Supernus Announces Fourth Quarter and Full Year 2019 Financial Results

February 25, 2020

- Fourth quarter and full year 2019 total revenue of $100.4 million and $392.8 million, respectively.
- Fourth quarter and full year 2019 net product sales of $97.9 million and $383.4 million, respectively.
- Fourth quarter and full year 2019 operating earnings of $40.8 million and $148.6 million, respectively.
- FDA assigned PDUFA target action date of November 8, 2020 for review of SPN-812 New Drug Application.
- Phase III P302 trial of SPN-810 for the treatment of IA in ADHD patients 6 to 11 years old did not meet primary endpoint.

ROCKVILLE, Md., Feb. 25, 2020 (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 fourth quarter and full year of 2019, and associated Company developments.

Commercial Update

Full year 2019 product prescriptions for Trokendi XR® and Oxtellar XR®, as reported by IQVIA, totaled 836,399, a 6.4% increase over full year 2018. Fourth quarter 2019 product prescriptions for Trokendi XR and Oxtellar XR totaled 212,780, a 1.4% increase over the fourth quarter of 2018.

	Prescriptions		
	FY 2019	**FY 2018**	**Change %**
Trokendi XR	672,485	638,923	5.3%
Oxtellar XR	163,914	147,488	11.1%
Total	836,399	786,411	6.4%

Source: IQVIA

As previously disclosed, wholesalers, distributors and pharmacies increased their inventory levels of the Company's products in the fourth quarter of 2018. The Company estimates that this caused net product sales in both the fourth quarter and full year 2018 to be approximately $10 million higher than would have been otherwise; i.e., had inventory levels remained consistent quarter to quarter. The inventory build in the fourth quarter of 2018 was then effectively reversed in the first quarter of 2019, causing net product sales to be $10 million lower in both the first quarter and full year 2019 than would have been otherwise.

Net product sales for full year 2019 were $383.4 million, compared to $399.9 million for full year 2018. Net product sales for the fourth quarter of 2019 were $97.9 million, compared to $113.5 million in the fourth quarter of 2018. The decrease in both quarter over quarter and year over year comparisons is due to the aforementioned increase in inventory holdings in the fourth quarter of 2018.

In addition, net product sales in both the fourth quarter and full year 2019 were adversely impacted by continued pressure on gross-to-net deductions, as compared to 2018.

Net Product Sales
($ in millions)

	FY 2019	**FY 2018**	**Change %**
Trokendi XR	$ 295.2	$ 315.3	(6.4)%
Oxtellar XR	88.2	84.6	4.3%
Total	$ 383.4	$ 399.9	(4.1)%

Progress of Product Pipeline

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

- The U.S. Food and Drug Administration (FDA) accepted for review a New Drug Application (NDA) for SPN-812 for the treatment of ADHD, with a Prescription Drug User Fee Act (PDUFA) target action date of November 8, 2020.
- The Company plans to launch SPN-812 at the end of 2020, if approved by the FDA.
- The Company expects to complete enrollment in the ongoing Phase III program in adult patients by the end of 2020.

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

- Phase III P302 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 36 mg showed a median percent reduction of 51.3% in the average weekly frequency of impulsive aggression episodes from baseline that was not statistically significant (p=0.961) compared to placebo. Consistent with the P301 trial,

the drug was safe and well tolerated.
- The Company will halt all development activities on SPN-810 in IA.

SPN-604 - Novel treatment of bipolar disorder

- The Company expects enrollment in the ongoing pivotal Phase III monotherapy trial for the treatment of bipolar disorder to continue through 2021.

“With our NDA for SPN-812 in ADHD accepted for review by the FDA, we continue to prepare the Company for the commercial launch of SPN-812 and look forward to bringing this important new treatment option to patients and physicians. If approved by the FDA, SPN-812 has the potential of becoming the first novel treatment to be introduced in the ADHD market in more than a decade” said Jack Khattar, President and CEO of Supernus.

“While we are certainly disappointed with the results from the second trial on SPN-810, Supernus continues to invest in R&D programs and is planning to provide an R&D update later in the year.” Mr. Khattar added, “We extend our sincere thanks to all our employees for working diligently to complete the SPN-810 studies, and to all our patients, their families, and our investigators for participating in our studies."

Operating Expenses

Full Year

Research and development (R&D) expenses for full year 2019 were $69.1 million, lower than the $89.2 million in 2018. This decrease is primarily due to the one-time upfront expense of approximately $14 million incurred in the fourth quarter of 2018 for the acquisition of Biscayne Neurotherapeutics, Inc. (Biscayne). To a lesser extent, the completion of four Phase III clinical trials for SPN-812 contributed to the year-over-year decline. These reductions were partially offset by SPN-812 manufacturing costs in 2019 to support the Company’s NDA submission.

Selling, general and administrative (SG&A) expenses for full year 2019 were $158.4 million, essentially unchanged from $159.9 million in 2018.

Fourth Quarter

R&D expenses in the fourth quarter of 2019 were $19.8 million, lower than the $29.8 million in the same quarter last year. This decrease was primarily due to the one-time upfront expense of approximately $14 million incurred in the fourth quarter of 2018 for the acquisition of Biscayne.

SG&A expenses in the fourth quarter of 2019 were $35.7 million, lower than the $42.1 million in the same quarter last year. This decrease is primarily due to expenses incurred in the fourth quarter of 2018 for the development and production of promotional materials and marketing programs associated with the launch of the monotherapy indication for Oxtellar XR. In addition, employee-related costs were lower.

Operating Earnings and Earnings Per Share

Operating earnings for full year 2019 were $148.6 million, compared to $144.4 million in 2018. The increase in operating earnings is primarily due to lower R&D and SG&A expenses in 2019. Operating earnings for the full year 2019 were negatively impacted by the aforementioned inventory drawdown in the first quarter of 2019. This resulted in full year 2018 operating earnings being $10 million higher, and the full year 2019 operating earnings being $10 million lower than would have been otherwise.

Operating earnings in the fourth quarter of 2019 were $40.8 million, compared to $39.9 million in the fourth quarter of 2018. The quarterly comparison was negatively impacted by the aforementioned increase in channel inventory holdings in the fourth quarter of 2018. The increase in channel inventory holdings in 2018 caused the fourth quarter 2018 operating earnings to be higher by approximately $10 million than would have been otherwise.

Net earnings (GAAP) were $113.1 million for full year 2019, or $2.10 per diluted share, compared to $111.0 million, or $2.05 per diluted share, for full year 2018.

Net earnings (GAAP) in the fourth quarter of 2019 were $33.1 million, or $0.62 per diluted share, an increase of 29% on a diluted share basis, as compared to $25.9 million, or $0.48 per diluted share, in the same period last year.

Weighted-average diluted common shares outstanding were approximately 53.8 million for the full year 2019 and 53.6 million for the fourth quarter of 2019, as compared to approximately 54.1 million for each of the respective prior year periods.

Balance Sheet Highlights

As of December 31, 2019, the Company had $938.8 million in cash, cash equivalents, marketable securities and long term marketable securities, as compared to $774.8 million at December 31, 2018. This increase primarily reflects cash generated from operations in 2019.

Financial Guidance

For full year 2020, the Company estimates net product sales and operating earnings as set forth below:

- Net product sales to range from $360 million to $390 million.
- Operating earnings to range from $70 million to $100 million.

Other than the impact from the addition of salesforce personnel at the end of 2020 in anticipation of the launch of SPN-812, SG&A expenses are expected to be consistent quarter to quarter in 2020.

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, February 26, 2020.

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:	7796907
Conference Call Name:	Supernus Pharmaceuticals Fourth Quarter and Full Year 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.
Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2019 (unaudited)	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 181,381	$ 192,248
Marketable securities	165,692	163,770
Accounts receivable, net	87,332	102,922
Inventories, net	26,628	25,659
Prepaid expenses and other current assets	11,611	8,888
Total current assets	472,644	493,487
Long term marketable securities	591,773	418,798
Property and equipment, net	17,068	4,095
Intangible assets, net	24,840	31,368
Lease assets	21,279	—
Deferred income taxes	32,063	29,683
Other assets	615	380
Total assets	$ 1,160,282	$ 977,811
Liabilities and stockholders’ equity		
Current liabilities		
Accounts payable	$ 10,141	$ 3,195
Accrued product returns and rebates	107,629	107,063
Accrued expenses and other current liabilities	37,130	36,535

Income taxes payable	2,443	12,377
Nonrecourse liability related to sale of future royalties; current portion	3,244	2,183
Total current liabilities	160,587	161,353
Convertible notes, net	345,170	329,462
Nonrecourse liability related to sale of future royalties; long term	19,248	22,575
Lease liabilities, long term	30,440	—
Other liabilities	9,409	11,398
Total liabilities	564,854	524,788
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 52,533,348 and 52,316,583 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	53	52
Additional paid-in capital	388,410	369,637
Accumulated other comprehensive earnings (loss), net of tax	7,417	(3,158)
Retained earnings	199,548	86,492
Total stockholders' equity	595,428	453,023
Total liabilities and stockholders' equity	$ 1,160,282	$ 977,811

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

	Three Months ended December 31,		Years ended December 31,	
	2019	**2018**	**2019**	**2018**
	(unaudited)		**(unaudited)**	
Revenues				
Net product sales	$ 97,909	$ 113,494	$ 383,400	$ 399,871
Royalty revenue	2,537	2,440	9,355	8,276
Licensing revenue	—	—	—	750
Total revenues	100,446	115,934	392,755	408,897
Costs and expenses				
Cost of goods sold	4,113	4,188	16,660	15,356
Research and development	19,792	29,841	69,099	89,209
Selling, general and administrative	35,725	42,050	158,425	159,888
Total costs and expenses	59,630	76,079	244,184	264,453
Operating earnings	40,816	39,855	148,571	144,444
Other (expense) income				
Interest expense	(5,870)	(5,600)	(22,707)	(18,111)
Interest income, net	5,966	4,512	21,623	13,843
Total other (expense) income	96	(1,088)	(1,084)	(4,268)
Earnings before income taxes	40,912	38,767	147,487	140,176
Income tax expense	7,783	12,874	34,431	29,183
Net earnings	$ 33,129	$ 25,893	$ 113,056	$ 110,993
Earnings per share				
Basic	$ 0.63	$ 0.50	$ 2.16	$ 2.13
Diluted	$ 0.62	$ 0.48	$ 2.10	$ 2.05
Weighted-average shares outstanding				
Basic	52,471,389	52,264,504	52,412,181	51,989,824
Diluted	53,649,083	54,104,036	53,816,754	54,098,872

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