Tyra Biosciences Reports Second Quarter 2023 Financial Results and Highlights

August 10, 2023

-Orphan Drug Designation granted to TYRA-300 for achondroplasia-
- SURF301 Phase 1/2 oncology study remains on target; enrollment ongoing in Part B -
-TYRA-200 Phase 1 study on track; first patient to be dosed in 2H 2023-
- Strong cash position of $232.4 million as of Q2 2023-

CARLSBAD, Calif., Aug. 10, 2023 /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 June 30, 2023 and highlighted recent corporate progress.

"TYRA is a precision medicine biotech company focused on large opportunities in FGFR biology, and we continued to advance our pipeline and approach during the last several months," said Todd Harris, CEO of TYRA. "We believe that TYRA-300, our oral FGFR3-selective inhibitor, is potentially a best-in-class agent designed to address unmet needs in oncology and skeletal dysplasias. Our SURF301 oncology study remains on target, and we are pleased to receive Orphan Drug Designation for TYRA-300 in achondroplasia from the U.S. FDA. This is another important milestone in the development of TYRA-300, and we are excited about the opportunity to deliver a new therapeutic option for patients."

Second Quarter 2023 and Recent Corporate Highlights

TYRA-300

- **Granted Orphan Drug Designation from U.S. FDA for Achondroplasia.** In July 2023, TYRA-300, an investigational oral FGFR3-selective inhibitor, was granted Orphan Drug Designation (ODD) for the treatment of achondroplasia. TYRA remains on track to submit an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) to enable a Phase 2 study of TYRA-300 in pediatric achondroplasia in 2024.
- **SURF301 Phase 1/2 Study for Oncology is On Target.** 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 and the recommended Phase 2 dose of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. The study remains on target and enrollment is ongoing in Part A and Part B in Phase 1 of the study at multiple clinical sites in the U.S., Europe, and Australia.

TYRA-200

- **Advanced Preparation Activities for Phase 1 Study.** TYRA continued to advance activities for its planned Phase 1 clinical study of TYRA-200, an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations, during the second quarter of 2023. 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 in the second half of 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 RET (REarranged during Transfection kinase) driven cancers.

Corporate

- **Strengthened Leadership.** TYRA made key senior appointments including Dr. Michael Bober, Vice President, Clinical Development and Medical Affairs, who, prior to joining TYRA, served as the Medical Director of the Skeletal Dysplasia Program, Nemours Children's Hospital, Delaware, and is a key opinion leader in the skeletal dysplasia community. Additionally, TYRA appointed George Melko, Vice President, Regulatory Affairs and Gary Price, Vice President, Quality.

Second Quarter 2023 Financial Results

- Second quarter 2023 net loss was $13.3 million compared to $15.1 million for the same period in 2022.
- Second quarter 2023 research and development expenses were $12.2 million compared to $12.0 million for the same period in 2022.
- Second quarter 2023 general and administrative expenses were $3.9 million compared to $3.4 million for the same period in 2022.
- As of June 30, 2023, TYRA had cash and cash equivalents of $232.4 million that will 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. 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 maximum tolerated doses (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.

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 safety and therapeutic benefits of TYRA-300 and other product candidates and the potential for TYRA-300 to become a best-in-class agent; 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; 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 our lead product candidate 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; 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.

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

	June 30, 2023	December 31, 2022
	(unaudited)	
Balance Sheet Data:		
Cash and cash equivalents	$ 232,413	$ 251,213
Working capital	235,341	251,587
Total assets	250,012	266,181
Accumulated deficit	(120,848)	(95,696)
Total stockholders' equity	238,572	257,829

Tyra Biosciences, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 12,162	$ 12,047	$ 22,570	$ 21,692
General and administrative	3,852	3,381	7,778	8,570
Total operating expenses	16,014	15,428	30,348	30,262
Loss from operations	(16,014)	(15,428)	(30,348)	(30,262)
Other income (expense):				
Interest income	2,763	346	5,218	364
Other expense	(21)	(13)	(22)	(23)
Total other income	2,742	333	5,196	341
Net loss and comprehensive loss	$ (13,272)	$ (15,095)	$ (25,152)	$ (29,921)
Net loss per share, basic and diluted	$ (0.31)	$ (0.36)	$ (0.59)	$ (0.72)
Weighted-average shares used to compute net loss per share, basic and diluted	42,589,213	41,777,206	42,492,377	41,665,155

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