

Tyra Biosciences Reports Fourth Quarter and Full Year 2024 Financial Results and Highlights

- Three INDs cleared by US FDA for TYRA's proprietary precision small molecules -

- TYRA-300 to be evaluated in three Phase 2 studies: SURF302 for Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR NMIBC), BEACH301 for pediatric achondroplasia (ACH) and SURF301 for metastatic urothelial cancer (mUC) -

- Cash, cash equivalents, and marketable securities of \$341.4 million at YE 2024; runway through at least 2027 -

CARLSBAD, Calif., March 27, 2025 /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, 2024, and highlighted recent corporate progress.

"2024 was a momentous year for TYRA and the patient communities we serve, highlighted by the positive interim results from our SURF301 study, which demonstrated a combination of high anti-tumor activity with favorable tolerability results in very sick, heavily pre-treated cancer patients. Importantly, the oncology doses tested in SURF301 are significantly higher than those to be tested in BEACH301, giving us confidence as we advance TYRA-300 in ACH," said Todd Harris, CEO of TYRA. "Our conviction in TYRA-300 has never been stronger and we are working diligently to advance this potential best-in-class agent for multiple high-value indications in oncology and skeletal dysplasia into three Phase 2 studies in NMIBC, ACH and mUC."

Fourth Quarter and Full Year 2024 and Recent Corporate Highlights

TYRA-300

- **Advanced Clinical Evaluation of TYRA-300 into Three Phase 2 Studies.** During 2024, TYRA progressed TYRA-300, an oral, investigational FGFR3-selective inhibitor, for the treatment of IR NMIBC, mUC and ACH, and achieved the following milestones:
 - **Cleared Phase 2 NMIBC IND with US FDA – SURF302.** TYRA expanded the clinical development of TYRA-300 into NMIBC to address the unmet needs in this cancer population for an efficacious, orally available therapy. SURF302 is an open-label Phase 2 clinical study evaluating the efficacy and safety of TYRA-300 in participants with FGFR3-altered low-grade, IR NMIBC. The study will enroll up to 90 participants at multiple sites primarily in the United States. Participants will be randomized initially to treatment with TYRA-300 at 50 mg once-daily (QD) (Cohort 1) or treatment with TYRA-300 at 60 mg QD (Cohort 2). Following a review of efficacy and safety, an additional dosing cohort may be evaluated. The primary endpoint is complete response (CR) rate at three months. Secondary endpoints include time to recurrence, the median duration of response, recurrence free survival (RFS), progression free survival (PFS), safety and tolerability.
 - **Cleared Phase 2 ACH IND with US FDA - BEACH301.** The study is 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. The study will initially enroll a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10.
 - **Reported Interim Clinical Proof-of-Concept Results in mUC Patients – SURF301.** TYRA-300 demonstrated encouraging preliminary anti-tumor activity in a heavily pre-treated population: at ≥ 90 mg 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 QD doses, with infrequent FGFR2/FGFR1-associated toxicities (data cutoff of August 15, 2024). TYRA-300 is being evaluated in Part B of SURF301 (NCT05544552) at potentially therapeutic QD doses in preparation for potential future Phase 2 studies.

TYRA-200

- **Advanced Phase 1 SURF201 Study.** TYRA-200 is an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. SURF201 (Study in Previously treated and Resistant FGFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors) (NCT06160752) is a multi-center, open label study designed to evaluate the safety,

tolerability, and pharmacokinetics of TYRA-200 and determine the optimal and maximum tolerated dose and recommended Phase 2 dose, as well as evaluate the preliminary antitumor activity of TYRA-200. 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

- **Cleared Phase 1 IND with US FDA – SURF431.** TYRA-430 is an oral, 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 Leadership Team and Board of Directors.** In 2024, TYRA appointed Doug Warner, MD, as Chief Medical Officer, and Erik Goluboff, MD, as SVP, Clinical Development to lead the Company's oncology strategy and clinical development plans. In 2025, TYRA appointed accomplished drug developer Adele Gulfo to its Board of Directors, Sinette Heys as SVP, Clinical Operations to lead the Company's clinical operations team, and Will Charlton, MD, as SVP, Clinical Development to lead the Company's skeletal dysplasia clinical development group.

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.

Fourth Quarter and Full-Year 2024 Financial Results

- **Cash, Cash Equivalents and Short-Term Investments.** As of December 31, 2024, TYRA had cash, cash equivalents, and marketable securities of \$341.4 million, compared to \$203.5 million at the end of 2023. The increase was primarily due to the completion of a private placement financing for net proceeds of \$199.6 million in the first quarter of 2024. The Company's current cash, cash equivalents and marketable securities are expected to allow TYRA to execute on its plans through at least 2027.
- **Research and Development (R&D) Expenses.** Research and development expenses for the three months ended December 31, 2024 were \$22.2 million compared to \$20.7 million for the same period in 2023, and \$80.1 million for the full year 2024 compared to \$62.5 million for the same period in 2023. The increases were primarily driven by increased expenses incurred in connection with our ongoing and planned clinical trials and personnel-related costs, including stock-based compensation, partially offset by decreased drug manufacturing and preclinical costs.
- **General and Administrative (G&A) Expenses.** General and administrative expenses for the three months ended December 31, 2024 were \$7.6 million compared to \$5.0 million for the same period in 2023, and \$24.1 million for the full year 2024 compared to \$17.4 million for the same period in 2023. The increases were primarily driven by increased personnel-related costs, including stock-based compensation.
- **Net Loss.** Fourth quarter 2024 net loss was \$25.6 million compared to \$22.8 million for the same period in 2023, and \$86.5 million for the full year 2024 compared to \$69.1 million for the same period in 2023.

Upcoming Anticipated Milestones and Events

- BEACH301: dose first child with achondroplasia with TYRA-300 – Q2 2025
- SURF302: dose first NMIBC patient with TYRA-300 – Q2 2025
- SURF431: dose first HCC patient with TYRA-430 – Q2 2025

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 dysplasia, including achondroplasia and hypochondroplasia. In oncology, TYRA-300 is being evaluated in mUC and IR NMIBC. In mUC, TYRA-300 is being evaluated in a multi-center, open label Phase 1/2 clinical study, SURF301 (Study in Untreated and Resistant FGFR3+ Advanced Solid Tumors) (NCT05544552). The study is designed to determine the optimal and the recommended Phase 2 dose of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. In October 2024, TYRA reported interim clinical proof-of-concept data in mUC from SURF301. TYRA has received IND clearance from the US FDA to proceed with its SURF302 clinical trial in patients with IR NMIBC. In skeletal dysplasia, TYRA-300 has demonstrated positive preclinical results in achondroplasia and hypochondroplasia, and its BEACH301 clinical trial in children with achondroplasia is now recruiting.

About TYRA-200

TYRA-200 is an oral, investigational, FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. The Phase 1 clinical study of TYRA-200, SURF201 (Study in Previously treated and Resistant FGFR2+ Cholangiocarcinoma and Other Advanced Solid Tumors) (NCT06160752), is a multi-center, open label study designed to evaluate the maximum tolerated dose (MTD) and the recommended Phase 2 dose of TYRA-200, as well as to evaluate the preliminary antitumor activity of TYRA-200. SURF201 is currently enrolling and dosing adults with advanced/metastatic intrahepatic cholangiocarcinoma and other advanced solid tumors with activating alterations in FGFR2.

About TYRA-430

TYRA-430 is an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers. The US FDA has cleared Tyra's IND to proceed with a Phase 1 clinical study of TYRA-430. The Phase 1 study will be a multicenter, open-label, first-in-human study of TYRA-430 in advanced HCC and other solid tumors with activating FGF/FGFR pathway aberrations (SURF431).

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 product candidates in clinical development 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 expected to be evaluated in three Phase 2 studies: SURF302 for IR NMIBC, BEACH301 for pediatric achondroplasia and SURF301 for metastatic urothelial cancer. TYRA is also developing TYRA-200, an oral, investigational, FGFR1/2/3 inhibitor, in the SURF201 study for metastatic intrahepatic cholangiocarcinoma, and TYRA-430, an oral, 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 expected advancement of our pipeline and our growth; the potential to develop next-generation precision medicines and their potential to be first-in-class and/or best-in-class; the potential safety and therapeutic benefits of, and market opportunities for, our product candidates; the expected trial design, timing and phase of development of our product candidates, including timing for patient dosing; the potential for SNÅP to develop therapies; and our expected cash runway. 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; later developments with the FDA may be inconsistent with prior feedback from the FDA; we are early in our development efforts, 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, recruitment, 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 our product candidates; 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; unfavorable results from preclinical studies; 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 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 Sheets
(in thousands)

	<u>December 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 91,966	\$ 58,006
Marketable securities	249,475	145,463
Prepaid expenses and other current assets	6,022	8,202
Total current assets	<u>347,463</u>	<u>211,671</u>
Restricted cash	1,000	1,000
Property and equipment, net	1,651	1,628
Right-of-use assets	6,068	6,526
Other long-term assets	7,376	5,032
Total assets	<u>\$ 363,558</u>	<u>\$ 225,857</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 590	\$ 4,662
Lease liabilities, current	412	280
Accrued expenses and other current liabilities	13,592	10,391
Total current liabilities	<u>14,594</u>	<u>15,333</u>
Lease liabilities, noncurrent	5,810	6,216
Other long-term liabilities	3	46
Total liabilities	<u>20,407</u>	<u>21,595</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	5	4
Additional paid-in capital	593,687	368,707
Accumulated other comprehensive income	770	381
Accumulated deficit	(251,311)	(164,830)
Total stockholders' equity	<u>343,151</u>	<u>204,262</u>
Total liabilities and stockholders' equity	<u>\$ 363,558</u>	<u>\$ 225,857</u>

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Operating expenses:				
Research and development	\$ 22,180	\$ 20,677	\$ 80,077	\$ 62,518
General and administrative	7,564	4,957	24,100	17,427

Total operating expenses	29,744	25,634	104,177	79,945
Loss from operations	(29,744)	(25,634)	(104,177)	(79,945)
Other income:				
Interest and other income, net	4,173	2,804	17,696	10,811
Total other income	4,173	2,804	17,696	10,811
Net loss	(25,571)	(22,830)	(86,481)	(69,134)
Unrealized gain (loss) on marketable securities available-for-sale, net	(982)	381	389	381
Comprehensive loss	\$ (26,553)	\$ (22,449)	\$ (86,092)	\$ (68,753)
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.53)	\$ (1.51)	\$ (1.62)
Weighted-average shares used to compute net loss per share, basic and diluted	59,060,385	42,965,744	57,217,746	42,704,876

SOURCE Tyra Biosciences

<https://tyrabio.investorroom.com/2025-03-27-Tyra-Biosciences-Reports-Fourth-Quarter-and-Full-Year-2024-Financial-Results-and-Highlights>