

## **Satsuma Pharmaceuticals Reports First Quarter 2021 Financial Results and Recent Business Highlights**

- New STS101 Phase 3 efficacy trial (the SUMMIT trial) expected to begin mid-2021 with topline results expected second half of 2022-*
- Results expected in Q2 from ongoing Phase 1 trial to inform dose selection for Phase 3-*
- \$133 million in cash, cash equivalents and marketable securities as of March 31, 2021 provides runway into second half of 2023-*

**South San Francisco, CA, May 11, 2021** – [Satsuma Pharmaceuticals, Inc.](https://www.satsuma.com) (Nasdaq: STSA), a clinical-stage biopharmaceutical company developing STS101, a novel therapeutic product candidate for the acute treatment of migraine, today reported financial results for the first quarter of 2021 and summarized recent business highlights.

“Our team continues to execute well against our updated STS101 development plan,” stated John Kollins, Satsuma’s President and Chief Executive Officer. “We look forward to completing and sharing results in the near future from our ongoing Phase 1 trial to evaluate the pharmacokinetics, safety and tolerability of STS101 5.2 mg and two higher dose strengths. Results from this Phase 1 trial will inform dose selection for our new pivotal SUMMIT study, a Phase 3 efficacy trial for which we are actively preparing to initiate patient enrollment.”

### **Recent Business Highlights**

#### **\$80 Million Private Placement of Common Stock Financing**

- In March 2021, Satsuma closed an \$80 million private placement of common stock. As of March 31, 2021, the Company had \$133 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.

#### **STS101 development update**

- In March 2021, Satsuma announced an updated STS101 development plan which includes a new double-blind, randomized, placebo-controlled Phase 3 efficacy trial (the SUMMIT trial) designed to enroll approximately 1,400 subjects. The new Phase 3 SUMMIT trial, which the Company anticipates initiating in mid-2021 with topline results expected in the second half of 2022, will take into account findings from analyses of the EMERGE Phase 3 pivotal trial results.
- In addition, the Company is conducting a new Phase 1 trial to evaluate the pharmacokinetics, safety, and tolerability of STS101 5.2 mg (the highest STS101 dose

strength evaluated in the EMERGE trial) and two higher dose strengths. The Company anticipates completing this Phase 1 trial in the second quarter of 2021 and based on trial results, plans to select the STS101 dose strength to evaluate in the new Phase 3 SUMMIT trial.

### **ASCEND Phase 3 open-label, long-term safety trial**

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 as an acute treatment for migraine.

- As of May 6, 2021, the Company has enrolled more than 290 subjects in the ASCEND trial who had treated more than 3,300 migraine attacks with STS101 5.2 mg. To date, STS101 5.2 mg continues to be generally well-tolerated, with low adverse event rates and no treatment-related serious adverse events reported.

### **Upcoming 2021 & 2022 expected milestones**

- Complete ongoing Phase 1 trial with STS101 5.2 mg and two higher dose strengths in the second quarter of 2021
- Initiate new STS101 SUMMIT Phase 3 efficacy trial in mid-2021 with a single STS101 dose selected from the Phase 1 trial
- Report top-line results from SUMMIT Phase 3 efficacy trial in second half of 2022
- Complete ASCEND Phase 3 open-label safety trial in second half of 2022
- File STS101 NDA by the end of 2022

### **Financial results for the first quarter of 2021**

Net losses for the first quarter of 2021 were \$10.5 million, or \$0.48 per common share. This compared to a net loss of \$11.8 million, or \$0.68 per common share, for the same period in 2020. As of March 31, 2021, the Company had \$133.1 million of cash, cash equivalents and marketable securities. The Company believes it has sufficient financial resources to fund operations into the second half of 2023.

Research and development expenses were \$7.2 million for the first quarter 2021, compared to \$9.6 million for the same period of 2020. First quarter expenses decreased by \$2.5 million, primarily due to a decrease in the clinical expenses from EMERGE and partially offset by increases for the ASCEND trial and higher payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses.

General and administrative expenses were \$3.3 million for the first quarter 2021, compared to \$2.5 million for the same period of 2020. First quarter expenses increased by \$0.8 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 candidate for the acute treatment of migraine. Its product candidate, STS101, is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate, or DHE, which is designed to be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine and have significant advantages over other therapeutics for many patients. However, broad use has been limited by invasive and burdensome administration and/or sub-optimal clinical performance of available injectable and liquid nasal spray products. STS101 is specifically designed to deliver the clinical advantages of DHE while overcoming these shortcomings.

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](http://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 trial, 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 March 31, 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 March 31,	
	2021	2020
Operating expenses		
Research and development	\$ 7,156	\$ 9,648
General and administrative	3,294	2,523
Total operating expenses	\$ 10,450	\$ 12,171
Loss from operations	(10,450)	(12,171)
Interest income	50	502
Interest expense	(57)	(104)
Net loss	\$ (10,457)	\$ (11,773)
Unrealized loss on marketable securities	(26)	(32)
Comprehensive loss	\$ (10,483)	\$ (11,805)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.48)	\$ (0.68)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	21,975,407	17,383,016

**SATSUMA PHARMACEUTICALS, INC.**  
**BALANCE SHEET DATA**

(in thousands)  
(unaudited)

	March 31, 2021	December 31, 2020
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ 133,120	\$ 68,236
Working capital	131,065	65,740
Total assets	144,057	81,033
Debt	2,549	3,032
Accumulated deficit	(101,021)	(90,564)
Total stockholders' equity	138,145	71,936

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