Tyra Biosciences Reports Third Quarter 2024 Financial Results and Highlights

- Reported positive interim clinical proof-of-concept results for TYRA-300 in mUC from SURF301 Ph1/2 study -

- IND cleared for Phase 2 study of TYRA-300 in pediatric achondroplasia (BEACH301) -

- Strengthened leadership with appointment of Doug Warner, MD as Chief Medical Officer -

- Cash, cash equivalents, and marketable securities of $360.1 million at Q3 2024 -

CARLSBAD, Calif., Nov. 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 September 30, 2024, and highlighted recent corporate progress.

"These are exciting times at TYRA. We are very pleased with the interim data reported with TYRA-300 at ENA 2024. TYRA-300 demonstrated impressive anti-tumor activity at dose levels ≥ 90 mg once daily and was generally well-tolerated with infrequent FGFR1 and FGFR2 toxicities that limit the tolerability of pan-FGFR inhibitors. These data provide clinical support that an FGFR3 inhibitor designed to be highly selective can deliver meaningful clinical benefit to heavily pretreated patients with cancer," said Todd Harris, CEO of TYRA. "These results allow us to expand into larger studies for multiple bladder cancer indications, including metastatic urothelial cancer (mUC) and non-muscle invasive bladder cancer (NMIBC), while aiming to achieve best-in-class annualized growth velocity in achondroplasia (ACH). We look forward to initiating the Phase 2 study for ACH in the first quarter of 2025 and submitting an IND for NMIBC by the end of this year."

Third Quarter 2024 and Recent Corporate Highlights

TYRA-300

- **Reported Interim Clinical Proof-of-Concept Results from SURF301 Phase 1/2 Study**(NCT05544552) **in Patients with mUC.** In October 2024, TYRA reported interim data with TYRA-300 during a late-breaking oral presentation at the 36th EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, Spain. The results included encouraging preliminary anti-tumor activity observed in a heavily pre-treated population: at ≥ 90 mg once daily (QD), 6 out of 11 (54.5%) patients with FGFR3+ mUC achieved a confirmed partial response (PR), with 100% disease control rate and sustained duration of activity; positive safety results were reported across all once-daily (QD) doses, with infrequent FGFR2/FGFR1-associated toxicities. The interim results warrant continued development of TYRA-300 for mUC and the Company is prioritizing QD dosing in SURF301 and future oncology studies. TYRA-300 is currently being evaluated in Part B of SURF301 at potentially therapeutic QD doses in preparation for potential future Phase 2 studies in NMIBC and mUC.

- **Phase 2 IND Submission for NMIBC on Track for Year-End 2024.**TYRA plans to expand the clinical development of TYRA-300 into NMIBC to address the unmet needs in this cancer population with an efficacious, orally available therapy. TYRA remains on track to submit an Investigational New Drug (IND) application for a Phase 2 study of TYRA-300 in NMIBC before year-end 2024.

- **IND Clearance Received for Phase 2 Achondroplasia (ACH) Study (BEACH301).**In October 2024, TYRA announced that the U.S. Food and Drug Administration (FDA) cleared its IND application for TYRA-300 allowing the company to proceed with a Phase 2 clinical trial of TYRA-300 for children with achondroplasia (BEACH301). The study will be a Phase 2, multicenter, open-label, dose-escalation/dose-expansion study evaluating TYRA-300 in children ages 3 to 10 with achondroplasia with open growth plates. The study will enroll children who are treatment-naïve (Cohort 1) and those who have received prior growth-accelerating therapy (Cohort 2) at multiple sites across the globe. Each of these cohorts is expected to enroll up to 10 participants per dose level (0.125, 0.25, 0.375, 0.50 mg/kg) for up to 12 months. Prior to initiation of Cohorts 1 and 2, the study will enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10. TYRA expects to dose the first child with achondroplasia in BEACH301 in Q1 2025.

- **Peer-Reviewed Manuscript Published in Journal of Medicinal Chemistry**. In September 2024, a manuscript titled "*Discovery of TYRA-300: First oral selective FGFR3 inhibitor for the treatment of urothelial cancers and achondroplasia*" was published in the Journal of Medicinal Chemistry (J. Chem) by the American Chemical Society. The published data provides preclinical evidence that TYRA-300 is a potentially best-in-class, novel precision small molecule

designed to be selective for FGFR3 while sparing FGFR1 and 2 isoform toxicities and on-target gatekeeper resistant mutations. These results support the advancement of TYRA-300 in the ongoing SURF301 Phase 1/2 clinical study and the expansion into achondroplasia and hypochondroplasia.

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

- **Continued Phase 1 Planning Following IND Clearance.** TYRA announced 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

- **Appointed Doug Warner, MD, as Chief Medical Officer (CMO).** In September 2024, TYRA announced the appointment of Dr. Warner as CMO, who brings over twenty years of proven clinical development leadership to TYRA having successfully led global development and secured approvals for medicines across oncology and skeletal disease. Prior to TYRA, Dr. Warner held roles of increasing responsibility over 18 years at Amgen where he oversaw clinical development for programs across oncology and bone diseases. This included being an Executive Director and Group Product Area Lead, where Dr. Warner led a team responsible for the development of a portfolio of medicines ranging from those in Phase 1 to those with approved indications, including Vectibix®, XGEVA®, and Prolia®. Most recently, Dr. Warner was Chief Medical Officer for eFFECTOR Therapeutics where he was responsible for overseeing eFFECTOR's clinical pipeline, including its KICKSTART Phase 2b trial of tomivosertib in non-small cell lung cancer, and its Phase 1/2 study of zotatifin in solid tumors. Dr. Warner is co-author of numerous peer-reviewed articles including those in The Lancet, The Lancet Oncology, and The Journal of Clinical Oncology. He received his B.A. from the University of Pennsylvania, his M.D. from the Duke University School of Medicine, and his M.B.A. from the UCLA Anderson School of Management.

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.

Third Quarter 2024 Financial Results

- Third quarter 2024 net loss was $24.0 million compared to $21.2 million for the same period in 2023.
- Third quarter 2024 research and development expenses were $22.7 million compared to $19.3 million for the same period in 2023. The increase was driven by increased expenses incurred in connection with our ongoing and planned clinical trials and personnel-related costs, partially offset by decreased drug manufacturing and preclinical costs.
- Third quarter 2024 general and administrative expenses were $5.9 million compared to $4.7 million for the same period in 2023. The increase was primarily driven by increased personnel-related costs, including stock-based compensation.
- As of September 30, 2024, TYRA had cash, cash equivalents, and marketable securities of $360.1 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) (NCT05544552). The study is 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. Part A of the study included patients with all solid tumors who are FGFR3 +/-, and explored doses of TYRA-300 ranging from 10mg -120mg once-daily (QD). Part A of SURF301 is complete. The Company

continues to advance TYRA-300 through dose expansion in Part B, which includes patients with solid tumors who are FGFR3^{+}, to evaluate potentially therapeutic doses in preparation for potential future Phase 2 studies in metastatic urothelial carcinoma (mUC) and non-muscle invasive bladder cancer (NMIBC). In skeletal dysplasia, TYRA-300 has demonstrated positive preclinical results in achondroplasia and hypochondroplasia and TYRA has received IND clearance from the FDA to proceed with its BEACH301 clinical trial in children with 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 expertise in FGFR biology has created a differentiated pipeline with three clinical-stage programs in targeted oncology and genetically defined conditions. The Company's lead precision medicine stemming from SNÅP, TYRA-300, is a potential first-in-class selective FGFR3 inhibitor that is designed to avoid the toxicities associated with inhibition of FGFR1, FGFR2 and FGFR4, while being agnostic for the FGFR3 gatekeeper mutations. TYRA-300 is in development for the treatment of cancer in the SURF301 Phase 1/2 study and for achondroplasia in the BEACH301 Phase 2 study. TYRA is also developing TYRA-200, an investigational, FGFR1/2/3 inhibitor, in the SURF201 study for metastatic intrahepatic cholangiocarcinoma, and TYRA-430, an investigational FGFR4/3-biased inhibitor for FGF19^{+}/FGFR4-driven cancers. 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 continued evaluation of TYRA-300 through Part B dose escalation in SURF301; 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 NMIBC and initiating dosing in BEACH301; the design and goals of BEACH301; 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: interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues and as more patient or final data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the potential for proof-of-concept results to fail to result in successful subsequent development of TYRA-300; we are early in our development efforts of 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; later developments with the FDA may be inconsistent with prior feedback from the FDA, including with respect to the proposed initiation and design of our BEACH301 study; 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 Orphan Drug Designation, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained, or from

the Rare Pediatric Disease 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.

Contact:

Amy Conrad
aconrad@tyra.bio

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

	September 30, 2024 (unaudited)	December 31, 2023
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 360,130	$ 203,469
Working capital	353,238	196,338
Total assets	380,592	225,857
Accumulated deficit	(225,740)	(164,830)
Total stockholders' equity	362,288	204,262

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 22,697	$ 19,271	$ 57,897	$ 41,841
General and administrative	5,907	4,692	16,536	12,470
Total operating expenses	28,604	23,963	74,433	54,311
Loss from operations	(28,604)	(23,963)	(74,433)	(54,311)
Other income:				
Interest and other income, net	4,588	2,811	13,523	8,007
Total other income	4,588	2,811	13,523	8,007
Net loss	(24,016)	(21,152)	(60,910)	(46,304)
Unrealized gain on marketable securities available-for-sale, net	1,936	—	1,371	—
Comprehensive loss	$ (22,080)	$ (21,152)	$ (59,539)	$ (46,304)
Net loss per share, basic and diluted	$ (0.41)	$ (0.49)	$ (1.08)	$ (1.09)
Weighted-average shares used to compute net loss per share, basic and diluted	58,874,497	42,868,340	56,599,050	42,619,075

SOURCE Tyra Biosciences

https://tyrabio.investorroom.com/2024-11-07-Tyra-Biosciences-Reports-Third-Quarter-2024-Financial-Results-and-Highlights