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): October 28, 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)**	**(IRS Employer Identification No.)**

2656 State Street **Carlsbad, California**	**92008**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (619) 728-4760

(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 (§ 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 Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 28, 2024, Tyra Biosciences, Inc. announced that the U.S. Food and Drug Administration (FDA) allowed the company's Investigational New Drug (IND) application for TYRA-300 to proceed with a Phase 2 clinical trial of TYRA-300 for children with achondroplasia (BEACH301). BEACH301 will be a Phase 2, multicenter, open-label, dose-escalation/dose-expansion study evaluating TYRA-300 in children ages 3 to 10 with achondroplasia with open growth plates. The study will enroll children who are treatment-naïve (Cohort 1) and those who have received prior growth-accelerating therapy (Cohort 2) at multiple sites across the globe. Each of these cohorts is expected to enroll up to 10 participants per dose level (0.125, 0.25, 0.375, 0.50 mg/kg) for up to 12 months. Prior to initiation of Cohorts 1 and 2, the study will enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10.

The primary objectives of the study will be to assess safety and tolerability in children with achondroplasia and evaluate change from baseline in annualized growth velocity to determine the dose(s) for further development. Secondary objectives will include evaluating change from baseline in height z-score, proportionality and pharmacokinetics (PK). The company is also planning exploratory assessments of clinical outcomes such as functional improvements, changes in the spine, and quality of life measures. The company expects to dose the first child with achondroplasia in the BEACH301 study in the first quarter of 2025.

Beyond achondroplasia, the company also announced that it plans to submit an IND for a Phase 2 study of TYRA-300 in non-muscle invasive bladder cancer (NMIBC) by year-end 2024.

Forward-Looking Statements

Tyra 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: expected initiation of the BEACH301 study and the timing thereof; the design and goals of the BEACH301 study; expected submission of an IND for NMIBC and the timing thereof; and the potential safety and therapeutic benefits of TYRA-300. 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: later developments with the FDA may be inconsistent with prior feedback from the FDA, including with respect to the proposed initiation and design of the company's planned Phase 2 study of TYRA-300 in achondroplasia; the company is early in its development efforts and has only recently begun testing TYRA-300 and TYRA-200 for oncology in clinical trials, and the approach the company is taking to discover and develop drugs based on the company's 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, data readouts and completion of preclinical studies and clinical trials; results from preclinical studies or early clinical trials not necessarily being predictive of future results; interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues and as more patient or final data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the potential for proof-of-concept results to fail to result in successful subsequent development of TYRA-300; 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; an accelerated development or approval pathway may not be available for TYRA-300 or other product candidates and any such pathway may not lead to a faster development process; 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 the company's competitors, including the results of studies or regulatory determinations relating to the company's competitors; unfavorable results from preclinical studies; 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, or from the Rare Pediatric Disease Designation, including receipt of a Priority Review Voucher or any value therefrom; regulatory developments in the United States and foreign countries; the company's ability to obtain and maintain intellectual property protection for the company's product candidates and proprietary technologies; 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: October 28, 2024

By: /s/ Ali Fawaz
Ali Fawaz
General Counsel and Secretary