Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Second Quarter 2021 Financial Results and Recent Business Highlights

- Initiated STS101 SUMMIT Phase 3 efficacy trial; topline results expected second half 2022-

- $121.2 million in cash as of June 30, 2021, provides runway into second half of 2023-

South San Francisco, CA, August 10, 2021 – 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 2021 and summarized recent business highlights.

"With the recent completion of a new STS101 Phase 1 trial with our 2nd-generation nasal delivery device, and initiation of our new SUMMIT Phase 3 efficacy trial, we continue to execute well against the updated STS101 development plan we announced in early March," stated John Kollins, Satsuma's President and Chief Executive Officer. "We look forward to continuing the strong operational momentum we've established in our STS101 development program."

Recent Business Highlights

STS101 Phase 1 trial with 2nd-generation delivery device showed positive pharmacokinetic, tolerability & safety results

- Phase 1 trial results, in conjunction with other STS101 development program results to date, supported the selection of the 5.2 mg dose strength for evaluation in the ongoing SUMMIT Phase 3 efficacy trial.
- STS101 rapidly achieved and sustained target plasma concentrations.
- All STS101 dose strengths evaluated were well-tolerated and exhibited low adverse event rates.

STS101 SUMMIT Phase 3 efficacy trial initiated

- The Company recently initiated and has begun treating subjects in its SUMMIT Phase 3 efficacy trial of STS101, a double-blind, randomized, placebo-controlled trial designed to enroll approximately 1,400 subjects.
- SUMMIT trial design and conduct incorporates learnings from the previous EMERGE Phase 3 efficacy trial.
- The SUMMIT trial, if successful, could provide the basis for STS101 to become the first and only DHE product to have established efficacy versus placebo control in a randomized trial on the current standard and FDA-accepted acute treatment of migraine co-primary endpoints of freedom from pain and freedom from most bothersome symptom at two hours post-treatment.
- Topline results expected in the second half of 2022.

ASCEND Phase 3 open-label, long-term safety trial update

In August 2020, Satsuma announced the initiation of patient enrollment in the ASCEND trial, a multi-center, open-label, 12-month trial to evaluate the safety and tolerability of STS101 5.2 mg for the acute treatment of migraine.

- As of July 31, 2021, ASCEND had enrolled more than 290 subjects and treated more than 4,500 migraine attacks with STS101 5.2 mg.
- STS101 5.2 mg continues to demonstrate a favorable safety and tolerability profile, with low rates of adverse events.
- Low utilization of a second STS101 dose (~15% of attacks) or need for a rescue medication (<5% of attacks).
- The Company plans to enroll approximately 180 additional subjects in the ASCEND trial to ensure adequate exposures and safety are established with the 2nd-generation STS101 nasal delivery device. Adding these subjects is not expected to affect the overall STS101 development timeline. To date, no differences in the safety or tolerability profiles of the first- and second-generation delivery devices have been observed.
- ASCEND trial completion expected by the second half of 2022.

Cash runway into second half 2023

As of June 30, 2021, Satsuma had $121.2 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 program and potential filing of a New Drug Application for STS101 by the end of 2022.

Financial results for the second quarter of 2021

Net losses for the second quarter of 2021 were $11.8 million, or $0.38 per common share. This compared to a net loss of $11.3 million, or $0.65 per common share, for the same period in 2020.

Research and development expenses were $8.4 million for the second quarter 2021, compared to $8.8 million for the same period of 2020. Second quarter expenses decreased by $0.4 million, due to a decrease of $0.4 million in clinical trial costs and a $0.3 million decrease in manufacturing fees, partly offset by an increase of $0.2 million in payroll and personnel expenses, and increase of $0.1 million in other expenses.

General and administrative expenses were $3.4 million for the second quarter 2021, compared to $2.7 million for the same period of 2020. Second quarter expenses increased by $0.7 million, primarily due to higher stock-based compensation expense, D&O insurance, legal expenses and other administrative costs.

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 2nd-generation 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 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. Although 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, disadvantages of current DHE liquid nasal spray and injectable products, including invasive and burdensome administration processes and/or sub-optimal clinical performance, have limited the widespread use of DHE. Featuring a compact and convenient 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.

About the SUMMIT Phase 3 Trial

The SUMMIT Phase 3 efficacy trial is designed to evaluate the efficacy and safety of STS101 in acutely treating migraine attacks. The SUMMIT trial is a multi-center, single-treatment, randomized, double-blind, placebo-controlled, parallel group trial being conducted in the United States which seeks to enroll approximately 1,400 subjects with migraine. The SUMMIT trial is designed in accordance with FDA recommendations outlined in the FDA Guidance *Migraine:*

Developing Drugs for Acute Treatment, February 2018. After establishing full eligibility, SUMMIT trial participants will be randomized (1:1) to receive either STS101 DHE 5.2 mg or matching placebo and instructed to treat their next migraine attack of at least moderate pain severity with the allocated blinded trial medication. The two co-primary endpoints of the SUMMIT trial are freedom from pain and freedom from most bothersome symptom (from among photophobia, phonophobia or nausea), both of which are assessed at two hours after administration of trial medication.

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 initiation and data readouts for ongoing and planned clinical trials, the anticipated timing for a potential NDA filing of STS-101, the potential for STS-101 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, 2021, 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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 8,443	$ 8,829	$ 15,599	$ 18,477
General and administrative	3,383	2,671	6,677	5,194
Total operating expenses	$ 11,826	$ 11,500	$ 22,276	$ 23,671
Loss from operations	(11,826)	(11,500)	(22,276)	(23,671)
Interest income	41	325	91	827
Interest expense	(47)	(94)	(104)	(198)
Net loss	$ (11,832)	$ (11,269)	$ (22,289)	$ (23,042)
Unrealized (loss) gain on marketable securities	(8)	250	(34)	218
Comprehensive loss	$ (11,840)	$ (11,019)	$ (22,323)	$ (22,824)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.65)	$ (0.83)	$ (1.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,529,417	17,394,466	26,778,804	17,388,741

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

	June 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 121,164	$ 68,236
Working capital	118,651	65,740
Total assets	135,319	81,033

Debt	2,062	3,032
Accumulated deficit	(112,853)	(90,564)
Total stockholders’ equity	127,739	71,936