Satsuma Pharmaceuticals, Inc.

Satsuma Pharmaceuticals Reports Third Quarter 2019 Financial and Business Results

Completed upsized initial public offering of $90.8 million in gross proceeds

Dosed first patient in Phase 3 EMERGE™ efficacy trial of STS101 for the acute treatment of migraine

Presented STS101 Phase 1 trial results and other STS101 data at medical meetings

SOUTH SAN FRANCISCO, Calif., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Satsuma Pharmaceuticals, Inc. (Nasdaq: STSA) a clinical-stage biopharmaceutical company, today reported financial results for the quarter ended September 30, 2019 and provided a business update on recent achievements.

“With the successful completion in September of our initial public offering, gross proceeds to Satsuma from private and public equity financings completed in the past two quarters exceed $150 million,” commented John Kollins, Satsuma President and Chief Executive Officer. “These financial resources position Satsuma to continue aggressively executing on the STS101 development plan. Our goal is to make STS101, a compact, simple-to-use, self-administered, and non-injectable DHE (or dihydroergotamine) product which incorporates proprietary nasal powder formulation and delivery technologies, available as a differentiated treatment option for people with migraine."

Third Quarter 2019 Business Highlights:

Completed IPO of approximately $90 million and Nasdaq listing (STSA)

- In September, Satsuma announced that it had closed its initial public offering (IPO) of 5,500,000 common shares at a price to the public of $15.00 per share. On October 1, 2019, the underwriters for the offering exercised their option to purchase an additional 552,000 common shares. Aggregate gross proceeds from the offering were $90.8 million, before deducting underwriting discounts and commissions and offering expenses payable by the Company. With completion of the IPO, the Company believes it has sufficient financial resources to fund operations through the end of 2021, by which time it anticipates filing a new drug application for STS101 with the U.S. Food and Drug Administration.

Dosed first patient in EMERGE™ Phase 3 efficacy trial of STS101

- In August, Satsuma announced it had dosed the first patient in its EMERGE™ Phase 3 efficacy trial of STS101 for the acute treatment of migraine. EMERGE is a multi-center, double-blind, placebo-controlled parallel group study in approximately 1,140 migraine patients that is being conducted in the United States. Satsuma believes that EMERGE is the largest-ever clinical trial undertaken with any DHE product. The trial is statistically designed with greater than 99% and 95% power, respectively, on the trial’s two co-primary endpoints: freedom from pain and freedom from most bothersome symptom, both assessed at two hours after administration of study medication. In addition, the EMERGE trial design incorporates a number of secondary endpoints and prospective evaluations of the clinical performance of STS101 in a number of patient subgroups that could differentiate the clinical profile of STS101. Satsuma expects to report top-line data from the EMERGE trial in the second half of 2020.

Presented STS101 Phase 1 trial results & STS101 data at key migraine-focused medical conferences:

- In July at the American Headache Society’s Annual Scientific meeting, Satsuma presented STS101 Phase 1 trial results demonstrating:
  -- rapid drug absorption, achieving within ten minutes the minimum threshold concentration it estimates is necessary for efficacy,
  -- sustained drug plasma levels,
  -- low pharmacokinetic variability, and
  -- favorable safety and tolerability.

These Phase 1 results support the Company’s belief that STS101 should demonstrate a favorable and differentiated clinical profile in the ongoing EMERGE Phase 3 clinical trial.

- In September at the 19th Congress of the International Headache Society, Satsuma presented two posters on STS101 results
  -- comparing the pharmacokinetics of STS101 with other intranasal, injectable and oral inhaled DHE dosage forms; and
  -- demonstrating that STS101 achieves consistent and robust delivery performance.

These posters are available for download on the Publications section of the Satsuma Pharmaceuticals website

(www.satsumarx.com/publications/).

Financial Results for Third Quarter 2019

Research and development expenses were $7.4 million for the third quarter of 2019, compared to approximately $1.4 million for the same period of 2018, an increase of $6.0 million. The increase was 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.

General and administrative expenses were $1.0 million for the third quarter of 2019 compared to $0.2 million for the same period in 2018, an increase of $0.8 million. The increase was primarily due to general administrative expenses, as well as increases in salaries and employee-related expenses.

Net loss for the quarter ended September 30, 2019 was $8.3 million or $2.26 per common share, compared to a net loss of $1.6 million or $1.48 per common share for the same period in 2018. As of September 30, 2019, the Company had approximately $118.9 million of cash and cash equivalents, and short-term investments.

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, recently 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 data to be derived from its planned Phase 3 clinical trials; the likelihood of regulatory filings and approvals for STS101; and the Company’s commercialization plans and expectations. 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, 2019, 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 Company’s ability to select suitable dosing regimens; the results of preclinical and clinical studies may not be predictive of future results; 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.

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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,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 7,441	$1,380	$ 15,046	$ 4,479
General and administrative	1,029	220	2,560	752
Total operating expenses	$ 8,470	$ 1,600	$ 17,606	$ 5,231
Loss from operations	(8,470)	(1,600)	(17,606)	(5,231)
Interest income	331	13	602	46
Interest expense	(121)	—	(365)	(2)
Other income, net	—	—	3	185
Net loss	$(8,260)	$(1,587)	$(17,366)	$(5,002)
Change in unrealized gains on marketable securities	12	—	—	—
Comprehensive loss	$ (8,248)	$ (1,587)	$ (17,366)	$ (5,002)
Net loss per share attributable to common stockholders, basic and diluted	$(2.26)	$(1.48)	$(8.74)	$(4.96)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	3,658,504	1,071,313	1,986,190	1,009,242

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

	September 30, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$118,948	$5,205
Working capital	120,645	3,439
Total assets	127,544	6,381
Long-term debt	5,062	4,965
Convertible preferred stock	—	11,648
Accumulated deficit	(32,192)	(14,826)
Total stockholders' equity (deficit)	118,121	(12,132)

https://investors.satsumarx.com/2019-11-12-Satsuma-Pharmaceuticals-Reports-Third-Quarter-2019-Financial-and-Business-Results