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): November 07, 2023

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 2.02 Results of Operations and Financial Condition.

On November 7, 2023, Tyra Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued on November 7, 2023
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 thereunto duly authorized.

TYRA BIOSCIENCES, INC.

Date: November 7, 2023

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

Exhibit 99.1

Tyra Biosciences Reports Third Quarter 2023 Financial Results and Highlights

- Enrollment and dose escalation ongoing in SURF301 Phase 1/2 oncology -
- Presented additional preclinical data on TYRA-300 in achondroplasia at ASBMR and ASHG -
- First patient to be dosed in TYRA-200 Phase 1 by YE 2023 -
- Strong cash position of $215.7 million as of Q3 2023 -

CARLSBAD, Calif., November 7, 2023 – Tyra Biosciences, Inc. (Nasdaq: TYRA), a clinical-stage biotechnology company focused on developing next-generation precision medicines that target large opportunities in Fibroblast Growth Factor Receptor (FGFR) biology, today reported financial results for the quarter ended September 30, 2023 and highlighted recent corporate progress.

"From the start, TYRA has focused on developing precision therapies that target large opportunities that exist in FGFR biology, and we continue to follow the data. We continue to advance TYRA-300, our oral FGFR3-selective inhibitor, as we dose expand and escalate in our SURF301 oncology study and strengthen our preclinical data package in achondroplasia," said Todd Harris, CEO of TYRA. "Before the end of the year, we expect to update our guidance on the timing and design of our planned Phase 2 study in achondroplasia and the dosing of our first patient with TYRA-200."

Third Quarter 2023 and Recent Corporate Highlights

TYRA-300

- **SURF301 Phase 1/2 Study for Oncology Continued to Advance.** SURF301 (**S**tudy in **U**ntreated and **R**esistant **F**GFR3+ Advanced Solid Tumors) (NCT05544552) is a multi-center, open label study designed to determine the optimal and maximum tolerated doses (MTD) and the recommended Phase 2 dose of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. Enrollment is ongoing in Part A and Part B and dose escalation is ongoing in Part B in Phase 1 of the study at multiple clinical sites in the U.S., Europe, and Australia. In this study, multiple doses and schedules of TYRA-300 will be evaluated to inform dosing decisions in future metastatic urothelial carcinoma (mUC), non-muscle invasive bladder cancer (NMIBC) and achondroplasia studies.
- **Presented Positive Preclinical Data for Achondroplasia at ASBMR and ASHG Meetings.** In October and early November 2023, TYRA presented additional preclinical results on TYRA-300 in achondroplasia at the American Society for Bone and Mineral Research (ASBMR) and the American Society of Human Genetics (ASHG) 2023 annual meetings, respectively. In preclinical mice models of achondroplasia conducted at The Imagine Institute in Paris, TYRA-300 increased bone growth, improved the shape of the skull, improved the shape of the foramen magnum, restored the architecture of the growth plate, and increased chondrocyte proliferation and differentiation.
- **Granted Orphan Drug Designation for Achondroplasia from FDA.** In July 2023, TYRA-300 was granted Orphan Drug Designation (ODD) for the treatment of achondroplasia from the U.S. Food and Drug Administration (FDA).

TYRA-200

- **Phase 1 Study on Track to be Initiated by YE '23.** TYRA continued to advance activities to support the initiation of the planned Phase 1 clinical study of TYRA-200, an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. The trial will be focused on intrahepatic cholangiocarcinoma resistant to prior FGFR inhibitors. TYRA remains on track to dose the first patient in this trial before year-end 2023.

SNÅP Platform and Pipeline

- TYRA continued to advance its in-house precision medicine discovery engine, SNÅP, to develop therapies in targeted oncology and genetically defined conditions including $FGF19^{+}$/FGFR4-driven cancers and others.

Third Quarter 2023 Financial Results

- Third quarter 2023 net loss was $21.2 million compared to $12.5 million for the same period in 2022.
- Third quarter 2023 research and development expenses were $19.3 million compared to $10.9 million for the same period in 2022.
- Third quarter 2023 general and administrative expenses were $4.7 million compared to $2.7 million for the same period in 2022.
- As of September 30, 2023, TYRA had cash and cash equivalents of $215.7 million that are expected to support TYRA's important clinical and operational milestones over at least the next two years.

About TYRA-300

TYRA-300 is the Company's lead precision medicine program stemming from its in-house SNÅP platform. TYRA-300 is an investigational, oral, FGFR3-selective inhibitor currently in development for the treatment of cancer and skeletal dysplasias, including achondroplasia. In oncology, TYRA-300 is being evaluated in a multi-center, open label Phase 1/2 clinical study, SURF301 (**S**tudy in **U**ntreated and **R**esistant **F**GFR3+ Advanced Solid Tumors). SURF301 (NCT05544552) was designed to determine the optimal and MTD and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. SURF301 is currently enrolling adults with advanced urothelial carcinoma and other solid tumors with FGFR3 gene alterations. In skeletal dysplasias, TYRA-300 has demonstrated positive preclinical results, and the Company expects to submit an IND for the initiation of a Phase 2 clinical study in pediatric achondroplasia in 2024. In July 2023, TYRA-300 was granted Orphan Drug Designation for the treatment of achondroplasia from the FDA.

About Tyra Biosciences

Tyra Biosciences, Inc. (Nasdaq: TYRA) is a clinical-stage biotechnology company focused on developing next-generation precision medicines that target large opportunities in FGFR biology. The Company's in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help predict genetic alterations most likely to cause acquired resistance to existing therapies. TYRA's initial focus is on applying its accelerated small molecule drug discovery engine to develop therapies in targeted oncology and genetically defined conditions. TYRA is based in Carlsbad, CA.

For more information about our science, pipeline and people, please visit www.tyra.bio and engage with us on LinkedIn.

Forward-Looking Statements

TYRA cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the potential to develop next-generation precision medicines and the potential safety and therapeutic benefits of TYRA-300 and other product candidates; the sufficiency of our cash position to support clinical and operational milestones; expected cash runway; the expected timing and phase of clinical development of TYRA-300 and TYRA-200, including timing of a submission of an IND for TYRA-300 in pediatric achondroplasia and patient dosing for TYRA-200; expected timing regarding updated guidance on the timing and design of our planned Phase 2 study in achondroplasia and dosing of our first patient with TYRA-200; and the potential for SNÅP to develop therapies in targeted oncology and genetically defined conditions. 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 for oncology in clinical trials and the approach we are taking to discover and develop drugs based on our 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; 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; we may expend our limited resources to pursue a particular product candidate and/or indication and fail to capitalize on product candidates or indications with greater development or commercial potential; 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; 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 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; we may not realize the benefits associated with ODD, 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; we may use our capital resources sooner than we expect; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may adversely affect our business and financial condition and the broader economy and biotechnology industry; 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.

Contact:

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Tyra Biosciences, Inc.
Condensed Balance Sheet Data
(in thousands)

	September 30, 2023 (unaudited)	December 31, 2022
Balance Sheet Data:		
Cash and cash equivalents	$ 215,652	$ 251,213
Working capital	214,483	251,587
Total assets	238,358	266,181
Accumulated deficit	(142,000)	(95,696)
Total stockholders' equity	222,170	257,829

Tyra Biosciences, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 19,271	$ 10,915	$ 41,841	$ 32,608
General and administrative	4,692	2,730	12,470	11,301
Total operating expenses	23,963	13,645	54,311	43,909
Loss from operations	(23,963)	(13,645)	(54,311)	(43,909)
Other income (expense):				
Interest income	2,816	1,131	8,035	1,496
Other income (expense)	(5)	5	(28)	(17)
Total other income, net	2,811	1,136	8,007	1,479
Net loss and comprehensive loss	$ (21,152)	$ (12,509)	$ (46,304)	$ (42,430)
Net loss per share, basic and diluted	$ (0.49)	$ (0.30)	$ (1.09)	$ (1.02)
Weighted-average shares used to compute net loss per share, basic and diluted	42,868,340	41,997,195	42,619,075	41,777,052