Supernus Announces Third Quarter 2019 Financial Results and Topline Data from Phase III Study of SPN-810 for Treatment of Impulsive Aggression (IA) in ADHD Patients

November 5, 2019

- Total revenue of $102.1 million, compared to $103.0 million in third quarter 2018
- Net product sales of $100.0 million, compared to $100.2 million in third quarter 2018
- Operating earnings of $39.7 million, compared to $37.5 million in third quarter 2018
- NDA submission for SPN-812 expected in November 2019
- Phase III P301 trial of SPN-810 for the treatment of IA in ADHD patients 6 to 11 years old did not meet its primary endpoint

ROCKVILLE, Md., Nov. 05, 2019 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (NASDAQ: SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today reported financial results for the third quarter of 2019, results from the Phase III P301 trial for SPN-810 and associated Company developments.

Commercial Update

Third quarter 2019 product prescriptions for Trokendi XR® and Oxtellar XR®, as reported by IQVIA, totaled 215,033, a 6.4% increase over the third quarter of 2018.

	Prescriptions		
	Q3 2019	**Q3 2018**	**Change %**
Trokendi XR	172,981	164,689	5.0%
Oxtellar XR	42,052	37,476	12.2%
Total	215,033	202,165	6.4%

Source: IQVIA

Net product sales for the third quarter of 2019 were $100.0 million, compared to $100.2 million in the third quarter of 2018. Net product sales by product are as follows:

Net Product Sales ($ in thousands)			
	Q3 2019	**Q3 2018**	**Change %**
Trokendi XR	$ 77,332	$ 79,834	(3.1)%
Oxtellar XR	22,702	20,393	11.3%
Total	$ 100,034	$ 100,227	(0.2)%

“For the quarter and year to date periods, the beneficial impact of volume growth and price increases has been offset by continued pressure on gross-to-net sales deductions,” said Jack Khattar, President and CEO of Supernus. “Going forward, we believe that competitive dynamics and pressure on gross-to-net deductions are not likely to abate; consequently, we believe that net product sales growth will essentially be flat, even with moderate growth in prescriptions.”

Progress of Product Pipeline

SPN-812 - Novel non-stimulant for the treatment of ADHD

- The Company expects to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for SPN-812 for the treatment of ADHD in November 2019.
- A Phase III program in adult patients was initiated during the third quarter of 2019.

SPN-810 - Novel treatment of Impulsive Aggression (IA) in patients with ADHD

- Phase III P301 trial in patients 6 to 11 years old did not meet its primary endpoint. The study was a randomized, double-blind, placebo controlled, multicenter, parallel group clinical trial in patients diagnosed with ADHD. Patients receiving SPN-810 36mg showed a median percent reduction of 58.6% in the average weekly frequency of impulsive aggression episodes from baseline that was not statistically significant (p= 0.092) compared to placebo. These results are based on the combined analysis of data from stages 1 and 2 in the study. In stage 1 (interim analysis stage), the median percent reduction was 60%, which was statistically significant (p= 0.029) compared to placebo. However, in stage 2 of the study, post the interim analysis, the increase in variability in the 36mg treatment arm seems to have adversely impacted the

results in the combined analysis.

Percent Change from Baseline (CFB) in the Frequency of IA Behaviors
Treatment Period - Primary Analysis (ITT Population)

Stage 1 - % CFB	**Placebo**	**SPN-810 18mg**	**SPN-810 36mg**
N	52	49	45
Mean (SD)	-42.9 (35.9)	-45.8 (33.5)	-56.6 (34.1)
Median	-48.6	-47.8	-60.0
P-value		0.651	0.029
Stage 2 - % CFB			
N	73	16	90
Mean (SD)	-43.8 (36.3)	-44.5 (34.6)	-44.0 (43.5)
Median	-47.2	-45.6	-58.5
P-value			0.102
Stages 1 & 2 Combined - % CFB			
N	125	65	135
Mean (SD)	-43.4 (36.0)	-45.5 (33.5)	-48.2 (40.9)
Median	-48.2	-47.9	-58.6
P-value		0.714	0.092

- The median percent reduction in frequency of IA behavior in this Phase III study is consistent with the range of percent improvement in the retrospective modified aggression scale (58% - 62%) we saw in the two positive treatment arms in the Phase IIb study. The Company will continue its analysis of the results to better understand the reasons behind the increased variability in the 36mg treatment arm in the P301 study.

- Overall, the trial exhibited favorable tolerability and safety profiles with low incidence of adverse events (AEs) across all doses. AEs were mild leading to low discontinuation rates of 0%, 7% and 5% for the 18mg, 36mg and combined treatment arms, respectively.

Adverse Event (AE) N (%)	**Placebo (N=126)**	**SPN-810 18mg (N=65)**	**SPN-810 36mg (N=137)**	**SPN-810 Combined (N=202)**
Fatigue	1 (0.8)	2 (3.1)	10 (7.3)	12 (5.9)
Headache	2 (1.6)	2 (3.1)	7 (5.1)	9 (4.5)
Increased Appetite	6 (4.8)	0	9 (6.6)	9 (4.5)
Blood Prolactin Increased	1 (0.8)	4 (6.2)	2 (1.5)	6 (3.0)
Upper Respiratory Tract Infection	8 (6.3)	2 (3.1)	2 (1.5)	4 (2.0)
Discontinuation Rate due to AE's	4 (3.1)	0 (0)	10 (7.2)	10 (4.9)

- Enrollment in the Phase III P302 trial in patients 6 to 11 years old is at 98% of the target. The Company will cease enrollment in the P302 trial and analyze the data, which are expected to be available by the end of 2019. In the meantime, enrollment in the P503 Phase III trial (adolescents) is on hold until data from the P302 study are available and a final decision is reached regarding the SPN-810 program in IA. Mr. Khattar added, “We are obviously disappointed with the efficacy results from our Phase III P301 trial with SPN-810. I thank all our employees for working diligently to complete the studies and believing in what we do for our patients. I also thank all our patients, their families, and our investigators for participating in our studies.”

SPN-604 - Novel treatment of bipolar disorder

- The Company initiated a pivotal Phase III monotherapy trial for the treatment of bipolar disorder in the fourth quarter of 2019.

Operating Expenses

Research and development (R&D) expenses in the third quarter of 2019 were $16.9 million, lower than the $20.4 million in the same quarter last year. This decrease is due to the completion of the four Phase III clinical trials for SPN-812, three of which were completed in December 2018 and one of which was completed in March 2019. These reductions were partially offset by SPN-812 manufacturing costs in support of the Company’s NDA submission.

Selling, general and administrative (SG&A) expenses in the third quarter of 2019 were $40.6 million, essentially unchanged from $40.9 million in the same quarter last year.

Operating Earnings and Earnings Per Share

Operating earnings in the third quarter of 2019 were $39.7 million, a 5.9% increase from $37.5 million in the same quarter last year. The increase in operating earnings was primarily due to lower R&D expenses in the third quarter of 2019.

Net earnings (GAAP) in the third quarter of 2019 were $28.9 million, or $0.54 per diluted share, compared to $28.0 million, or $0.52 per diluted share, in the same period last year. Growth in operating earnings was offset by a modestly higher effective tax rate in the third quarter of 2019 compared to the year earlier period (27.1% compared to 23.0%), resulting in net earnings in the third quarter of 2019 that were comparable to net earnings in third quarter 2018.

Weighted-average diluted common shares outstanding were approximately 53.8 million in the third quarter of 2019, as compared to approximately 54.2 million in the prior year period.

Balance Sheet Highlights

As of September 30, 2019, the Company had $893.1 million in cash, cash equivalents, marketable securities and long term marketable securities, compared to $774.8 million at December 31, 2018. This increase primarily reflects cash generated from operations in the first nine months of 2019.

Financial Guidance

The Company is revising its full year 2019 guidance for net product sales, R&D expenses and operating earnings, and reaffirming expectations for the effective tax rate as set forth below:

- Net product sales in the range of $390 million to $395 million, compared to the previously expected range of $400 million to $410 million.
- R&D expenses of approximately $70 million, compared to the previously expected range of $70 million to $80 million.
- Operating earnings in the range of $150 million to $155 million, compared to the previously expected range of $150 million to $160 million.
- Effective tax rate of approximately 23% to 25%.

Looking forward to 2020, the Company expects that the combined impact of product unit volume growth and price increases will be offset by continued pressure on gross-to-net sales deductions. In addition, the Company expects to launch SPN-812 in the second half of 2020. As such, the Company expects SG&A expenses to exceed $200 million for 2020, driven by pre-launch and launch marketing expenses, as well as the impact of fielding the psychiatry sales force in the second half of the year. Finally, R&D expenses are expected to be comparable to 2019.

Conference Call Details

The Company will hold a conference call hosted by Jack Khattar, President and Chief Executive Officer, and Greg Patrick, Senior Vice President and Chief Financial Officer, to discuss these results at 9:00 a.m. Eastern Time, on Wednesday, November 6, 2019.

Please refer to the information below for conference call dial-in information and webcast registration. Callers should dial in approximately 10 minutes prior to the start of the call.

Conference dial-in:	(877) 288-1043
International dial-in:	(970) 315-0267
Conference ID:	8278897
Conference Call Name:	Supernus Pharmaceuticals Third Quarter 2019 Earnings Conference Call

Following the live call, a replay will be available on the Company's website, www.supernus.com, under “Investor Relations”.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company currently markets Trokendi XR® (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR® (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-812 for the treatment of ADHD and SPN-604 for the treatment of bipolar disorder.

Forward-Looking Statements:

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company’s ability to sustain and increase its profitability; the Company’s ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company’s corporate strategy; the Company’s future financial performance and projected expenditures; the Company’s ability to increase the number of prescriptions written for each of its products; the Company’s ability to increase its net revenue; the Company’s ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; the Company’s product research and development activities, including the timing and progress of the Company’s clinical trials, and projected expenditures; the Company’s

ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs and potential funding sources; the Company's staffing needs; and other risk factors set forth from time to time in the Company's filings with the Securities and Exchange Commission made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

Supernus Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 116,889	$ 192,248
Marketable securities	179,808	163,770
Accounts receivable, net	86,699	102,922
Inventories, net	25,504	25,659
Prepaid expenses and other current assets	18,182	8,888
Total current assets	427,082	493,487
Long term marketable securities	596,442	418,798
Property and equipment, net	9,977	4,095
Intangible assets, net	26,101	31,368
Lease assets	18,780	—
Deferred income taxes	27,953	29,683
Other assets	574	380
Total assets	$ 1,106,909	$ 977,811
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,090	$ 3,195
Accrued product returns and rebates	98,050	107,063
Accrued expenses and other current liabilities	40,800	36,535
Income taxes payable	4,818	12,377
Nonrecourse liability related to sale of future royalties, current portion	2,959	2,183
Total current liabilities	149,717	161,353
Convertible notes, net	341,163	329,462
Nonrecourse liability related to sale of future royalties, long term	20,305	22,575
Lease liabilities, long term	27,256	—
Other liabilities	11,211	11,398
Total liabilities	549,652	524,788
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 52,462,936 and 52,316,583 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	52	52
Additional paid-in capital	383,525	369,637
Accumulated other comprehensive earnings (loss), net of tax	7,261	(3,158)
Retained earnings	166,419	86,492
Total stockholders' equity	557,257	453,023
Total liabilities and stockholders' equity	$ 1,106,909	$ 977,811

Supernus Pharmaceuticals, Inc.
Condensed Consolidated Statements of Earnings
(in thousands, except share and per share data)

	Three Months ended	Nine Months ended

	September 30, 2019 (unaudited)	2018	September 30, 2019 (unaudited)	2018
Revenues				
Net product sales	$ 100,034	$ 100,227	$ 285,491	$ 286,377
Royalty revenues	2,106	2,769	6,818	5,836
Licensing revenues	—	—	—	750
Total revenues	102,140	102,996	292,309	292,963
Costs and expenses				
Cost of goods sold	4,819	4,207	12,547	11,168
Research and development	16,943	20,422	49,307	59,368
Selling, general and administrative	40,649	40,892	122,700	117,838
Total costs and expenses	62,411	65,521	184,554	188,374
Operating earnings	39,729	37,475	107,755	104,589
Other income (expenses), net	(139)	(1,104)	(1,180)	(3,180)
Earnings before income taxes	39,590	36,371	106,575	101,409
Income tax expense	10,730	8,360	26,648	16,309
Net earnings	$ 28,860	$ 28,011	$ 79,927	$ 85,100
Earnings per share				
Basic	$ 0.55	$ 0.54	$ 1.53	$ 1.64
Diluted	$ 0.54	$ 0.52	$ 1.48	$ 1.57
Weighted-average shares outstanding				
Basic	52,453,384	52,227,630	52,392,232	51,897,240
Diluted	53,805,838	54,239,847	53,898,486	54,098,330

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