Tyra Biosciences Reports Second Quarter 2024 Financial Results and Highlights

August 7, 2024

- SURF301 Ph1 initial results and ACH IND submission expected in 2H24 -

- Reported preclinical proof-of-concept with TYRA-300 in HCH, demonstrating increases in long bone length and binding against the HCH altered protein -

- IND cleared for TYRA-430, an FGFR4/3 biased inhibitor for HCC -

- Announced Chief Medical Officer transition plan; search for an external candidate underway with guidance from Science & Technology (S&T) Committee of the Board, including recent additions Dr. Susan Moran and Dr. S. Michael Rothenberg -

- Cash, cash equivalents, and marketable securities of $373.8 million at Q2 2024 -

CARLSBAD, Calif., Aug. 7, 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 June 30, 2024, and highlighted recent corporate progress.

"This is an exciting time at TYRA. With the recent clearance of our IND for TYRA-430, our FGFR4/3 biased inhibitor, we are well positioned with three potentially best-in-class precision molecules in the clinic for oncology. In skeletal dysplasias, we made great progress with preclinical proof-of-concept data in hypochondroplasia and continued execution towards the filing of our IND anticipated in the second half of 2024 to support our planned Phase 2 study in achondroplasia," said Todd Harris, CEO of TYRA.

Mr. Harris continued, "We also announce today the transition of our Chief Medical Officer position by the end of the year. We thank Hiroomi for his many contributions to TYRA over the past four years. He was instrumental in the translation of our SNÅP drug discovery platform into a robust pipeline of product candidates. As we move forward, I am delighted to have the support of our S&T Committee, including recent additions to our Board Susan Moran and Michael Rothenberg, whose collective expertise in solid tumors and achondroplasia will be invaluable."

Dr. Moran added, "I am pleased to have the opportunity to support the TYRA team as we prepare to advance multiple early-stage clinical programs into later-stage clinical development and evaluate the broad potential of our precision molecules in oncology and rare diseases."

Second Quarter 2024 and Recent Corporate Highlights

TYRA-300

- **SURF301 Phase 1/2 Study for Oncology Continued to Advance.** The SURF301 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 dosing schedule of TYRA-300 we intend to evaluate in potential 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 potential future Phase 2 studies in NMIBC and mUC. TYRA remains on track to report initial results from the 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.
- **Expanded Development into Hypochondroplasia (HCH).** In July 2024, TYRA announced the expansion of development of TYRA-300 into HCH based on positive preclinical results. In a preclinical HCH model, TYRA-300 demonstrated increases in long bone length and binding against the HCH altered protein. HCH is a skeletal dysplasia closely related to achondroplasia (ACH), the most common form of dwarfism. HCH is most commonly caused by the N540K mutation (~70-80%) in the FGFR3 gene. The design of TYRA-300 may inhibit the alteration driving FGFR3-related skeletal dysplasias including ACH, HCH and others.

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 investigational, 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.

TYRA-430

- **IND Cleared by the FDA.** TYRA announced today that the FDA cleared its IND to proceed with a Phase 1 clinical study of TYRA-430, an investigational, FGFR4/3-biased inhibitor for $FGF19^{+}$/FGFR4-driven cancers. The Phase 1 study will be a multicenter, open-label, first-in-human study of TYRA-430 in advanced hepatocellular carcinoma (HCC) and other solid tumors with activating FGF/FGFR pathway aberrations (SURF431). We believe TYRA-430 has the potential to address a significant unmet need in HCC, where there are no approved biomarker-driven, targeted therapies.

Corporate

- **Strengthened Board with New Appointments.** 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.
- **Announced Chief Medical Officer Transition.** TYRA announced today that Hiroomi Tada, M.D., Ph.D., the Company's Chief Medical Officer (CMO), will be departing from his position by the end of year to transition to an advisor role. TYRA is conducting a search for an external candidate to replace Dr. Tada, who will stay on as CMO to assist in the transition process until a successor has been named. TYRA's Science and Technology Committee of the Board of Directors, which includes, among others, Board members Susan Moran, M.D., M.S.C.E. and S. Michael Rothenberg, M.D., Ph.D., will be involved in the CMO search and transition period. The Company does not expect any disruption to ongoing clinical work during this time.

  Dr. Tada joined TYRA in 2020 as CMO prior to the Company's initial public offering. He was integral in the development of the Company's clinical strategy and building the in-house clinical operations group who have advanced multiple product candidates into clinical development.

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.

Second Quarter 2024 Financial Results

- Second quarter 2024 net loss was $18.7 million compared to $13.3 million for the same period in 2023.
- Second quarter 2024 research and development expenses were $18.0 million compared to $12.2 million for the same period in 2023.
- Second quarter 2024 general and administrative expenses were $5.5 million compared to $3.9 million for the same period in 2023.
- As of June 30, 2024, TYRA had cash, cash equivalents, and marketable securities of $373.8 million. The Company's current cash, cash equivalents and marketable securities are expected to 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 and hypochondroplasia. 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), which was designed to determine the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate preliminary antitumor activity. In skeletal dysplasias, TYRA-300 has demonstrated positive preclinical results in achondroplasia and hypochondroplasia, 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 and potentially best-in-class precision medicines and the potential safety and therapeutic benefits of TYRA-300, TYRA-200, TYRA-430 and other product candidates; the ability to advance multiple early-stage clinical programs into later-stage clinical development; the sufficiency of our cash position to support our clinical and operational plans; expected cash runway; the expected timing and phase of clinical development of TYRA-300, TYRA-200, and TYRA-430, 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, 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; potential difficulty or delay in transitioning the CMO position and any resulting adverse impacts on our development programs or otherwise; 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 and hypochondroplasia; 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)

	June 30, 2024	December 31, 2023
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 373,796	$ 203,469
Working capital	368,192	196,338
Total assets	392,461	225,857
Accumulated deficit	(201,724)	(164,830)
Total stockholders' equity	376,043	204,262

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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 17,997	$ 12,162	$ 35,199	$ 22,570
General and administrative	5,535	3,852	10,654	7,778
Total operating expenses	23,532	16,014	45,853	30,348
Loss from operations	(23,532)	(16,014)	(45,853)	(30,348)
Other income:				
Interest and other income, net	4,830	2,742	8,959	5,196
Total other income	4,830	2,742	8,959	5,196
Net loss	(18,702)	(13,272)	(36,894)	(25,152)
Unrealized loss on marketable securities available-for-sale, net	(178)	—	(565)	—
Comprehensive loss	$ (18,880)	$ (13,272)	$ (37,459)	$ (25,152)
Net loss per share, basic and diluted	$ (0.32)	$ (0.31)	$ (0.67)	$ (0.59)
Weighted-average shares used to compute net loss per share, basic and diluted	58,668,712	42,589,213	55,448,823	42,492,377

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