

**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): December 22, 2023

TYRA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40800
(Commission
File Number)

83-1476348
(I.R.S. Employer
Identification No.)

2656 State Street
Carlsbad, California
(Address of principal executive offices)

92008
(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 December 22, 2023, Tyra Biosciences, Inc. (the Company) announced that it has initiated and dosed the first patient in the SURF201 Phase 1 study of TYRA-200. The SURF201 study is currently enrolling and dosing adults with unresectable locally advanced/metastatic intrahepatic cholangiocarcinoma and other advanced solid tumors with activating FGFR2 gene alterations. SURF201 (Study in Previously treated and Resistant FGFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors) (NCT06160752), is a Phase 1/2 multi-center, open label study designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TYRA-200 and determine the optimal and maximum tolerated doses (MTD), as well as evaluate the preliminary antitumor activity of TYRA-200.

In addition, the Part A Phase 1 portion of the SURF301 study of TYRA-300 in oncology continues to dose escalate and has cleared multiple dose cohorts that are above the anticipated dose(s) planned for use in the Phase 2 pediatric achondroplasia (ACH) study. Current expansion cohorts in Part B are at dose level(s) anticipated to be evaluated in oncology. The Company expects to submit initial results from the SURF301 Phase 1 portion for presentation at a scientific congress in 2024.

The Company also plans to submit an Investigational New Drug (IND) application to the FDA in the second half of 2024 for the initiation of a randomized Phase 2 clinical trial with multiple dose cohorts of TYRA-300 for children with ACH. The primary objective of this study is to assess safety and tolerability in children with ACH and determine the dose(s) for further development. Secondary objectives will include evaluating change in growth velocity, growth proportionality and pharmacokinetics, as well as an assessment of quality of life and evaluation of biomarkers indicating dose-response relationships to TYRA-300. The Company's expectation is that the study will initially evaluate treatment naïve children ages 5-12 to determine optimal dose ranges and will also include a separate analysis of children ages 5-12 with ACH who have not responded to a prior growth accelerating therapy.

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, TYRA-200 and other product candidates; and the expected timing, design (including dosing levels) and phase of clinical development of TYRA-300 and TYRA-200, including timing of a submission of an IND for TYRA-300 in pediatric ACH and submission of initial results from the SURF301 Phase 1 portion of the study to a scientific congress. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: we are early in our development efforts, have only recently begun testing TYRA-300 and TYRA-200 for oncology in clinical trials and the approach we are taking to discover and develop drugs based on our SNĀP 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; our 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 ACH; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval, and/or commercialization; the potential for our programs and prospects to be negatively impacted by developments relating to our competitors, including the results of studies or regulatory determinations relating to our competitors; regulatory developments in the United States and foreign countries; we may use our capital resources sooner than we expect; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our 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 we undertake 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: December 22, 2023

By: /s/ Alan Fuhrman

Name: Alan Fuhrman

Title: Chief Financial Officer