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) **January 3, 2022**

IMMIX BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41159**	**45-4869378**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I. R. S. Employer Identification No.)

11400 West Olympic Blvd., Suite 200
Los Angeles, CA 90064
(Address of principal executive offices, including zip code)

(310) 651-8041
(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:

☐ 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	IMMX	The Nasdaq Stock Market LLC

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 X

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 8.01 Other Events.

On January 3, 2022, Immix Biopharma, Inc. announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease (RPD) designation for IMX-110 for the treatment of a life-threatening form of pediatric cancer in children, rhabdomyosarcoma. IMX-110, an investigational product, is currently being evaluated in a Phase 1b/2a clinical trial. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release dated January 3, 2022

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.

Date: January 3, 2022

Immix Biopharma, Inc.

/s/ Ilya Rachman
Ilya Rachman
Chief Executive Officer

Exhibit 99.1

U.S. Food and Drug Administration Approves Immix Biopharma Rare Pediatric Disease Designation for IMX-110 as a Treatment for Life-Threatening Pediatric Cancer in Children

- Rare Pediatric Disease Designation ("RPDD") qualifies Immix Biopharma to receive fast track review, and a priority review voucher ("PRV") at the time of marketing approval of IMX-110.
- PRV holders can benefit from an expedited six-month review of a new drug application for any disease by the FDA.
- While their future value is uncertain, PRVs are transferable to other companies and have historically sold for $67 to $350 million according to a January 2020 report on drug development by the Government Accountability Office.

LOS ANGELES, January 3, 2021 (GLOBE NEWSWIRE) — Immix Biopharma, Inc. (Nasdaq: IMMX) ("ImmixBio" or the "Company"), a biopharmaceutical company pioneering Tissue-Specific Therapeutics (TSTx)™ targeting oncology and immuno-dysregulated diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease (RPD) designation for IMX-110 for the treatment of a life-threatening form of pediatric cancer in children, rhabdomyosarcoma. IMX-110, an investigational product, is currently being evaluated in a Phase 1b/2a clinical trial.

The FDA grants Rare Pediatric Disease designation for serious and life-threatening diseases that primarily affect children aged 18 years or younger and impact fewer than 200,000 people in the United States.

If a New Drug Application in the United States for IMX-110 is approved, ImmixBio may be eligible to receive a Priority Review Voucher (PRV) from the FDA, which can be redeemed to obtain priority review for any subsequent marketing application, or may be sold or transferred.

"We are pleased by FDA's acknowledgment of the urgent need for a safe and effective treatment for children with this devastating disease," stated ImmixBio's Chief Executive Officer Ilya Rachman, M.D., PhD. "We are encouraged by our Phase 1b/2a clinical data in soft tissue sarcoma. IMX-110 is a tissue-specific therapeutic that simultaneously attacks all 3 components of the tumor micro-environment, severing the critical lifelines between the tumor and its metabolic and structural support. We believe our SMARxT platform generating Tissue-Specific Therapeutics represents a distinct alternative to the traditional 'single target, single mutation' development model."

Rhabdomyosarcoma ("RMS") is a high-grade, malignant neoplasm, the most common soft tissue sarcoma in pediatric and adolescent populations and which rarely occurs in adults. The prevalence of RMS in the United States is approximately 20,000 children of all ages. The five-year survival rate ranges from 20% to 30% for children in the high-risk group where cancer spreads widely in the body.

IMX-110 is the first clinical-stage product of ImmixBio's SMARxT Tissue-Specific™ Platform, which produces Tissue-Specific Therapeutics that accumulate at intended therapeutic sites at 3 to 5 times the rate of conventional medicines. The FDA has already granted orphan drug designation (ODD) to IMX-110 for the treatment of soft tissue sarcoma.

ImmixBio recently shared clinical data across multiple soft tissue sarcoma subtypes in several heavily pretreated patients demonstrating median progression-free survival (PFS) of 4 months with zero drug-related severe adverse events and zero dose interruptions due to toxicity. The data can be viewed in the Immix Biopharma Corporate Presentation at http://www.immixbio.com/pres

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About ImmixBio

ImmixBio™ is a clinical-stage biopharmaceutical company pioneering a novel class of Tissue-Specific Therapeutics (TSTx)™ targeting oncology and immuno-dysregulated diseases. Our proprietary System Multi-Action RegulaTors SMARxT Tissue-Specific™ Platform produces drugs that accumulate at intended therapeutic sites at 3-5 times the rate of conventional medicines. Our TME Normalization™ Technology allows our drug candidates to circulate in the bloodstream, exit through tumor blood vessels and simultaneously attack all components of the tumor micro-environment, or TME. We have uncovered fundamental biological systems that link oncology and immuno-dysregulated diseases. In addition to oncology, our pipeline includes Tissue-Specific Biologic™ candidates to treat inflammatory bowel disease, including ulcerative colitis and Crohn's disease. Learn more at www.immixbio.com.

Forward Looking Statements

This press release contains "forward-looking statements" Forward-looking statements reflect our current view about future events. When used in this press release, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements include, but are not limited to, statements contained in this press release relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward–looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, our ability to raise capital to fund continuing operations; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize products and services; changes in government regulation; our ability to complete capital raising transactions; and other factors relating to our industry, our operations and results of operations. Actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. The Company assumes no obligation to update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this release

Contacts

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