

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

- STS101 SUMMIT Phase 3 efficacy trial enrollment ongoing and on track to read out topline results in Q4 2022 -
- New Drug Application (NDA) submission anticipated in Q1 2023 -
- \$80.6 million in cash, cash equivalents and marketable securities as of March 31, 2022, provides runway into second half of 2023 -

South San Francisco, CA, May 10, 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 first quarter of 2022 and summarized recent business highlights.

“We are pleased to report continued progress during the first quarter as we advance toward readouts of our STS101 SUMMIT Phase 3 efficacy trial and ASCEND Phase 3 long-term safety trial in the second half of the year, prepare for a potential STS101 NDA submission, and lay the groundwork for a successful STS101 commercial launch,” stated John Kollins, President and Chief Executive Officer of Satsuma. “We look forward to sharing further STS101 and DHE data at the upcoming American Headache Society scientific meeting in June and providing additional updates in the coming months.”

Recent Business Highlights

STS101 SUMMIT Phase 3 Efficacy Trial Update

- Satsuma plans to report topline results in Q4 2022. The Company believes the SUMMIT trial--a double-blind, randomized, placebo-controlled efficacy trial expected to enroll approximately 1,400 subjects--if successful, will support a planned New Drug Application (NDA) submission in Q1 2023.
- The SUMMIT trial is designed to provide the basis for (i) 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) 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}.

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

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

- The ASCEND trial is 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.
- Satsuma completed subject enrollment in the ASCEND trial in early 2022.
- As of April 30, 2022 more than 480 subjects were enrolled in ASCEND, treating more than 7,000 migraine attacks with STS101.
- The company plans to report updated interim results from the ASCEND trial at the American Headache Society's Annual Scientific Meeting (June 9-12) and to report topline results in the second half of 2022.

Upcoming Events and Key Milestones

- Present STS101 and DHE data, including interim results from the ongoing ASCEND trial, at the American Headache Society's Annual Scientific Meeting, June 9-12, 2022
- Host Key Opinion Leader event, June 16, 2022
- Plan to report topline results from ASCEND Phase 3 open-label safety trial in 2H 2022
- Plan to report topline results from SUMMIT Phase 3 efficacy trial in Q4 2022
- Plan to submit STS101 New Drug Application (NDA) in Q1 2023

Financial results for the first quarter of 2022

Net losses for the first quarter of 2022 were \$15.5 million, or \$0.49 per common share. This compared to a net loss of \$10.5 million, or \$0.48 per common share, for the same period in 2021.

Research and development expenses were \$11.6 million for the first quarter 2022, compared to \$7.2 million for the same period of 2021. First quarter expenses increased by \$4.4 million, primarily due to increases in clinical expenses for SUMMIT and ASCEND 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 \$4.0 million for the first quarter 2022, compared to \$3.3 million for the same period of 2021. First quarter expenses increased by \$0.7 million, primarily 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 March 31, 2022, Satsuma had \$80.6 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.

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 March 31, 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
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 March 31,	
	2022	2021
Operating expenses		
Research and development	\$ 11,556	\$ 7,156
General and administrative	3,990	3,294
Total operating expenses	\$ 15,546	\$ 10,450
Loss from operations	(15,546)	(10,450)
Interest income	40	50
Interest expense	(11)	(57)
Net loss	\$ (15,517)	\$ (10,457)
Unrealized loss on marketable securities	(79)	(26)
Comprehensive loss	\$ (15,596)	\$ (10,483)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.49)	\$ (0.48)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>31,545,564</u>	<u>21,975,407</u>

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

	March 31, 2022	December 31, 2021
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 80,597	\$ 95,770
Working capital	77,498	91,356
Total assets	93,672	109,832
Debt	583	1,080
Accumulated deficit	(157,253)	(141,736)
Total stockholders' equity	86,983	101,340

#