Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- STS101 SUMMIT Phase 3 efficacy trial enrollment ongoing, with topline results expected second half of 2022 -

- Appointed Mutya Harsch to the Board of Directors –

- $110 million in cash as of September 30, 2021 provides runway into second half of 2023 –

South San Francisco, CA, November 9, 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 third quarter of 2021 and provided a corporate update.

"We continue to progress development of STS101 in accordance with our overall plan and timeline objectives," stated John Kollins, Satsuma's President and Chief Executive Officer. "We are confident our evidence-based approach to establishing the efficacy of STS101 in the SUMMIT Phase 3 trial, if successful, will underscore the differentiating clinical features of STS101 and enable favorable positioning within the large, dynamic and growing migraine therapeutics market."

Recent Business Highlights

Appointed Mutya Harsch to Board of Directors

- Ms. Harsch is a highly regarded and established pharmaceutical industry professional who brings over 20 years of legal, corporate governance, corporate transaction, and operating experience to the Satsuma Board of Directors. She currently serves as General Counsel, Chief Legal Officer and Secretary of VYNE Therapeutics, a publicly traded biopharmaceutical company.

First subjects randomized and treated in STS101 SUMMIT Phase 3 efficacy trial Commenced randomization and treatment of subjects in the SUMMIT Phase 3 efficacy trial of STS101, a double-blind, randomized, placebo-controlled trial designed to enroll approximately 1,400 subjects.

- The SUMMIT trial, if successful, could provide the basis for STS101 to become the first and only DHE product to have established efficacy in a randomized and controlled trial on co-primary endpoints -- freedom from pain and freedom from most bothersome symptom at two hours post-treatment -- the endpoints currently recommended by the FDA in its guidance document and by the International Headache Society in its current controlled trials guidelines[1],[2].
- Topline results expected in the second half of 2022.

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

In August 2020, Satsuma announced initiation of subject 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 September 30, 2021, more than 300 subjects had enrolled in ASCEND and treated more than 5,000 migraine attacks with STS101 5.2 mg. The Company anticipates the ASCEND trial, if successful, will support an NDA filing projected for the second half of 2022.

- STS101 5.2 mg continues to demonstrate a favorable safety and tolerability profile, with low rates of adverse events.
- Although no differences in the safety or tolerability profiles of the 1st- and 2nd-generation STS101 delivery devices utilized by ASCEND subjects have been observed to date, enrollment of approximately 180 additional subjects has commenced to ensure adequate exposures and safety profile are established with the 2nd-generation nasal delivery device. The addition of these subjects is not expected to affect the overall STS101 development timeline.

Expansion of intellectual property portfolio
Satsuma continues to expand its intellectual property portfolio. Notably, the European Patent Office recently notified the Company that it intends to grant a European patent on the basis of European Patent Application 14830861.2; *Intranasal DHE for the Treatment of Headache*. Satsuma currently owns or has exclusive license rights to more than sixty U.S. and international patents and pending applications. The Company believes that the breadth of its intellectual property portfolio reflects the highly innovative and differentiated nature of the proprietary dry-powder nasal delivery and formulation technologies incorporated in STS101.

Cash runway into second half 2023
As of September 30, 2021, Satsuma had $110.1 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 program and potential filing of a New Drug Application for STS101 by the end of 2022.

Financial results for the third quarter of 2021
Net losses for the third quarter of 2021 were $13.3 million, or $0.42 per common share. This compared to a net loss of $12.0 million, or $0.69 per common share, for the same period in 2020.

Research and development expenses were $10.2 million for the third quarter 2021, compared to $8.8 million for the same period of 2020. Third quarter expenses increased by $1.4 million, due to increases of $1.1 million in clinical trial costs, $0.6 million in payroll and personnel expenses, and $0.1 million in other expenses partly offset by a decrease of a $0.4 million in manufacturing fees.

General and administrative expenses were $3.2 million for the third quarter 2021, compared to $3.4 million for the same period of 2020. Third quarter expenses decreased by $0.3 million, primarily due to a decrease of $0.6 million in expenses related to pre-commercialization activities partially offset by an increase of $0.3 million in 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 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.

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 September 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 10,170	$ 8,750	$ 25,769	$ 27,227
General and administrative	3,160	3,420	9,837	8,614
Total operating expenses	$ 13,330	$ 12,170	$ 35,606	$ 35,841
Loss from operations	(13,330)	(12,170)	(35,606)	(35,841
Interest income	33	209	124	1,036
Interest expense	(35)	(82)	(139)	(280
Net loss	$ (13,332)	$ (12,043)	$ (35,621)	$ (35,085
Unrealized (loss) gain on marketable securities	(7)	(150)	(41)	68
Comprehensive loss	$ (13,339)	$ (12,193)	$ (35,662)	$ (35,017
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (0.69)	$ (1.26)	$ (2.02
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,529,417	17,415,146	28,379,743	17,397,607

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

	September 30, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$ 110,146	$ 68,236
Working capital	103,334	65,740
Total assets	122,295	81,033

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

Debt	1,573	3,032
Accumulated deficit	(126,185)	(90,564)
Total stockholders' equity	115,673	71,936

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[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

https://investors.satsumarx.com/2021-11-9-Satsuma-Pharmaceuticals-Reports-