMP manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations and development teams. 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, such as statements regarding plans regarding ImmunityBio's ATM offering, the timing of the filing of ImmunityBio's BLA, timing of regulatory approval of ImmunityBio's product candidates, additional manufacturing capacity to produce vaccines, the development of therapeutics for cancer and infectious diseases, the efficacy of the combination approach in conferring long-term immunity against COVID-19 and its variants, potential advantages of ImmunityBio's vaccine candidates as compared to existing COVID-19 vaccines, and clinical trial enrollment and advancements, among others. 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. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. 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 information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. 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) 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, (ii) risks related to ImmunityBio's reliance on third parties including its partners, licensors and strategic collaborators, (iii) inability to retain and hire key personnel, (iv) whether interim, initial, "top-line" and preliminary data from ImmunityBio's preclinical and clinical trials that it announces or publishes 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, (v) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vi) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, (vii) ImmunityBio's

ability to successfully commercialize its product candidates and (viii) the unknown future impact of the COVID-19 pandemic delay on certain clinical trials or their 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 the Company's Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 10, 2021, Form 10-Q filed with the SEC on November 12, 2021 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.

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