Tyra Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights

- Advanced SURF301 Phase 1 oncology study; Initial Phase 1 results to be reported in 2H 2024 -
- TYRA-300 Phase 2 ACH IND submission on track for 2H 2024 -
- Initiated SURF201 Phase 1 study and dosed first patient with TYRA-200 -
- Strengthened balance sheet with approximately $200 million PIPE in Q1 2024; pro-forma cash, cash equivalents, and marketable securities of approximately $403.5 million -

CARLSBAD, Calif., March 19, 2024 /PRNewswire/ -- 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 fourth quarter and full year ended December 31, 2023 and highlighted recent corporate progress.

"2023 was an outstanding year for TYRA and we are pleased to have positive momentum at the start of 2024," said Todd Harris, CEO of TYRA. "We have strong conviction in our pipeline and believe our lead program TYRA-300 has the potential to become a best-in-class agent for multiple high-value indications. TYRA-300 remains our top priority and we are focused on submitting our Phase 2 IND for achondroplasia, while optimizing dose in SURF301 in preparation for Phase 2 studies in NMIBC and metastatic urothelial carcinoma."

"TYRA is in our strongest financial position to date, with a pro-forma cash position of over $400 million following our PIPE last month. Our ability to retain and attract high quality investors reflects the excitement around our pipeline to deliver value for both shareholders and patient communities," added Alan Fuhrman, Chief Financial Officer of TYRA. "Our current cash, cash equivalents and marketable securities on hand allow us to execute on our plans through at least 2026."

Fourth Quarter 2023 and Recent Corporate Highlights

- **Closed a $200M Private Placement Financing**. In February 2024, TYRA entered into a securities purchase agreement with new and existing institutional and accredited investors to sell securities in a private placement financing (the PIPE) for gross proceeds of approximately $200 million. The financing was led by RA Capital Management, with participation by new and existing institutional investors, including Boxer Capital, BVF Partners, Nextech Invest Ltd (on behalf of one or more funds managed by it), OrbiMed, 5AM Ventures, a large investment management firm and a life-sciences focused institutional investor.

TYRA-300

- **Received FDA Rare Pediatric Disease Designation for the Treatment of Achondroplasia**. In January 2024, TYRA-300 was granted Rare Pediatric Disease (RPD) Designation for the treatment of achondroplasia from the U.S. Food and Drug Administration (FDA). TYRA-300 has also received Orphan Drug Designation (ODD) for the treatment of achondroplasia from the FDA.

- **SURF301 Phase 1/2 Study for Oncology Continued to Advance.** The SURF301 Phase 1 study for oncology (**S**tudy in **U**ntreated and **R**esistant **F**GFR3+ Advanced Solid Tumors) (NCT05544552) continues to advance. The study is a multi-center, open label study designed to determine the optimal and maximum tolerated dose (MTD) and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. TYRA expects that the Phase 1 portion of SURF301 will provide data to inform multiple doses and schedules of TYRA-300 in future studies in metastatic urothelial carcinoma (mUC), non-muscle invasive bladder cancer (NMIBC) and achondroplasia. As of March 2024, the Part A Phase 1 portion of SURF301 has completed dose escalation, and the current expansion cohorts in Part B are evaluating potentially therapeutic once daily and twice daily doses. TYRA expects to submit initial results from its SURF301 Phase 1 portion for presentation at a scientific congress in the second half of 2024.

- **Phase 2 Achondroplasia (ACH) Study On Track.** TYRA is planning to initiate a Phase 2 clinical trial testing multiple doses of TYRA-300 to support children with achondroplasia. TYRA expects that the primary objective of this study will be to assess safety and tolerability in children with achondroplasia and determine the dose(s) for further development. TYRA also expects that secondary objectives will include

evaluating change in growth velocity, growth proportionality and pharmacokinetics (PK). TYRA is also planning exploratory assessments of clinical outcomes and quality of life measures, and an evaluation of biomarkers to determine dose-response relationships to TYRA-300. TYRA's current 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 cohort and analysis of children ages 5-12 with achondroplasia who have received and did not tolerate or respond to a prior growth accelerating therapy. TYRA plans to submit an Investigational New Drug (IND) application to the FDA in the second half of 2024 for the initiation of the Phase 2 study.

TYRA-200

- **Phase 1 SURF201 Study Initiated.** SURF201 (**S**tudy in Previo**U**sly treated and **R**esistant **F**GFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors) (NCT06160752) is a multi-center, open label study designed to evaluate the safety, tolerability, and PK of TYRA-200 and determine the optimal and MTD and RP2D, as well as evaluate the preliminary antitumor activity of TYRA-200.

  TYRA-200 is an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. 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.

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.

Fourth Quarter and Full Year 2023 Financial Results

- Fourth quarter 2023 net loss was $22.8 million compared to $12.9 million for the same period in 2022.
- Fourth quarter 2023 research and development expenses were $20.7 million compared to $10.4 million for the same period in 2022.
- Fourth quarter 2023 general and administrative expenses were $5.0 million compared to $4.6 million for the same period in 2022.
- Full year 2023 net loss was $69.1 million compared to $55.3 million for the same period in 2022.
- Full year 2023 research and development expenses were $62.5 million compared to $43.0 million for the same period in 2022.
- Full year 2023 general and administrative expenses were $17.4 million compared to $15.9 million for the same period in 2022.
- As of December 31, 2023, TYRA had cash, cash equivalents, and marketable securities of $203.5 million. Following completion of the approximately $200 million PIPE in February 2024, TYRA's pro-forma cash position of approximately $403.5 million is expected to support the Company's important clinical and operational milestones through at least 2026.

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 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 in the second half of 2024 for the initiation of a Phase 2 clinical study in pediatric achondroplasia. In July 2023 and January 2024, the FDA granted ODD and RPD Designation to TYRA-300, respectively, for the treatment of achondroplasia.

About TYRA-200

TYRA-200 is an investigational, oral, FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations currently in development for the treatment of cancer. TYRA-200 is being evaluated in a multi-center, open label Phase 1 clinical study, SURF201 (**S**tudy in Previo**U**sly treated and **R**esistant **F**GFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors). SURF201 (NCT06160752) was designed to determine the optimal and MTD and the RP2D of TYRA-200, as well as to evaluate the preliminary antitumor activity of TYRA-200. SURF201 is currently enrolling adults with advanced/metastatic intrahepatic cholangiocarcinoma and other advanced solid tumors with activating alterations in FGFR2.

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, the potential for TYRA-300 to become a best-in-class agent, and the potential safety and therapeutic benefits of TYRA-300, TYRA-200 and other product candidates; the ability to deliver value for shareholders and patient communities; the sufficiency of our cash position to support clinical and operational milestones; expected cash runway; the potential benefits of regulatory designations; 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, design of our planned Phase 2 study in achondroplasia, and the presentation of SURF301 clinical data at a scientific congress; 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 and TYRA-200 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; later developments with the FDA may be inconsistent with the minutes from our prior meetings, including with respect to the design of our planned Phase 2 study of TYRA-300 in 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; unfavorable results from preclinical studies; 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, or from the RPD Designation, including receipt of a Priority Review Voucher (PRV) or any value therefrom; regulatory developments in the United States and foreign countries; our ability to obtain and maintain intellectual property protection for our product candidates and proprietary technologies; 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.

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Tyra Biosciences, Inc.
Condensed Balance Sheet Data

(in thousands)

	December 31, 2023	December 31, 2022
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 203,469	$ 251,213
Working capital	196,338	251,587
Total assets	225,857	266,181
Accumulated deficit	(164,830)	(95,696)
Total stockholders' equity	204,262	257,829

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 20,677	$ 10,400	$ 62,518	$ 43,008
General and administrative	4,957	4,618	17,427	15,919
Total operating expenses	25,634	15,018	79,945	58,927
Loss from operations	(25,634)	(15,018)	(79,945)	(58,927)
Other income (expense):				
Interest income	2,815	2,156	10,850	3,652
Other expense	(11)	(33)	(39)	(50)
Total other income, net	2,804	2,123	10,811	3,602
Net loss	$ (22,830)	$ (12,895)	$ (69,134)	$ (55,325)
Unrealized gain on marketable securities available-for-sale, net	381	—	381	—
Comprehensive loss	$ (22,449)	$ (12,895)	$ (68,753)	$ (55,325)
Net loss per share, basic and diluted	$ (0.53)	$ (0.31)	$ (1.62)	$ (1.32)
Weighted-average shares used to compute net loss per share, basic and diluted	42,965,744	42,207,685	42,704,876	41,883,904

SOURCE Tyra Biosciences

https://tyrabio.investorroom.com/2024-03-19-Tyra-Biosciences-Reports-Fourth-Quarter-and-Full-Year-2023-Financial-Results-and-Highlights