Tyra Biosciences Reports First Quarter 2024 Financial Results and Highlights

- TYRA-300 on track in ACH and oncology; SURF301 Ph1 initial results and ACH IND submission expected in 2H24 -

- Cash, cash equivalents, and marketable securities of$382.5 million at Q1 2024 -

- Susan Moran, M.D., M.S.C.E. and S. Michael Rothenberg, M.D., Ph.D. appointed to TYRA Board of Directors -

CARLSBAD, Calif., May 9, 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 quarter ended March 31, 2024, and highlighted recent corporate progress.

"During the first quarter of 2024, we focused on execution across our pipeline including delivering on our near-term milestones for TYRA-300 in both achondroplasia and oncology," said Todd Harris, CEO of TYRA. "In oncology, the TYRA-300 clinical profile continues to mature in SURF301, and our clinical team is focused on Part B dose expansion to evaluate multiple dosing regimens of TYRA-300. We believe this work will support future Phase 2 studies in NMIBC and metastatic urothelial carcinoma, where we see tremendous opportunity for an oral FGFR3-selective inhibitor. In achondroplasia, we remain on track to submit our IND in the second half of 2024 to support our planned Phase 2 study."

First Quarter 2024 and Recent Corporate Highlights

- **Strengthened Board with New Appointments.** On May 7, 2024, TYRA announced changes to its Board of Directors with the appointments of Susan Moran, M.D., M.S.C.E. and S. Michael Rothenberg, M.D., Ph.D. as independent directors, and the resignation of Isan Chen, M.D.

TYRA-300

- **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) continued to advance. The study is a multi-center, open label study designed to determine the optimal 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 the appropriate dosing schedule of TYRA-300 in future studies in metastatic urothelial carcinoma (mUC) and non-muscle invasive bladder cancer (NMIBC). Part A of SURF301 is complete and the expansion cohorts in Part B are evaluating potentially therapeutic once daily and twice daily doses, in preparation for future Phase 2 studies in NMIBC and mUC. TYRA remains on track to report initial results from its SURF301 Phase 1 portion at a scientific congress in the second half of 2024.

- **Phase 2 Achondroplasia (ACH) Study Planning Continued to Advance.** TYRA remains on track to submit an Investigational New Drug application (IND) to the FDA in the second half of 2024 for the initiation of 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-200

- **Phase 1 SURF201 Study Continued to Advance.** The SURF201 (**S**tudy in Previo**U**sly treated and **R**esistant **F**GFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors) (NCT06160752) continued to advance. The study is a multi-center, open label study designed to evaluate the safety, tolerability, and PK of TYRA-200 and determine the optimal and maximum tolerated dose (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.

Corporate

- **Closed a $200M Private Placement Financing.** In February 2024, TYRA completed a private placement financing, pursuant to which it sold shares of its common stock and pre-funded warrants to purchase its common stock to new and existing institutional and accredited investors for gross proceeds of approximately $200 million.

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.
- TYRA nominated its third candidate for clinical development, TYRA-430, an FGFR4/3 selective inhibitor for $FGF19^{+}$/FGFR4-driven cancers. TYRA is focused on completing IND-enabling studies for this program.

Fourth Quarter and Full Year 2023 Financial Results

- First quarter 2024 net loss was $18.2 million compared to $11.9 million for the same period in 2023.
- First quarter 2024 research and development expenses were $17.2 million compared to $10.4 million for the same period in 2023.
- First quarter 2024 general and administrative expenses were $5.1 million compared to $3.9 million for the same period in 2023.
- As of March 31, 2024, TYRA had cash, cash equivalents, and marketable securities of$382.5 million. The company's current cash, cash equivalents and marketable securities on hand allow TYRA to execute on its plans 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 Orphan Drug Designation (ODD) and Rare Pediatric Designation (RPD) 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 and the potential safety and therapeutic benefits of TYRA-300, TYRA-200 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, 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 SNAP 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; 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 proposed 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 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 military conflict 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)
(unaudited)

	March 31, 2024	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 382,462	$ 203,469
Working capital	382,062	196,338
Total assets	404,741	225,857
Accumulated deficit	(183,022)	(164,830)
Total stockholders' equity	389,879	204,262

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 17,203	$ 10,408
General and administrative	5,119	3,926
Total operating expenses	22,322	14,334
Loss from operations	(22,322)	(14,334)

Other income:		
Interest and other income, net	4,130	2,454
Total other income	4,130	2,454
Net loss	$ (18,192)	$ (11,880)
Unrealized loss on marketable securities available-for-sale, net	(387)	—
Comprehensive loss	$ (18,579)	$ (11,880)
Net loss per share, basic and diluted	$ (0.35)	$ (0.28)
Weighted-average shares used to compute net loss per share, basic and diluted	52,228,934	42,394,623

SOURCE Tyra Biosciences

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https://tyrabio.investorroom.com/2024-05-09-Tyra-Biosciences-Reports-First-Quarter-2024-Financial-Results-and-Highlights