Tyra Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results and Highlights

-Initiated patient dosing with TYRA-300 in SURF301 oncology study-

-Expanded pipeline beyond oncology into genetically defined conditions with TYRA-300 for achondroplasia-

-Cleared IND for TYRA-200 Phase 1 study; first patient dosed expected in 2H 2023 -

-Well-capitalized with cash and cash equivalents of $251.2 million as of YE 2022-

CARLSBAD, Calif., March 22, 2023 /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 and year ended December 31, 2022, and highlighted recent corporate progress.

"2022 was a momentous year for TYRA – we achieved significant milestones, evolved into a clinical-stage company, and leveraged our expertise in FGFR biology to expand our therapeutic focus beyond oncology to include genetically defined conditions," said Todd Harris, CEO of TYRA. "We believe TYRA-300 has the potential to become a best-in-class agent and we look forward to advancing it in both oncology and achondroplasia. Further, we have made steady progress utilizing our SNÅP discovery engine and expect to nominate additional clinical candidates."

Alan Fuhrman, CFO of TYRA, added, "TYRA is in a very strong financial position to begin 2023, with $251.2 million in cash and cash equivalents at year-end 2022, representing more than two years of expected cash runway to support our current development plans across our precision medicine platform."

Fourth Quarter 2022 and Recent Corporate Highlights

TYRA-300

- **Initiated SURF301 Phase 1/2 Study for Oncology.** In November 2022, TYRA announced that patient dosing had commenced in its Phase 1/2 SURF301 clinical study of TYRA-300. SURF301 (NCT05544552) was designed to determine the optimal and maximum tolerated doses (MTD) and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300.
- **Expanded Development into Achondroplasia.** In March 2023, TYRA announced the expansion of development of TYRA-300 into achondroplasia (ACH) based on positive preclinical results in a study performed in collaboration with the Imagine Institute in Paris, France. TYRA-300, an investigational agent, is a once-daily oral FGFR3 selective inhibitor whose design may have a meaningful impact on achondroplasia and other skeletal dysplasias.
    - In the study, TYRA-300 was evaluated in FGFR3 wild-type and mutant preclinical models to measure increases in growth and bone length, compared to vehicle-treated mice. In an FGFR3 $^{Y367C/+}$ model, TYRA-300 was administered daily at a 1.2 mg/kg dose for 15 days. TYRA-300 increased body length in mice by 17.6% compared to the vehicle ($p<0.0001$) and increased the length of the femur (+24.4%), tibia (+38.3%) and L4-L6 (+23.9%) in mice ($p<0.0001$).
    - TYRA expects to submit an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) to enable a Phase 2 study of TYRA-300 in pediatric achondroplasia in 2024.

TYRA-200

- **Announced IND Clearance.** In March 2023, TYRA announced that the FDA cleared its IND to proceed with a Phase 1 clinical study of TYRA-200, an FGFR1/2/3 inhibitor with potency against activating FGFR2 gene alterations and resistance mutations. The trial will be focused on intrahepatic cholangiocarcinoma resistant to prior FGFR inhibitors. TYRA expects the first patient will be dosed in this trial in the second half of 2023.

SNÅP Platform and Pipeline

- TYRA continued to use its in-house precision medicine discovery engine, SNÅP, to develop therapies in targeted oncology and genetically defined conditions including FGF19^{+}/FGR4-driven cancers, and RET (REarranged during Transfection kinase) driven cancers.

Corporate

- **Strengthened Executive Team with Key Hire.** During the fourth quarter of 2022, TYRA appointed experienced

biotechnology veteran Alan Fuhrman as Chief Financial Officer.

Fourth Quarter and Full-Year 2022 Financial Results

- Fourth quarter 2022 net loss was $12.9 million compared to $9.9 million for the same period in 2021.
- Fourth quarter 2022 research and development expenses were $10.4 million compared to $7.2 million for the same period in 2021.
- Fourth quarter 2022 general and administrative expenses were $4.6 million compared to $2.7 million for the same period in 2021.
- Full year 2022 net loss was $55.3 million compared to $26.3 million for the same period in 2021.
- Full year 2022 research and development expenses were $43.0 million compared to $20.6 million for the same period in 2021.
- Full year 2022 general and administrative expenses were $15.9 million compared to $5.7 million for the same period in 2021.
- As of December 31, 2022, TYRA had cash and cash equivalents of $251.2 million.

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. 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). SURF301 (NCT05544552) was designed to determine the optimal and maximum tolerated doses (MTD) and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. SURF301 is currently enrolling adults with advanced urothelial carcinoma and other solid tumors with FGFR3 gene alterations. In skeletal dysplasias, TYRA-300 has demonstrated positive preclinical results and the Company expects to submit an IND for the initiation of a Phase 2 clinical study in pediatric achondroplasia in 2024.

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 precision medicines and the potential safety and therapeutic benefits of TYRA-300 and other product candidates and the potential for TYRA-300 to become a best-in-class agent; the expectation to nominate clinical candidates from our FGF19+/FGFR4 and RET programs; the sufficiency of our cash position; expected cash runway; the expected timing and phase of clinical development of TYRA-300 and TYRA-200; and the potential for SNAP 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 our lead product candidate 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, 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; 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; 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; our ability to maintain undisrupted business operations due to the COVID-19 pandemic or other epidemic diseases, including delaying or disrupting our preclinical studies and clinical trials, manufacturing, and supply chain; regulatory developments in the United States and foreign countries; we may use our capital resources sooner than we expect; unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk 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.
Balance Sheet Data
(in thousands)
(unaudited)

	December 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash and cash equivalents	$ 251,213	$ 302,182
Working capital	251,587	300,441
Total assets	266,181	306,701
Accumulated deficit	(95,696)	(40,371)
Total stockholders' equity	257,829	301,737

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 10,400	$ 7,250	$ 43,008	$ 20,636
General and administrative	4,618	2,682	15,919	5,652
Total operating expenses	15,018	9,932	58,927	26,288
Loss from operations	(15,018)	(9,932)	(58,927)	(26,288)
Other income (expense):				
Interest income	2,156	5	3,652	13
Other income (expense)	(33)	(3)	(50)	(19)
Total other income (expense)	2,123	2	3,602	(6)
Net loss and comprehensive loss	$ (12,895)	$ (9,930)	$ (55,325)	$ (26,294)
Net loss per share, basic and diluted	$ (0.31)	$ (0.24)	$ (1.32)	$ (1.91)
Weighted-average shares used to compute net loss per share, basic and diluted	42,207,685	41,304,731	41,883,904	13,780,546

SOURCE Tyra Biosciences, Inc.

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https://tyrabio.investorroom.com/2023-03-22-Tyra-Biosciences-Reports-Fourth-Quarter-and-Full-Year-2022-Financial-Results-and-Highlights