

Tyra Biosciences Reports Third Quarter 2025 Financial Results and Highlights

- Dosed first patients with dabogratinib in BEACH301 and SURF302; interim results from both studies expected in 2026 -

- Expanded development of dabogratinib into low-grade upper tract urothelial carcinoma (LG-UTUC); IND cleared with U.S. FDA

- Cash, cash equivalents, and marketable securities of \$274.9 million at Q3 2025; runway through at least 2027 -

CARLSBAD, Calif., Nov. 5, 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 third quarter ended September 30, 2025, and highlighted recent corporate progress.

"Our focus remains on patients – those living with skeletal dysplasia and bladder cancer who need improved, precise options of care," said Todd Harris, Ph.D., CEO of TYRA. "Enrollment continues to progress across our BEACH301 and SURF302 Phase 2 studies, reflecting strong engagement from the clinical and patient communities. We are also expanding the Phase 2 development of dabogratinib into low-grade upper tract urothelial carcinoma, where FGFR3 alterations occur in approximately 85% of LG-UTUC cases, further reinforcing our commitment to addressing FGFR3-driven disorders."

Dr. Harris continued, "We believe 2026 will be a pivotal year for TYRA. We expect to report interim Phase 2 results that could validate dabogratinib's broad potential across achondroplasia, IR-NMIBC and LG-UTUC."

Third Quarter 2025 and Recent Corporate Highlights

Dabogratinib (formerly TYRA-300)

- Dabogratinib is an oral investigational FGFR3-selective inhibitor being developed for the treatment of pediatric achondroplasia (ACH), low-grade intermediate risk non-muscle invasive bladder cancer (IR NMIBC) and LG-UTUC. TYRA previously reported interim clinical proof-of-concept results in metastatic urothelial cancer (mUC) – dabogratinib demonstrated encouraging anti-tumor activity and was generally well-tolerated, with infrequent FGFR2- and FGFR1-associated toxicities.
 - **Enrolling Phase 2 ACH Study – BEACH301.** BEACH301 is a Phase 2, multicenter, open-label, dose-escalation/dose-expansion study evaluating dabogratinib in children ages 3 to 10 with achondroplasia with open growth plates. The study is enrolling a safety sentinel cohort of at least 3 participants per dose level in children ages 5 to 10. The Company remains on track to report interim results from the safety sentinel cohort in 2H 2026.
 - **Enrolling Phase 2 NMIBC Study – SURF302.** SURF302 is a Phase 2 open-label clinical study evaluating the efficacy and safety of dabogratinib in participants with FGFR3-altered low-grade IR NMIBC. The Company remains on track to report initial three-month complete response data in 1H 2026.
 - **Expanded Development into LG-UTUC – SURF303.** TYRA advanced dabogratinib into LG-UTUC, where FGFR3 alterations occur in approximately 85% of cases. An Investigational New Drug application (IND) was cleared by the US Food and Drug Administration (FDA) to enable a Phase 2 study of dabogratinib in LG-UTUC patients (SURF303), which is expected to be initiated in 2026.
 - **Phase 1/2 mUC Study – SURF301.** Dabogratinib continues to be evaluated in Part B of SURF301 at potentially therapeutic once-daily doses in support of determining an optimal dose for mUC.

TYRA-430

- **Advanced Phase 1 HCC Study – SURF431.** TYRA-430 is an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers. The SURF431 study continues to enroll and dose adults with hepatocellular carcinoma (HCC) and other solid tumors with activating FGF/FGFR pathway aberrations. We believe TYRA-430 has the potential to address a significant unmet need in HCC, where there are no approved biomarker-driven, targeted therapies.

TYRA-200

- **Advanced Phase 1 ICC Study – SURF201.** TYRA-200 is an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. The SURF201 study continues to enroll and dose adults with unresectable locally advanced/metastatic intrahepatic cholangiocarcinoma (ICC) and other advanced solid tumors with activating

FGFR2 gene alterations.

SNÁP Platform and Pipeline

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

Third Quarter 2025 Financial Results

- **Cash, Cash Equivalents and Short-Term Investments.** As of September 30, 2025, TYRA had cash, cash equivalents and marketable securities of \$274.9 million. TYRA'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 September 30, 2025 were \$25.5 million compared to \$22.7 million for the same period in 2024. The increase was primarily associated with start-up and enrollment activities for BEACH301, SURF302 and SURF431.
- **General and Administrative (G&A) Expenses.** G&A expenses for the three months ended September 30, 2025 were \$7.5 million compared to \$5.9 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.** Third quarter net loss was \$29.9 million compared to \$24.0 million for the same period in 2024.

Upcoming Clinical Milestones:

- BEACH301: initial results from safety sentinel cohort – 2H 2026
- SURF302: initial three-month complete response data – 1H 2026
- SURF303: initiate Phase 2 study – 2026

About Dabogratinib (formerly TYRA-300)

Dabogratinib is TYRA's lead precision medicine candidate stemming from its in-house SNÁP platform. Dabogratinib is an investigational, oral, FGFR3-selective inhibitor currently in development for the treatment of skeletal dysplasia and cancer that has demonstrated interim clinical proof-of-concept results in mUC. The current planned clinical development for dabogratinib includes Phase 2 clinical trials for pediatric achondroplasia (BEACH301), intermediate risk (IR) non-muscle invasive bladder cancer (SURF302), low-grade upper tract urothelial carcinoma (SURF303) and potentially future mUC clinical trials. The FDA has granted Orphan Drug Designation (ODD) and Rare Pediatric Disease (RPD) Designation to dabogratinib for the treatment of achondroplasia.

BEACH301 is a Phase 2, multicenter, open-label, dose-escalation/dose-expansion study evaluating dabogratinib 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 at least 3 participants per dose level in children ages 5 to 10.

SURF302 is a Phase 2, open-label, clinical study evaluating the efficacy and safety of dabogratinib in participants with FGFR3-altered low-grade IR NMIBC. Participants will be randomized initially to treatment with dabogratinib at 50 mg once-daily (QD) (Cohort 1) or treatment with dabogratinib at 60 mg QD (Cohort 2). The primary endpoint is complete response (CR) rate at three months. Secondary endpoints include time to recurrence, median duration of response, recurrence free survival, progression free survival, safety and tolerability.

SURF303 will be a Phase 2, open-label, clinical study evaluating the efficacy and safety of dabogratinib in participants with FGFR3-altered LG-UTUC. This study has not yet begun enrolling patients.

About TYRA-430

TYRA-430 is an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers. The Phase 1 clinical 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.

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, 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.

Please visit the [Patients](#) page of our website for more information on our clinical trials.

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. TYRA's in-house precision medicine platform, SNĀP, enables rapid and precise drug design through iterative molecular SNĀPshots 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 clinical-stage programs in targeted oncology and genetically defined conditions. TYRA's lead precision medicine stemming from SNĀP, dabogratinib, is a potential first-in-class selective FGFR3 inhibitor. Dabogratinib's current planned clinical development includes BEACH301 for pediatric ACH, SURF302 for IR NMIBC, SURF303 for LG-UTUC and potentially mUC. TYRA is also developing TYRA-430, an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers, in the SURF431 study for advanced HCC, and TYRA-200, an oral, investigational, FGFR1/2/3 inhibitor, in the SURF201 study for metastatic intrahepatic cholangiocarcinoma. 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 initiate Phase 2 studies of dabogratinib in LG-UTUC and mUC and the timing thereof, and 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 data readouts and patient dosing; the potential for SNĀP 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 dabogratinib; 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 SNĀP 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 dabogratinib 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 and changes in healthcare legislation, tariffs and trade policies 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)

	<u>September 30,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 61,951	\$ 91,966
Marketable securities	212,973	249,475
Prepaid expenses and other current assets	6,292	6,022
Total current assets	<u>281,216</u>	<u>347,463</u>
Restricted cash	1,000	1,000
Property and equipment, net	1,346	1,651
Right-of-use assets	5,699	6,068
Other long-term assets	12,590	7,376
Total assets	<u>\$ 301,851</u>	<u>\$ 363,558</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,991	\$ 590
Lease liabilities, current	456	412
Accrued expenses and other current liabilities	13,432	13,592
Total current liabilities	<u>15,879</u>	<u>14,594</u>
Lease liabilities, noncurrent	5,463	5,810
Other long-term liabilities	—	3
Total liabilities	<u>21,342</u>	<u>20,407</u>
Stockholders' equity:		
Preferred stock	—	—
Common stock	5	5
Additional paid-in capital	617,486	593,687
Accumulated other comprehensive income	442	770
Accumulated deficit	(337,424)	(251,311)
Total stockholders' equity	<u>280,509</u>	<u>343,151</u>
Total liabilities and stockholders' equity	<u>\$ 301,851</u>	<u>\$ 363,558</u>

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Operating expenses:				
Research and development	\$ 25,469	\$ 22,697	\$ 74,742	\$ 57,897
General and administrative	7,475	5,907	21,504	16,536
Total operating expenses	<u>32,944</u>	<u>28,604</u>	<u>96,246</u>	<u>74,433</u>
Loss from operations	(32,944)	(28,604)	(96,246)	(74,433)
Other income:				
Interest and other income, net	3,076	4,588	10,133	13,523
Total other income	<u>3,076</u>	<u>4,588</u>	<u>10,133</u>	<u>13,523</u>
Net loss	<u>(29,868)</u>	<u>(24,016)</u>	<u>(86,113)</u>	<u>(60,910)</u>
Unrealized gain (loss) on marketable securities available-for-sale, net	6	1,936	(328)	1,371
Comprehensive loss	<u>\$ (29,862)</u>	<u>\$ (22,080)</u>	<u>\$ (86,441)</u>	<u>\$ (59,539)</u>
Net loss per share, basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.41)</u>	<u>\$ (1.45)</u>	<u>\$ (1.08)</u>

Weighted-average shares used to compute net loss per share, basic and diluted	59,670,757	58,874,497	59,523,977	56,599,050
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SOURCE Tyra Biosciences

<https://tyrabio.investorroom.com/2025-11-05-Tyra-Biosciences-Reports-Third-Quarter-2025-Financial-Results-and-Highlights>