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):
June 15, 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 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 5.07 Submission of Matters to a Vote of Security Holders.

Say-On-Pay Frequency Vote Determination

As described in the Form 8-K filed by ImmunityBio, Inc., a Delaware corporation (the "Company") on June 11, 2021, the Company held its Annual Meeting of Stockholders (the "Annual Meeting") on June 10, 2021. At the Annual Meeting, stockholders were provided the opportunity to cast non-binding advisory votes on the compensation of the Company's named executive officers (the "Say on Pay Vote") and the frequency with which stockholders should be provided the opportunity to vote on future Say on Pay Votes (the "Frequency Vote"). Following the recommendation of the Company's Board of Directors, approximately 99% of votes cast by stockholders at the Annual Meeting were voted to approve the Say on Pay Vote and approximately 97% of votes cast were voted in favor of the Three (3) Year frequency for the Frequency Vote. Consistent with these results, it is the Company's decision to include an advisory vote on the compensation of the Company's named executive officers every three years until the next required vote on the frequency of such an advisory vote.

Item 8.01 Other Events.

NCI Phase I M7824 Combination Trial

The National Cancer Institute (the "NCI") is currently conducting a Phase I clinical trial that includes the investigational agent M7824 (bintrafusp alfa) from EMD Serono Research & Development Institute, Inc., the biopharmaceutical business of Merck KGaA, in combination with additional investigational agents including ImmunityBio's TriAd Vaccine and N-803. The trial is titled, "A Sequential Window of Opportunity Trial of Anti-PD-L1/TGF-beta trap (M7824) Alone and in Combination with TriAd Vaccine, and N-803 for p16-Negative Resectable Head and Neck Squamous Cell Carcinoma" (the "NCI Phase I M7824 Combination Trial").

This Phase I M7824 Combination Trial has been developed and is being led by the NCI. The United States Food and Drug Administration (the "FDA") has placed a clinical hold on the NCI Phase I M7824 Combination Trial after a death associated with pneumonitis. To date, no severe adverse events in the NCI Phase I M7824 Combination Trial have been attributed to either the TriAd vaccine or N-803, and the NCI has not enrolled any subjects in the N-803 arm to date. The FDA has requested an autopsy and analysis of similar events with M7824 and a risk mitigation proposal. At this time, no analysis or risk mitigation strategy has been requested for ImmunityBio's TriAd vaccine or N-803 in connection with this clinical hold. Further, this hold does not affect any ImmunityBio-sponsored clinical trials, investigator-initiated trials, or single patient INDs that are ongoing. The Company intends to continue to monitor the FDA's further review process through the NCI, which is ongoing, for any further developments.

Press Release Regarding Authorization of Triple-Negative Breast Cancer Study

On June 15, 2021, the Company issued a press release announcing that the FDA has authorized the Company's study of Anktiva (N-803) and PD-L1 t-haNK to increase effectiveness of Trodelvy in Triple-Negative Breat Cancer (the "Press Release"). As described in the Press Release, the open-label Phase 1b/2 study will evaluate the safety and preliminary efficacy of Anktiva (N-803) and PD-L1 t-haNK in combination with antibody-drug conjugate Trodelvy and low-dose chemotherapy in subjects with advanced triple-negative breast cancer after prior therapy. The study design is based on the results of a Phase 1 trial of haNK cells combined with Anktiva and low dose chemo in refractory triple negative breast cancer, where a disease control rate of 78% and an overall response rate of 67% was reached. Enrollment in the study is expected to begin in the third quarter of 2021. A copy of the Press Release is included herewith as Exhibit 99.1 to this report and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 15, 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: June 15, 2021

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

ImmunityBio

NEWS RELEASE

FDA Authorizes ImmunityBio Study of Anktiva and PD-L1 t-haNK to Increase Effectiveness of Trodelvy in Triple-Negative Breast Cancer

- Open-label Phase 1b/2 study will evaluate the safety and preliminary efficacy of Anktiva (N-803) and PD-L1 t-haNK in combination with antibody-drug conjugate Trodelvy and low-dose chemotherapy in subjects with advanced triple-negative breast cancer (TNBC) after prior therapy
- The FDA approved Trodelvy for TNBC in April 2020 based on an overall response rate of 33.3%, with a median duration of response of 7.7 months; 55.6% maintained their response for 6 or more months and 16.7% maintained their response for 12 or more months
- Study design is based on results of a Phase 1 trial of haNK cells combined with Anktiva and low dose chemo in refractory triple negative breast cancer, where disease control rate of 78% and overall response rate of 67% was reached
- Enrollment expected to begin in Q3 2021

CULVER CITY, Calif., June 15, 2021 – ImmunityBio, Inc. (NASDAQ: IBRX), a clinical-stage immunotherapy company, today announced it has received FDA authorization to conduct a Phase 1b/2 open-label study to evaluate the safety and preliminary efficacy of its superagonist Anktiva (N-803, an IL-15 superagonist) and PD-L1 targeted high-affinity natural killer (t-haNK) cells in combination with standard chemo and Trodelvy (sacituzumab govitecan-hziy), in subjects with advanced triple-negative breast cancer (TNBC). The study may provide data indicating whether this combination can increase the effectiveness of Trodelvy in patients who have failed to respond to other treatments.

Triple-negative breast cancer is a serious, aggressive cancer with a high mortality rate. While Trodelvy displayed efficacy against TNBC in phase 3 testing, only a third of third-line patients respond to it, and less than 17% of them continue to respond after a year. ImmunityBio proposed this new study based on data from a Phase 1 trial (NCT03387085) with Anktiva and the company's haNK cells that elicited a significant response rate in refractory TNBC. Anktiva and PD-L1 t-haNK when used in combination with Trodelvy may show additive or even synergistic effects, greatly increasing the response rate and, importantly, durability of responses.

"Antibody-drug conjugates like Trodelvy have made tremendous progress in giving patients with TNBC more and higher-quality time, but we believe Anktiva could potentially fill remaining treatment gaps and offer patients additional hope," said Patrick Soon-Shiong, M.D., Founder and Executive Chairman of ImmunityBio. "We're conducting multiple studies with Anktiva across different tumor types, in some cases in combination with our NK cell line, that are designed to determine if they can enhance the activity of therapeutic monoclonal antibodies like Trodelvy—and, ultimately, provide patients with longer, progression-free survival."

The strategy behind this approach is to attack the tumor in two distinct, complementary ways—with Trodelvy delivering the initial blow by targeting the protein Trop-2 displayed by many TNBC cells and delivering a chemotherapy payload while Anktiva recruits key cells of the immune system, including NK and T cells, to continue fighting the tumor. To further unleash the power of the immune system, PD-L1 t-haNK will be introduced.

“If Trodelvy is a missile that delivers a chemo ‘payload’ to a tumor target, a superagonist like Anktiva is the army that follows to finish the job and keep the target in check,” said Adam Brufsky, M.D., Ph.D., Professor of Medicine in the Division of Hematology/Oncology at the University of Pittsburgh and a member of ImmunityBio’s scientific advisory board. “Anktiva’s role in using the body’s immune system in the battle is a key part of the broader strategy to provide a long-term cure to breast and other types of cancer.”

QUILT 3.058 Study Details

This phase 1b/2 open-label study will evaluate the safety and efficacy of sacituzumab govitecan-hziy in combination with chemoimmunotherapy (cyclophosphamide, N-803, and PD-L1 t-haNK) in subjects with TNBC after at least two prior treatments for metastatic disease.

The study consists of two phases and the maximum total enrollment for this study is 79 subjects.

- The phase 1b portion of the study will be conducted in 2 parts: part 1 will involve dose escalation using a 3 + 3 design, and part 2 will involve the expansion of the recommended phase 2 dose (RP2D) to further evaluate the safety and efficacy of sacituzumab govitecan-hziy plus chemoimmunotherapy. The phase 2 portion of the study will be based on Simon’s two-stage optimal design.
- In phases 1b and 2, all subjects will receive sacituzumab govitecan-hziy plus chemo- and immuno-therapy: cyclophosphamide, N-803, and PD-L1 t-haNK on a 3-week schedule. . The dose of sacituzumab govitecan-hziy will be dependent on dose level cohort for phase 1b and will be set at the RP2D for phase 2. The doses of cyclophosphamide, N-803, and PD-L1 t haNK will remain the same in all dose level cohorts and phases.

An estimated 2.3 million women globally were diagnosed with breast cancer last year and 685,000 died from it. Triple negative breast cancer is an especially aggressive form of the disease and accounts for 10% to 15% of breast cancers, according to the American Cancer Society. TNBC tests negative for estrogen receptors (ER), progesterone receptors (PR) and human epidermal growth factor receptor 2 (HER2) protein. Therefore, TNBC does not respond to hormonal therapy or medicines that target ER, PR, or HER2 and other treatment options are limited, particularly after initial lines of therapy have failed. Innovative treatment approaches, such as the combination of Trodelvy, Anktiva, and PD-L1 t-haNK with chemotherapy described here may offer new hope to these advanced TNBC patients.

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 has a comprehensive immunotherapy pipeline with more than 40 clinical trials (company sponsored or investigator initiated) —of which 25 are at Phase II and III stage of development—across 19 indications in solid and liquid cancers and infectious diseases. 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.

ImmunityBio is a 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 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. 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 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 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) inability to retain and hire key personnel, (iii) uncertainty of the expected financial performance and successful integration of the combined company following completion of the recent merger of ImmunityBio with NantCell (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, (iv) whether 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, (v) our ability to obtain additional financing to fund our operations and complete the development and commercialization of our various product candidates, and (vi) 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 May 14, 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.

Contacts

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

Media

Katie Dodge
Salutem
978-360-3151
Katie.Dodge@salutemcomms.com