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): March 20, 2023

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)

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

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**	**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 Section13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Update Regarding Non-Muscle Invasive Bladder Cancer ("NMIBC") Initiatives

As previously disclosed, in May 2022 ImmunityBio, Inc. (the "Company") announced the submission of a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA") for N-803 in combination with bacillus Calmette-Guérin ("BCG") for the treatment of patients with BCG-unresponsive NMIBC with carcinoma in situ ("CIS") with or without Ta or T1 disease. In July 2022, we announced that the FDA had accepted our BLA for review and set a target Prescription Drug User Fee Act ("PDUFA") action date of May 23, 2023. The Company continues to engage in ongoing discussions and dialogue with the FDA, including the proposed label for the product candidate under review in the BLA. It remains unclear if the FDA will approve our BLA on the PDUFA action date, if at all.

In anticipation of the PDUFA date and as part of the Company's overall strategy, the Company continues to explore partnering with a large biopharmaceutical company for commercialization of N-803 for administration intravesically. The Company continues to engage in active discussions regarding a partnering strategy with the view of completing such a transaction during the first half of 2023, though there can be no assurance that the Company will complete a transaction on acceptable terms in accordance with this timeline or at all.

Financing

As the Company remains focused on preparing for the potential approval of the BLA by the FDA as described above, it intends to continue to explore opportunities to engage in incremental financing transactions to raise the working capital needed to fund the Company's ongoing operations through the anticipated May 23, 2023 PDUFA date and execute the Company's business strategy and initiatives. Such financings may include, without limitation, debt and/or equity financing transactions with the Company's Executive Chairman and Global Chief Scientific and Medical Officer and/or related entities.

Update Regarding Lung Cancer Trials

ImmunityBio has reviewed the updated QUILT 3.055 data, through February 5, 2023, from several cohorts of non-small cell lung cancer ("NSCLC") patients who have progressed after checkpoint inhibitor therapy. These cohorts are:

1. NSCLC patients with initial response on single-agent checkpoint inhibitor therapy and subsequently progressed on or after that therapy.
2. NSCLC patients having high PD-L1 expression (tumor proportion score ("TPS") ≥50%) and disease progression on a PD-1/PD-L1 checkpoint inhibitor after experiencing an initial response when received checkpoint inhibitor as a single-agent for first-line treatment.
3. NSCLC patients with initial response but subsequently relapsed on maintenance PD-1/PD-L1 checkpoint inhibitor therapy when initially received checkpoint inhibitor therapy in combination with chemotherapy as first-line treatment.
4. NSCLC patients currently receiving PD-1/PD-L1 checkpoint inhibitor therapy that progressed after experiencing stable disease for at least 6 months during previous treatment with PD-1/PD-L1 checkpoint inhibitor therapy.

The results are listed in the table below:

Overall Survival – NSCLC Subjects
Safety Population

Variable	Cohort 1a (N=19)	Cohort 2 (N=9)	Cohort 3 (N=20)	Cohort 4 (N=38)	All Subjects (N=86)
Number of Deaths	13 (68%)	6 (67%)	15 (75%)	21 (55%)	55 (64%)
Median Survival (months)	14.1	18.5	15.8	12.6	13.9
95% confidence intervals ("CI") for the Median Survival	11.7, 28.7	6.1, –	7.5, 24.9	8.8, 25.5	11.7, 17.4

These results show a median overall survival of 13.9 months in the 86 patients in the pooled analysis. This is in contrast to the overall survival of 6.1 months reported by *Freeman et al.*[1] for patients who received any therapy post-checkpoint inhibitor therapy progression or an overall survival of 7.5 months, as reported by *Brueckl et al.*, for patients who received docetaxel plus ramucirumab after initial failure of first-line chemotherapy plus checkpoint inhibitor[2].

The Company is currently exploring other clinical trial designs that are designed to utilize this overall survival advantage demonstrated by N-803 in the post-checkpoint inhibitor setting. The Company remains committed to studying ways in which N-803, based on its unique mechanism of action and additional study results, could be used in combination with a cell therapy or other immunotherapies to bolster a lung cancer patient's own natural killer ("NK") cells and T cells to fight the disease. The Company is actively working to modify the protocol for its non-small cell lung cancer study (QUILT 2.023) based on these findings and has begun planning a study of small cell lung cancer combining N-803 with the Company's memory-like cytokine-enhanced NK cells ("M-ceNK"), as well as a checkpoint inhibitor. The Company believes that preliminary preclinical data of M-ceNK in small cell cancers are promising.

The Company was recently notified by the National Cancer Institute and SWOG Cancer Research Network ("SWOG") that S1800D, a sub-study of the Lung Cancer Master Protocol ("Lung-MAP"), involving N-803 and pembrolizumab has been closed to accrual due to preliminary analysis indicating that the combination therapeutic may not meet the study's initial endpoint of 60% disease control at 12 weeks. The endpoint is different from the endpoint of median overall survival for the same patient population in the Company's QUILT 3.055 trial (updated data for QUILT 3.055 is provided above). No differences in the relatively well-tolerated adverse event profile were reported prior to the closure of the S1800D study.

The first interim analysis of S1800D was specified to be based on the first 25 eligible participants randomized to the N-803 plus pembrolizumab arm. This analysis would recommend continuation of accrual if the observed rate of disease control at 12 weeks ("DC12W") in the N-803 plus pembrolizumab arm is at least a 60%. The SWOG Data Safety Committee determined that <60% of the participants will achieve DC12W and on this basis made a recommendation that the study be closed at this time. These findings are consistent with the recent studies (including the KEYNOTE-789 study) in which pembrolizumab in combination with other agents failed to yield statistically significant overall survival benefits.

S1800D was designed and administered by Lung-MAP and was activated in February 2022. The study was based, in part, on results from a similar study, QUILT 3.055, which showed activity of N-803 in checkpoint inhibitor relapsed NSCLC patients, and with updated results discussed above showing median overall survival of 13.9 months in N=86 NSCLC patients.

The Company believes that these two studies provide insight into the contribution of effect of N-803 when combined with checkpoint inhibitors alone and provides support for the addition of off-the-shelf NK therapy or M-ceNK therapy to tip the scales towards maximizing tumor cell death.

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[1] Freeman AT, Lesperance M, Wai ES, Croteau NS, Fiorino L, Geller G, Brooks EG, Poonja Z, Fenton D, Irons S, Ksienski D. Treatment of Non-Small-Cell Lung Cancer after Progression on Nivolumab or Pembrolizumab. Current Oncology. 2020; 27(2):76-82. https://doi.org/10.3747/co.27.5495.

[2] Brueckl WM, Reck M, Rittmeyer A, Kollmeier J, Wesseler C, Wiest GH, Christopoulos P, Stenzinger A, Tufman A, Hoffknecht P, Ulm B, Reich F, Ficker JH, Laack E. Efficacy of docetaxel plus ramucirumab as palliative second-line therapy following first-line chemotherapy plus immune-checkpoint-inhibitor combination treatment in patients with non-small cell lung cancer (NSCLC) UICC stage IV. Transl Lung Cancer Res. 2021 Jul;10(7):3093-3105. doi: 10.21037/tlcr-21-197. PMID: 34430350; PMCID: PMC8350088.

Lead Independent Director Appointment

The Company's Board of Directors (the "Board") has appointed Cheryl L. Cohen, an existing member of the Board, to the newly-created position of Lead Independent Director of the Board as part of the Company's commitment to strong and effective corporate governance. In connection with the appointment of Ms. Cohen as Lead Independent Director, the Board adopted certain amendments to the Company's Corporate Governance Guidelines, including setting forth the duties and responsibilities of the current role. The Corporate Governance Guidelines are available on the Company's website at IR.immunitybio.com. Ms. Cohen has served as a member of the Board since June 2019 and has extensive experience with and knowledge of the healthcare industry, commercialization expertise, and experience serving on boards of directors of public companies.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding future clinical trials and trial designs, clinical trial enrollment and results, the regulatory review process and timing thereof, the Company's commercialization strategy for N-803 for administration intravesically, potential capital raise transactions, regulatory review and approval process and timelines, and potential strategic partnering transactions, among others. Statements 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," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "strategy," 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) whether the FDA will approve ImmunityBio's filed BLA and the risks and uncertainties associated with the regulatory approval process, (ii) the ability of ImmunityBio to execute a partnering relationship with a large biopharmaceutical company for commercialization of N-803 plus BCG for administration intravesically on acceptable terms, if at all, (iii) 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, (iv) ImmunityBio's ability to retain and hire key personnel, (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 successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (vii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, (viii) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies, and (ix) the unknown future impact of the COVID-19 pandemic on certain clinical trials or their milestones and/or ImmunityBio's business 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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2023 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.

Item 9.01 Financial Statements and Exhibits.

(a) *Financial statements of businesses or funds acquired.*

None.

(b) *Pro forma financial information.*

None.

(c) *Shell company transactions.*

None.

(d) *Exhibits*.

Exhibit Number	Description of Exhibit
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.
Registrant

Date: March 20, 2023

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