Tyra Biosciences Reports First Quarter 2025 Financial Results and Highlights

May 8, 2025

- BEACH301 study of TYRA-300 for Pediatric Achondroplasia (ACH) Open for Enrollment -

- Initiated patient dosing in SURF431 study of TYRA-430 for hepatocellular carcinoma (HCC) -

- Cash, cash equivalents, and marketable securities of $318.9 million at Q1 2025; runway through at least 2027 -

CARLSBAD, Calif., May 8, 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 first quarter ended March 31, 2025, and highlighted recent corporate progress.

"In 2025, we are focused on clinical execution across our portfolio of next-generation precision therapies for oncology and skeletal dysplasia. We continued to advance TYRA-300 for ACH and intermediate risk non-muscle invasive bladder cancer and will begin dosing in BEACH301 and SURF302 in the second quarter," stated Todd Harris, CEO of TYRA. "In addition, our SURF431 study is now underway, and we dosed the first HCC patient with TYRA-430, our oral FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers."

First Quarter 2025 and Recent Corporate Highlights

TYRA-300

- **Advanced Clinical Evaluation of TYRA-300 and Published Preclinical Research.** TYRA continued to progress TYRA-300, an oral, investigational FGFR3-selective inhibitor, for the treatment of intermediate risk non-muscle invasive bladder cancer (IR NMIBC), pediatric achondroplasia (ACH), and metastatic urothelial cancer (mUC).

    - **Advanced Phase 2 ACH Study - BEACH301 - Open for Enrollment.** 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 is now enrolling a safety sentinel cohort of up to 3 treatment-naïve participants per dose level in children ages 5 to 10.

    - **Advanced Phase 2 NMIBC Study Activities – SURF302.** 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.

    - **Advanced Phase 1/2 mUC Study – SURF301.** TYRA-300 is currently being evaluated in Part B of SURF301 (NCT05544552) at potentially therapeutic QD doses in preparation for potential future Phase 2 studies.

    - **Preclinical Results with TYRA-300 Published in JCI Insight.** In April 2025, preclinical results with TYRA-300 were published in JCI Insight 2025 in a manuscript titled "*TYRA-300, an FGFR3 selective inhibitor, promotes bone growth in two FGFR3-driven models of chondrodysplasia."* TYRA-300 was evaluated in three genetic contexts: wild-type mice, the *Fgfr3*$^{Y367C/+}$ mouse model of ACH, and the *Fgfr3*$^{N534K/+}$ mouse model of HCH. In each model, TYRA-300 treatment increased naso-anal length, tibia and femur length. In the two FGFR3-altered models, TYRA 300-induced growth partially restored the disproportionality of long bones. Histologic analysis of the growth plate in *Fgfr3*$^{Y367C/+}$ mice revealed that TYRA-300 mechanistically increased both proliferation and differentiation of chondrocytes. Importantly, TYRA-300 also significantly improved the size and shape of the skull and foramen magnum in *Fgfr3*$^{Y367C/+}$ mice. These studies demonstrate that TYRA-300 led to a significant increase in bone growth in two independent FGFR3-driven preclinical models, as well as in wild-type mice.

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 (**S**tudy in Previo**U**sly Treated and **R**esistant **F**GFR2+ 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 continues to enroll and dose adults with unresectable locally advanced/metastatic intrahepatic cholangiocarcinoma and other advanced solid tumors with activating FGFR2 gene alterations.

TYRA-430

- **Initiated Patient Dosing in Phase 1 Study – SURF431.** TYRA-430 is an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers. Patient dosing has commenced in SURF431, a Phase 1, 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 (NCT06915753). SURF431 is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of TYRA-430 and determine the maximum tolerated dose and recommended Phase 2 dose, as well as evaluate the preliminary antitumor activity of TYRA-430. We believe TYRA-430 has the potential to address a significant unmet need in HCC, where there are no approved biomarker-driven, targeted therapies.

SNÅP Platform and Pipeline

- TYRA continued to advance its in-house precision medicine discovery engine, SNÅP, used to develop therapies in targeted oncology and genetically defined conditions.

First Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Short-Term Investments.** As of March 31, 2025, TYRA had cash, cash equivalents, and marketable securities of $318.9 million. 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.** R&D expenses for the three months ended March 31, 2025 were $25.0 million compared to $17.2 million for the same period in 2024. The increase was primarily driven by higher clinical costs associated with start-up activities for BEACH301, SURF302 and SURF431, as well as increased CMC and personnel-related costs, including non-cash stock-based compensation.

- **General and Administrative (G&A) Expenses.** G&A expenses for the three months ended March 31, 2025 were $6.9 million compared to $5.1 million for the same period in 2024. The increase was primarily driven by higher personnel-related costs, including non-cash stock-based compensation.

- **Net Loss.** First quarter net loss was $28.1 million compared to $18.2 million for the same period in 2024.

Upcoming Anticipated Milestones and Events

- BEACH301: dose first child with ACH with TYRA-300 – Q2 2025
- SURF302: dose first IR NMIBC patient with TYRA-300 – 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 (**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 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 enrolling.

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 (NCT06160752), is a multi-center, open label study designed to evaluate the maximum tolerated dose 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 Phase 1 study (SURF431) is a multicenter, open-label, first-in-human study of TYRA-430 and is currently enrolling and dosing adults with advanced HCC and other solid tumors with activating

FGF/FGFR pathway aberrations (NCT06915753).

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; 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 Sheet Data
(in thousands)
(unaudited)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 100,721	$ 91,966
Marketable securities	218,222	249,475
Prepaid expenses and other current assets	5,623	6,022
Total current assets	324,566	347,463
Restricted cash	1,000	1,000

Property and equipment, net	1,522	1,651
Right-of-use assets	5,946	6,068
Other long-term assets	10,442	7,376
Total assets	$ 343,476	$ 363,558
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,500	$ 590
Lease liabilities, current	426	412
Accrued expenses and other current liabilities	11,320	13,592
Total current liabilities	14,246	14,594
Lease liabilities, noncurrent	5,696	5,810
Other long-term liabilities	—	3
Total liabilities	19,942	20,407
Stockholders' equity:		
Preferred stock	—	—
Common stock	5	5
Additional paid-in capital	602,299	593,687
Accumulated other comprehensive income	688	770
Accumulated deficit	(279,458)	(251,311)
Total stockholders' equity	323,534	343,151
Total liabilities and stockholders' equity	$ 343,476	$ 363,558

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 24,964	$ 17,203
General and administrative	6,886	5,119
Total operating expenses	31,850	22,322
Loss from operations	(31,850)	(22,322)
Other income:		
Interest and other income, net	3,703	4,130
Total other income	3,703	4,130
Net loss	(28,147)	(18,192)
Unrealized loss on marketable securities available-for-sale, net	(82)	(387)
Comprehensive loss	$ (28,229)	$ (18,579)
Net loss per share, basic and diluted	$ (0.47)	$ (0.35)
Weighted-average shares used to compute net loss per share, basic and diluted	59,336,550	52,228,934

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