Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Third Quarter 2022 Financial Results and Recent Business Highlights

- On track to report topline results from STS101 SUMMIT Phase 3 efficacy trial in November 2022; NDA submission planned in Q1 2023 -

- $64.4 million in cash, cash equivalents and marketable securities as of September 30, 2022, provides runway into second half of 2023 -

South San Francisco, CA, November 3, 2022 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-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 third quarter of 2022 and summarized recent business highlights.

"We are pleased to announce that we anticipate reporting topline results from the STS101 SUMMIT Phase 3 efficacy trial this month," stated John Kollins, Satsuma's President and Chief Executive Officer. "Results from the ASCEND long-term, open-label safety trial of STS101 that we reported in September confirmed the favorable STS101 safety and tolerability profile observed to date in more than 1,600 clinical trial participants, and further suggested STS101 has robust antimigraine activity by two hours post-treatment. In addition, the second-generation nasal delivery device, for which we intend to seek marketing approval, demonstrated improved first-attack clinical performance, increasing our confidence in a positive outcome for the SUMMIT Phase 3 efficacy trial."

Recent Business Highlights

STS101 SUMMIT Phase 3 Efficacy Trial Update (NCT04940390)

- In August 2022, Satsuma announced completion of subject enrollment in the SUMMIT trial. With a total of 1,591 subjects randomized and more than 1,400 subjects expected in the modified intent-to-treat population on which statistical analyses of co-primary endpoints will be performed, SUMMIT is the largest-ever randomized, controlled clinical trial conducted on a DHE product and is highly powered to potentially demonstrate statistically significant effects on co-primary endpoints and key secondary endpoints.
- Satsuma plans to report SUMMIT topline results in November 2022.
- The SUMMIT trial is designed to provide the basis for (i) STS101 to become the first and only DHE product to have demonstrated efficacy in a randomized, controlled trial on co-primary endpoints (freedom from pain and freedom from most bothersome symptom at two hours post-treatment) currently recommended by the FDA in its guidance document and by the International Headache Society in its current controlled trials guidelines; and (ii) the STS101 prescribing information to include differentiating efficacy claims in the event STS101 is approved for marketing.[1],[2]

STS101 ASCEND Phase 3 Open-Label, Long-Term Safety Trial Update (NCT04406649)

- Announced positive results in September from the ongoing STS101 ASCEND open-label, long-term safety trial.
- STS101 demonstrated a favorable safety and tolerability profile, consistent with clinical experience to date.
- As of June 30, 2022, ASCEND subjects had treated over 8,000 migraine attacks with more than 10,000 doses of STS101; of which, over 5,500 migraine attacks were treated with more than 6,900 doses of $STS101_{Mk2}$, the investigational product incorporating the improved, second-generation nasal delivery device for which Satsuma intends to seek marketing approval. [3]
- Subject exposures over time with $STS101_{Mk2}$ exceeded the FDA requirement to support the planned NDA submission in Q1 2023, and potential approval.
- Subjects exclusively using $STS101_{Mk2}$, achieved freedom from pain by two hours post-treatment (2hPF response) in 34.2% of treated attacks and freedom from most-bothersome-symptom by two hours post-treatment (2hMBS response) in 53.4% of treated attacks.
- In an exploratory post-hoc analysis, among subjects who treated their first migraine attack following trial enrollment with $STS101_{Mk2}$, the 2hPF and 2hMBS response rates for the first treated attack were 7.8% and 6.9% greater, respectively, in absolute percentage points, than the corresponding 2hPF and 2hMBS response rates reported by subjects who treated their first migraine attack in the trial with $STS101_{Mk1}$. The Company believes the higher first-treated-attack 2hPF and 2hMBS response rates with $STS101_{Mk2}$ may reflect its demonstrated improved drug delivery performance versus $STS101_{Mk1}$. $STS101_{Mk2}$ is being evaluated for efficacy and safety in the SUMMIT Phase 3, placebo-controlled trial.
- Subjects had predominantly favorable impressions of STS101, particularly with respect to global impression, ease-of-use and likelihood-of-use, and its antimigraine effects in comparison to their usual medications.

Upcoming Events and Key Milestones

- Plan to report topline results from SUMMIT Phase 3 efficacy trial in November 2022.
- Plan to submit STS101 New Drug Application (NDA) in Q1 2023.

Financial results for the third quarter of 2022

Net losses for the third quarter of 2022 were $15.1 million, or $0.48 per common share. This compared to a net loss of $13.3 million, or $0.42 per common share, for the same period in 2021.

Research and development expenses were $11.3 million for the third quarter 2022, compared to $10.2 million for the same period of 2021. Third quarter expenses increased due to increases in clinical expenses and higher payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, partially offset by a decrease in manufacturing activities.

General and administrative expenses were $4.1 million for the third quarter 2022, compared to $3.2 million for the same period of 2021. Third quarter expenses increased due to increased pre-commercialization expenses, higher payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, and increases in professional services for consulting, accounting, tax, legal and other administrative fees.

Cash runway into second half 2023

As of September 30, 2022, Satsuma had $64.4 million in combined cash, cash equivalents and marketable securities, which it believes is sufficient to fund operations into the second half of 2023 and through projected completion of STS101 Phase 3 clinical development and potential submission of an NDA for STS101 in Q1 2023.

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-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 early efficacy, and sustained DHE plasma levels over time with low dose-to-dose variability. STS101 also now incorporates an improved 2nd-generation nasal delivery device designed to provide more consistent nasal dosing, irrespective of user administration technique. 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 Company's expectations regarding the potential safety and efficacy of STS101, the potential results of the ASCEND and SUMMIT trials, the timing of data readouts for ongoing clinical trials, the anticipated timing for a potential STS101 NDA submission, the potential for STS101 to be an important and differentiated acute treatment option, and the expected cash runway of the Company. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, to be 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.

INVESTOR AND CORPORATE CONTACTS:

Corey Davis, PhD

LifeSci Advisors, LLC

212-915-2577

cdavis@lifesciadvisors.com

Tom O'Neil, Chief Financial Officer

Satsuma Pharmaceuticals, Inc.

tom@satsumarx.com

SATSUMA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 11,342	$ 10,170	$ 35,394	$ 25,769
General and administrative	4,067	3,160	11,961	9,837
Total operating expenses	$ 15,409	$ 13,330	$ 47,355	$ 35,606
Loss from operations	(15,409)	(13,330)	(47,355)	(35,606)
Interest income	269	33	443	124
Interest expense	—	(35)	(13)	(139)
Net loss	$ (15,140)	$ (13,332)	$ (46,925)	$ (35,621)
Unrealized gain (loss) on marketable securities	44	(7)	(21)	(41)
Comprehensive loss	$ (15,096)	$ (13,339)	$ (46,946)	$ (35,662)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.48)	$ (0.42)	$ (1.48)	$ (1.26)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,855,051	31,529,417	31,652,318	28,379,743

SATSUMA PHARMACEUTICALS, INC.

BALANCE SHEET DATA

(in thousands)

(unaudited)

	September 30, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 64,436	$ 95,770
Working capital	60,905	91,356
Total assets	75,037	109,832
Debt	–	1,080
Accumulated deficit	(188,661)	(141,736)
Total stockholders' equity	68,379	101,340

[1] FDA Guidance, *Migraine: Developing Drugs for Acute Treatment*, February 2018

[2] Diener et al., *Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth Edition, Cephalalgia, 2019*

[3] In this communication, we refer to "STS101Mk2" as the investigational product incorporating the improved, second-generation nasal delivery device that demonstrates improved drug delivery performance and to "STS101Mk1" as the investigational product incorporating a previous first-generation nasal delivery device. We intend to seek marketing approval for STS101Mk2, and all investigational product (placebo and STS101 active) used in the SUMMIT Phase 3 efficacy trial utilizes the improved, second-generation nasal delivery device.