Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Business Highlights

- Announced topline results from STS101 SUMMIT Phase 3 efficacy trial that the company believes demonstrate STS101 provides differentiated, robust and sustained anti-migraine effects -

- Submitted STS101 New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) in March 2023 -

- Company seeking to maximize value for stockholders via strategic transaction -

- ~36% workforce reduction to be implemented effective March 31, 2023 -

- $52.5 million in cash, cash equivalents and marketable securities as of December 31, 2022 -

South San Francisco, CA, March 28, 2023 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a development-stage biopharmaceutical company developing STS101 (dihydroergotamine (DHE) nasal powder), a novel investigational therapeutic product candidate for the acute treatment of migraine, today reported financial results for the fourth quarter and full-year 2022 and summarized recent business highlights.

“After having had the opportunity to review complete results from the SUMMIT trial, discuss them with headache specialists, and undertake further qualitative and quantitative primary market research that takes into account the results of the SUMMIT trial, we continue to believe that STS101, if approved, could be a differentiated and important treatment option for many people with migraine,” stated John Kollins, President and Chief Executive Officer. “Although we have decided not to build commercial infrastructure and independently commercialize STS101, we believe STS101 could ultimately be an attractive addition to the portfolio of an established pharmaceutical company.”

“In parallel with our efforts to conclude a strategic transaction, we have implemented necessary cost-saving initiatives, including the workforce reduction announced today. While it’s difficult to part company with committed employees who have made significant contributions to Satsuma and its STS101 development efforts, given the challenging environment we face, it’s imperative that we optimally position Satsuma and STS101 to maximize potential value for our stockholders. I thank and recognize all of our employees for their commitment and hard work over the past six-plus years in taking STS101 from an abstract concept to an NDA-stage product candidate that has the potential to address the unmet needs of many people with migraine.”

Recent Business Highlights

STS101 New Drug Application (NDA) Submitted to FDA

- Earlier this month, Satsuma submitted an NDA to the FDA seeking approval of STS101 for the acute treatment of migraine with or without aura in adults. As has been its longstanding plan, the company is seeking FDA approval under the 505(b)(2) regulatory pathway that allows for referencing of some of the information required for STS101 approval from studies not conducted by Satsuma. The FDA has 60 days to conduct a preliminary review of the NDA to determine and notify the company as to whether the NDA is sufficiently complete for it to perform a complete review.

STS101 SUMMIT Phase 3 Efficacy Trial Results

- In November 2022, Satsuma announced topline data from its 1,591-subject, double-blind, placebo controlled STS101 SUMMIT Phase 3 efficacy trial. Although single-dose treatment of subjects’ migraine attacks with STS101 demonstrated numerical superiority versus placebo on the SUMMIT trial co-primary outcome measures, freedom from pain and freedom from most-bothersome-symptom (from among photophobia, phonophobia and nausea) assessed at the two-hour post-administration regulatory timepoint, the difference did not reach statistical significance ($p<0.05$).
- STS101 was, however, statistically superior ($p<0.001$) to placebo on the freedom from pain and most-bothersome-symptom endpoints by three hours post-administration and at all subsequent timepoints (4, 6, 12, 24 and 48 hours). Additionally, STS101 was statistically superior to placebo on multiple key secondary endpoints, including pain relief at 2 hours post-administration and all timepoints thereafter and total

migraine freedom at 3 hours post-administration and all timepoints thereafter. The company believes the results of the SUMMIT trial convincingly demonstrate that a single dose of STS101 provides differentiated, robust and sustained anti-migraine effects.
- STS101 was safe and well-tolerated, consistent with clinical trial experience to date.
- Based on previous interactions with the FDA, Satsuma believes that the efficacy results of the SUMMIT trial, which were not required by the FDA to support the STS101 NDA filing and its potential approval, provide a totality of evidence supporting the efficacy of STS101 for the acute treatment of migraine. The company further believes that ST101, if approved, can address the unmet needs of many people with migraine, and that the efficacy results from the SUMMIT trial, if included in the STS101 labeling approved by the FDA, would provide important treatment information to physicians and patients.

STS101 ASCEND Phase 3 Long-term, Open-label Safety Trial

- In January 2023, the Company completed the STS101 ASCEND Phase 3 long-term safety trial, the primary goal of which was to establish the local nasal safety profile of STS101 following repeated administration over time. STS101 was safe and well-tolerated, consistent with clinical experience to date, and final results from the trial were similar to previously-reported interim results, with no new safety signals identified.
- Final results include data from more than 150 subjects who treated their migraines with STS101 for more than six month and 50 subjects who treated their migraines with STS101* for more than 12 months, satisfying the long-term safety exposure requirements previously communicated to Satsuma by the FDA. Based on its communications with the FDA, the Company believes the results from the 12-month cohort are not required to support the NDA filing and approval, but as previously agreed with the FDA, the company plans to submit these results to the STS101 NDA at the 120-Day Safety Update.

Business update

- As previously announced, Satsuma does not intend to independently commercialize STS101 and is seeking to maximize value for stockholders via a strategic transaction.

Upcoming Events and Milestones

- Three poster presentations featuring interim analyses from the STS101 ASCEND Phase 3 open-label, long-term safety study at the American Academy of Neurology (AAN) Annual Meeting, which is being held April 22-27 in Boston, MA and virtually
- Potential acceptance of the STS101 NDA in May 2023
- Multiple abstracts submitted for presentation at the American Headache Society (AHS) 65th Annual Scientific Meeting, which is being held June 15-18 in Austin, TX
- Potential marketing approval of STS101 by January 2024

Financial results for the fourth quarter and full-year of 2022

Net losses for the fourth quarter and full year 2022 were $23.1 million and $70.1 million, respectively, or $0.70 and $2.19 per common share, respectively. This compared to a net loss of $15.6 million and $51.2 million, respectively, or $0.49 and $1.75 per common share, respectively, for the same periods in 2021.

Research and development expenses were $8.7 million and $44.1 million for the fourth quarter and full year 2022, respectively, compared to $11.9 million and $37.6 million for the same periods of 2021, respectively. Fourth quarter expenses decreased by $3.2 million due to decreases in clinical expenses for SUMMIT and ASCEND and lower payroll and personnel expenses due to decreases in annual bonuses, partially offset by an increase in NDA preparation work and other clinical analysis.

Impairment loss was $11.7 million for the fourth quarter and full year 2022 to write down the property and equipment to its fair market value, to write off prepaid expenses and other current assets related to purchase of property and equipment and accrue non-cancelable future payments related to purchase of the property and equipment. The impairment loss was a result of our reported topline results from the STS101 SUMMIT Phase 3 efficacy trial and our plan not to invest in commercialization of STS101. No impairment of long-lived asset has been recorded in prior years.

General and administrative expenses were $3.2 million and $15.1 million for the fourth quarter and full year 2022, respectively, compared to $3.7 million and $13.5 million for the same periods of 2021, respectively. Fourth quarter expenses decreased due to decreased pre-commercialization expenses and lower payroll and personnel expenses due to decreases in annual bonuses.

Satsuma has implemented cost reduction initiatives, including a reduction in force, effective March 31, 2023, of approximately 36%.

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a development-stage biopharmaceutical company developing a novel therapeutic product, STS101, for the acute treatment of migraine. STS101 is a unique and proprietary nasal powder formulation of the well-established anti-migraine drug, dihydroergotamine mesylate (DHE), administered via Satsuma's proprietary nasal delivery device. STS101 is designed to provide significant benefits versus existing acute treatments for migraine, including the combination of quick and convenient self-administration and other clinical advantages, that current DHE liquid nasal spray products and injectable dosage forms lack. Satsuma's dry powder DHE formulation has demonstrated fast absorption, rapid achievement of high DHE plasma concentrations which Satsuma believes is necessary for robust efficacy, and sustained DHE plasma levels over time with low dose-to-dose variability. DHE has long been recommended in published migraine treatment guidelines as a first-line acute treatment option for migraine and has significant advantages versus other anti-migraine treatments for many patients. However, disadvantages of current DHE liquid nasal spray and injectable products, including invasive and burdensome administration and/or sub-optimal clinical performance, have limited the widespread use of DHE. Featuring an easy-to-carry and easy-to-use dosage form, STS101 is designed to overcome these shortcomings and provide patients an improved therapeutic solution for acutely treating migraines that consistently delivers robust clinical performance.

Satsuma is headquartered in South San Francisco, California with operations in both California and Research Triangle Park, North Carolina. For further information, please visit www.satsumarx.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements concerning the business, operations and financial performance and condition of Satsuma Pharmaceuticals, Inc. (the "Company"), as well as the Company's plans, objectives and expectations for its business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about the potential timing and FDA approval of the Company's STS101 NDA submission, the potential for STS101 to be an important and differentiated acute treatment option, the ability of the Company to continue as a going concern, the potential and anticipated success of a strategic transaction, timing and scope of the reduction in force and the risk that the Company may not achieve the intended outcomes of its March 31, 2023 reduction in force. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The Company's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of STS101; the results of preclinical and clinical studies may not be predictive of future results; and the risk that the COVID-19 worldwide pandemic may negatively impact the Company's business, operations, clinical trials or ability to raise capital. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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SATSUMA PHARMACEUTICALS, INC.
CONDENSED 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	$ 8,698	$ 11,866	$ 44,092	$ 37,635
General and administrative	3,165	3,694	15,126	13,531
Impairment loss	11,729	—	11,729	—
Total operating expenses	$ 23,592	$ 15,560	$ 70,947	$ 51,166
Loss from operations	(23,592)	(15,560)	(70,947)	(51,166)
Interest income	462	33	905	157
Interest expense	—	(24)	(13)	(163)
Net loss	$ (23,130)	$ (15,551)	$ (70,055)	$ (51,172)
Unrealized (loss) gain on marketable securities	33	(30)	12	(71)
Comprehensive loss	$ (23,097)	$ (15,581)	$ (70,043)	$ (51,243)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.49)	$ (2.19)	$ (1.75)
Weighted-average shares used in computing net loss per share attributable to common stockholders,	33,130,859	31,532,401	32,024,991	29,174,386

basic and diluted																

SATSUMA PHARMACEUTICALS, INC.
BALANCE SHEET DATA
(in thousands)
(unaudited)

	December 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 52,481	$ 95,770
Working capital	46,694	91,356
Total assets	54,939	109,832
Debt	—	1,080
Accumulated deficit	(211,791)	(141,736)
Total stockholders' equity	46,824	101,340

* STS101 incorporating the improved, second-generation nasal delivery device.

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https://investors.satsumarx.com/2023-03-28-Satsuma-Pharmaceuticals-Reports-Fourth-Quarter-and-Full-Year-2022-Financial-Results-and-Recent-Business-Highlights