Satsuma Pharmaceuticals, Inc.

PRESS RELEASE

Satsuma Pharmaceuticals Reports Second Quarter 2022 Financial Results and Recent Progress in STS101 Development Program

- Completed enrollment in the SUMMIT pivotal Phase 3 efficacy trial of STS101, randomizing more than 1,400 subjects -

- On track to announce SUMMIT trial topline results in Q4 2022 -

- Completed STS101 clinical and CMC pre-NDA meetings with FDA -

- Presented nine abstracts at major medical meetings highlighting STS101 and its differentiated profile -

- $68.1 million in cash, cash equivalents and marketable securities as of June 30, 2022, provides runway into second half of 2023 -

South San Francisco, CA, August 9, 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 second quarter of 2022 and summarized progress in its STS101 development program. The Company also summarized STS101 clinical trial and DHE data recently presented at major medical meetings and in a Key Opinion Leader webinar hosted by the Company in June 2022.

"The second quarter of 2022 saw us increasing operational momentum across our clinical trial, regulatory, CMC and pre-commercial activities as we prepare for a planned STS101 NDA filing in Q1 2023 and subsequent commercial launch," stated John Kollins, Satsuma's President and Chief Executive Officer. "People with migraine continue to need better treatment options that offer robust and evidence-based clinical efficacy, favorable safety and tolerability, and ease-of-use. To date, results from our STS101 clinical development program, in which more than 1,400 subjects have self-administered more than 10,000 doses of STS101 5.2 mg to treat their migraines, suggest STS101 could be a highly differentiated treatment option that addresses these unmet needs."

STS101 Development Program Progress

STS101 SUMMIT Pivotal Phase 3 Efficacy Trial (NCT04940390)

In July 2022, Satsuma completed enrollment of the SUMMIT trial, the largest-ever randomized and controlled trial of a DHE product, with more than 1,400 subjects randomized. Satsuma is on track to report topline results from the SUMMIT trial in the fourth quarter of 2022.

- The SUMMIT trial is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in more than 1,400 subjects with migraine that is being conducted in the United States.

- The SUMMIT trial is designed in accordance with recommendations contained in the U.S. Food and Drug Administration's (FDA) current guidance document for industry (*Migraine Developing Drugs for Acute Treatment, February 2018*) and the International Headache Society's (IHS) published guidelines for controlled trials of acute treatment of migraine attacks in adults.[1]
- The SUMMIT trial provides a basis for STS101 to become the first and only DHE product to demonstrate efficacy in a randomized and controlled trial on co-primary endpoints (freedom from pain and freedom from most bothersome symptom (MBS) at two hours post-treatment) currently recommended by the FDA and IHS.

Pre-New Drug Application (NDA) Meetings with FDA

In May 2022, Satsuma completed clinical and chemistry, manufacturing and controls (CMC) pre-NDA meetings with the FDA for STS101. The purpose of the meetings was to discuss and confirm required non-clinical, clinical and CMC content of the STS101 NDA, which Satsuma anticipates submitting to the FDA in the first quarter of 2023.

Based on Satsuma's communications with the FDA, the Company believes the SUMMIT trial, if successful, will support inclusion of differentiating efficacy data in the STS101 prescribing information, presuming STS101 is approved for marketing.

STS101 ASCEND Pivotal Phase 3 Open-label, Long-term Safety Trial (NCT04406649)

Subjects in the ongoing ASCEND pivotal Phase 3 open-label safety trial of STS101 have fulfilled target exposure requirements communicated to us by the FDA (at least 150 subjects completing six months of treatment with STS101 incorporating the second-generation delivery device) that are necessary to support an STS101 NDA filing. The Company anticipates announcing ASCEND trial topline results in the third quarter of 2022.

- The ASCEND trial is an open-label trial designed to evaluate the long-term safety and tolerability of STS101 5.2 mg for the acute treatment of migraine. Satsuma completed subject enrollment in the ASCEND trial in early 2022. As of July 31, 2022, more than 480 subjects had enrolled in ASCEND and treated more than 8,000 migraine attacks with STS101.

Recent STS101 Clinical Trial and DHE Data Presentations

- Leading headache experts and Satsuma presented four abstracts highlighting STS101 and its differentiating features at the American Academy of Neurology Annual Meeting (April 2022). Poster presentations are available for download from the publications section of the Satsuma website.

- Leading headache experts and Satsuma presented five abstracts at the American Headache Society's Annual Scientific Meeting (June 2022). Poster presentations are available for download from the publications section of the Satsuma website.

  The abstracts included:

- An oral presentation by Dr. Stewart J. Tepper, M.D., Professor of Neurology at the Geisel School of Medicine at Dartmouth, *Long-Term Safety and Tolerability of STS101, A Dry Powder Intranasal Dihydroergotamine Product: Initial Data from The ASCEND Study*. Dr. Tepper's presentation concluded, based on analysis of all data available as of December 31, 2021 from 271 ASCEND subjects who self-administered 6,501 doses of STS101 to treat their migraine attacks, that STS101 was safe and well-tolerated, with no clinically relevant systemic safety findings and no clinically relevant nasal tolerability or safety findings.

- A poster presentation by Dr. Jessica Ailani, M.D., Professor of Neurology at Georgetown University Hospital in Washington, DC, indicating subjects in the ongoing ASCEND trial who used STS101 for three and six months to treat their migraine attacks had very favorable impressions of STS101 and its anti-migraine effects. More than 75% of subjects indicated they were "likely" or "very likely" to use the product, if commercially available, to treat their migraine attacks, and more than 90% of subjects indicated STS101 was "easy" or "very easy" to use.

- A poster presentation by Satsuma suggesting DHE, irrespective of route of administration, has an optimal plasma concentration range which maximizes efficacy at two hours post-administration while keeping the signature DHE side effect of nausea to a minimum. STS101 is the only DHE product approved or in active development to demonstrate a pharmacokinetic profile that lies within this proposed optimal plasma concentration range.

- Hosted a Key Opinion Leader webinar in June 2022 featuring Drs. Amaal J. Starling, M.D., from the Mayo Clinic College of Medicine and Science, and Stewart J. Tepper, M.D. The webinar, which is available for replay in the investor section of the Satsuma website, focused on the acute treatment of migraine (including the current treatment landscape and unmet medical needs), DHE and STS101.

Upcoming Events and Key Milestones

- Expect to report topline results from ASCEND Phase 3 open-label safety trial in Q3 2022
- Expect to report topline results from SUMMIT Phase 3 efficacy trial in Q4 2022
- Expect to submit STS101 NDA in Q1 2023

Financial results for the second quarter of 2022

Net loss for the Second quarter of 2022 was $16.3 million, or $0.52 per common share. This compared to a net loss of $11.8 million, or $0.38 per common share, for the same period in 2021.

Research and development expenses were $12.5 million for the second quarter 2022, compared to $8.4 million for the same period of 2021. Second quarter expenses increased due to increases in clinical expenses for the SUMMIT and ASCEND clinical trials and higher payroll and personnel

expenses, including salaries, benefits and stock-based compensation expenses, partially offset by a decrease in manufacturing expenses.

General and administrative expenses were $3.9 million for the second quarter 2022, compared to $3.4 million for the same period of 2021. Second quarter expenses increased due to increased pre-commercialization expenses and higher payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses partly offset by a decrease in professional services for consulting, accounting, tax and other administrative fees.

Cash runway into second half 2023

As of June 30, 2022, Satsuma had $68.1 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 the STS101 Phase 3 clinical development programs and potential submission of an NDA for STS101 in Q1 2023.

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

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 second-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

Satsuma Pharmaceuticals, Inc.

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 June 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.

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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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 12,496	$ 8,443	$ 24,052	$ 15,599
General and administrative	3,904	3,383	7,894	6,677
Total operating expenses	$ 16,400	$ 11,826	$ 31,946	$ 22,276
Loss from operations	(16,400)	(11,826)	(31,946)	(22,276)
Interest income	134	41	174	91
Interest expense	(2)	(47)	(13)	(104)
Net loss	$ (16,268)	$ (11,832)	$ (31,785)	$ (22,289)
Unrealized gain (loss) on marketable securities	14	(8)	(65)	(34)
Comprehensive loss	$ (16,254)	$ (11,840)	$ (31,850)	$ (22,323)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.38)	$ (1.01)	$ (0.83)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,552,936	31,529,417	31,549,270	26,778,804

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

	June 30, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 68,063	$ 95,770
Working capital	64,582	91,356
Total assets	80,151	109,832
Debt	–	1,080
Accumulated deficit	(173,521)	(141,736)
Total stockholders' equity	72,189	101,340

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