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): February 1, 2024

TYRA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40800**	**83-1476348**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2656 State Street **Carlsbad, California**	**92008**
(Address of principal executive offices)	**(Zip Code)**

(619) 728-4760
(Registrant's telephone number, including area code)

(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, par value $0.0001 per share	TYRA	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 (Sec.230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec.240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On February 1, 2024, Tyra Biosciences, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease (RPD) Designation to TYRA-300, an oral FGFR3 selective inhibitor, for the treatment of achondroplasia.

RPD Designation is granted by the FDA to investigational drugs and biologics designed to address serious or life-threatening diseases which affect fewer than 200,000 people in the United States, or for which there is no reasonable expectation that the cost of developing and making the drug or biologic available in the U.S. for the applicable disease or condition will be recovered from sales in the U.S., and in which the serious or life-threatening manifestations primarily affect individuals less than 18 years of age. If a New Drug Application (NDA) for TYRA-300 to treat achondroplasia is approved by the FDA, including pediatric populations, TYRA may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed to receive a priority review for any subsequent marketing application or may be sold or transferred. The FDA has implemented this program to encourage development of new drugs for treatment of rare pediatric diseases.

TYRA is planning to submit an Investigational New Drug application (IND) to the FDA in the second half of 2024 for the initiation of a randomized Phase 2 clinical trial evaluating multiple dose cohorts of TYRA-300 for children with achondroplasia.

Forward-Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the Company's current beliefs and expectations and include, but are not limited to: the potential safety and therapeutic benefits of TYRA-300; the expected timing, design (including dosing levels) and phase of clinical development of TYRA-300, including timing of a submission of an IND for TYRA-300 in pediatric achondroplasia; and the potential benefits of RPD Designation. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: the Company is early in its development efforts, has only recently begun testing TYRA-300 for oncology in clinical trials and the approach the Company is taking to discover and develop drugs based on its SNÅP platform is novel and unproven and it may never lead to product candidates that are successful in clinical development or approved products of commercial value; potential delays in the commencement, enrollment, and completion of preclinical studies and clinical trials; interim results of a clinical trial do not predict final results and clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; results from preclinical studies or early clinical trials not necessarily being predictive of future results; the Company's dependence on third parties in connection with manufacturing, research and preclinical testing; acceptance by the FDA of INDs or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of TYRA-300 in pediatric achondroplasia; unexpected adverse side effects or inadequate efficacy of the Company's product candidates that may limit their development, regulatory approval, and/or commercialization; the potential for the Company's programs and prospects to be negatively impacted by developments relating to its competitors, including the results of studies or regulatory determinations relating to its competitors; the FDA may not approve an NDA for TYRA-300 in pediatric achondroplasia, and the Company may not receive a PRV as a result; an accelerated development or approval pathway may not be available for TYRA-300 or other product candidates and any such pathway, including any priority review through the use of a PRV, may not lead to a faster development process; the Company may not be able to sell or transfer any unused PRV for any expected or adequate value or at all; the Company may not realize the benefits associated with Orphan Drug Designation, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; regulatory developments in the United States and foreign countries; the Company may use its capital resources sooner than expected; and other risks described in the Company's prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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.

TYRA BIOSCIENCES, INC.

Date: February 1, 2024

By: /s/ Alan Fuhrman
Name: Alan Fuhrman
Title: Chief Financial Officer