

Satsuma Pharmaceuticals Reports First Quarter 2020 Financial and Business Results

STS101 EMERGE™ Phase 3 efficacy trial remains on track with announcement of topline data expected in second half of 2020

Company well-capitalized with cash, cash equivalents, and marketable securities of \$104.1 million at the end of Q1 2020, providing runway through planned STS101 NDA filing by year-end 2021

South San Francisco, CA, May 12, 2020 – Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter 2020 and summarized recent business results.

“Despite challenges posed by the COVID-19 pandemic, the Satsuma team has continued to advance the development of STS101 with no significant changes to program timelines,” commented John Kollins, Satsuma’s President and Chief Executive Officer. “We very much appreciate the significant and ongoing commitment and contributions of our team, vendors, investigators and trial sites, and above all the people with migraines participating in our STS101 EMERGE Phase 3 efficacy trial. We look forward to providing further updates on the EMERGE trial in the near future.”

Recent Highlights:

STS101 EMERGE Phase 3 efficacy trial

Satsuma continues to randomize and treat patients in the ongoing EMERGE trial and does not currently anticipate delays in study execution due to the COVID-19 pandemic. Consistent with prior guidance, Satsuma expects to report topline data for the EMERGE trial in the second half of 2020.

Key Opinion Leader Webinar

STS101 and Acute Treatment of Migraine, Tuesday, May 5, 2020, with featured presentations by Jessica Ailani, MD (Medstar Georgetown Headache Center) and Alan Rapaport, MD (The David Geffen School of Medicine at UCLA).

- The acute treatment of migraine continues to represent an area of high unmet need. The majority of patients do not adequately achieve established treatment goals with current therapies, and nearly all have at least one unmet acute treatment need.
- STS101 has a differentiated profile and could potentially address many unmet needs and play a broad role in the acute treatment of migraine.

Link to Webinar Replay: <https://bit.ly/35Sbr4z>

Financial results for first quarter 2020

Net loss for the first quarter 2020 was \$11.8 million, or \$0.68 per common share, compared to a net loss of \$2.8 million, or \$2.51 per common share, for the same period in 2019. As of March 31, 2020, the Company had \$104.1 million of cash, cash equivalents and marketable securities. The Company believes it has sufficient financial resources to fund operations through the end of 2021.

Research and development expenses were \$9.7 million for the first quarter 2020, compared to \$2.2 million for the same period of 2019. First quarter expenses increased by \$7.5 million, primarily due to additional expenses for the EMERGE clinical trial and drug supply manufacturing activities, as well as increases in salaries and employee-related expenses as a public company.

General and administrative expenses were \$2.5 million for the first quarter 2020, compared to \$0.5 million for the same period of 2019. First quarter expenses increased by \$2.0 million, primarily due to an increase of \$1.5 million of professional fees for legal, consulting, accounting, tax and other services and an increase of \$0.5 million of payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increase in headcount.

About the EMERGE trial and STS101 Clinical Program

The EMERGE trial, which Satsuma believes is the largest-ever clinical trial undertaken with any dihydroergotamine (DHE) product, is a double-blind, parallel-group, placebo-controlled, multicenter trial that is expected to enroll approximately 1,140 patients. EMERGE is designed to evaluate the efficacy, safety, and tolerability of STS101 (DHE nasal powder) in treating a single migraine attack and is highly powered on its two co-primary endpoints, both assessed two hours following administration of study medication:

- freedom from pain (>99% power); and
- freedom from most-bothersome-symptom (from among photophobia, phonophobia, or nausea) (>95% power)

In addition, EMERGE is designed to prospectively evaluate a number of secondary endpoints and the performance of STS101 in patient subgroups that could significantly enhance its differentiated clinical profile.

The EMERGE trial is the first of two pivotal Phase 3 trials Satsuma plans to complete in support of the STS101 registration. In Q3 2020, Satsuma plans to initiate an open-label, Phase 3 safety trial of STS101 in which up to approximately 300 patients with migraine will treat their migraine attacks with STS101 on an as-needed basis for up to 12 months with at least 150 patients completing 6 months of treatment.

About Satsuma Pharmaceuticals and STS101

Satsuma Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic product for the acute treatment of migraine, STS101. STS101 is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate (DHE), which can be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. In developing STS101, Satsuma has applied proprietary nasal drug delivery, dry-powder formulation, and engineered drug particle technologies to create a compact, simple-to-use, non-injectable DHE product that can be rapidly self-administered in a matter of seconds. The Company believes STS101 would, if approved, be an attractive migraine treatment option for many patients and may enable a larger number of people with migraine to realize the long-recognized therapeutic benefits of DHE therapy. STS101 has undergone extensive pre-clinical development, completed a Phase 1 clinical trial, and is currently in Phase 3 development.

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 Company’s clinical and regulatory development plans; the Company’s expectations with regard to the initiation and availability of data to be derived from its ongoing and planned Phase 3 clinical trials; the timing and likelihood of regulatory filings and approvals for STS101; the impact of COVID-19 on the Company’s operations, clinical trials and expected cash needs and sufficiency of cash on hand. 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, 2020, 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; the risk that the COVID-19 worldwide pandemic may

negatively impact the Company's business, operations, clinical trials or ability to raise capital; the unpredictability of the regulatory process; regulatory developments in the United States and foreign countries; the costs of clinical trials may exceed expectations; and the Company's ability to raise additional 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.

This press release discusses STS101, a product candidate that is in clinical development, and which has not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of STS101 for the therapeutic use for which STS101 is being studied.

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,	
	2020	2019
Operating expenses		
Research and development	\$ 9,648	\$ 2,150
General and administrative	2,523	564
Total operating expenses	\$ 12,171	\$ 2,714
Loss from operations	(12,171)	(2,714)
Interest income	502	21
Interest expense	(104)	(122)
Net loss	\$ (11,773)	\$ (2,815)
Unrealized gains on marketable securities	(32)	—
Comprehensive loss	\$ (11,805)	\$ (2,815)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.68)	\$ (2.51)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	17,383,016	1,123,219

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

	March 31, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 104,119	\$ 117,900
Working capital	101,646	106,773
Total assets	113,716	126,276
Debt	4,460	4,930
Accumulated deficit	(54,774)	(43,001)
Total stockholders' equity	103,990	115,335

#