Supernus Announces Record Full Year 2018 Financial Results

February 26, 2019

- Fourth quarter 2018 total revenue of $115.9 million, a 31% increase over 2017, and fourth quarter 2018 net product sales of $113.5 million, a 32% increase over 2017.
- Fourth quarter 2018 operating earnings of $39.9 million, a 16% increase over 2017.
- Full year 2018 total revenue of $408.9 million, a 35% increase over 2017. Full year 2018 net product sales of $399.9 million, a 36% increase over 2017.
- Full year 2018 operating earnings of $144.4 million, a 45% increase over 2017.
- Positive results from three Phase III studies for SPN-812 in ADHD announced in December 2018.
- Oxtellar XR® launched in January 2019 with expanded indication to include monotherapy for partial seizures.

ROCKVILLE, Md., Feb. 26, 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 record financial results for the fourth quarter and full year 2018 and associated Company developments.

Commercial Update

Fourth quarter 2018 product prescriptions for Trokendi XR® and Oxtellar XR®, as reported by IQVIA, totaled 209,901, a 16.7% increase over the fourth quarter of 2017. Full year 2018 product prescriptions for Trokendi XR® and Oxtellar XR®, as reported by IQVIA, totaled 786,411, a 29.1% increase over full year 2017.

Prescriptions

	Q4 2018	Q4 2017	Change %	FY 2018	FY 2017	Change %
Trokendi XR	170,671	145,152	17.6%	638,923	477,113	33.9%
Oxtellar XR	39,230	34,782	12.8%	147,488	132,071	11.7%
Total	209,901	179,934	16.7%	786,411	609,184	29.1%

Source: IQVIA, data restatement 2/13/19.

Net product sales for the fourth quarter of 2018 were $113.5 million, a 31.5% increase over $86.3 million in the same period in the prior year. Net product sales for full year 2018 were $399.9 million, a 36.0% increase over $294.1 million in 2017.

In the fourth quarter of 2018, the increase in wholesaler and pharmacy channel inventory had the effect of increasing net product sales by approximately $10 million. The Company expects inventory levels to revert to historical levels in 2019.

Net Product Sales ($millions)

	Q4 2018	Q4 2017	Change %	FY 2018	FY 2017	Change %
Trokendi XR	$ 88.4	$ 69.1	27.9%	$ 315.3	$ 226.5	39.2%
Oxtellar XR	$ 25.1	$ 17.2	45.9%	$ 84.6	$ 67.6	25.1%
Total	$ 113.5	$ 86.3	31.5%	$ 399.9	$ 294.1	36.0%

“We reported another year of strong operating results in 2018, driven by continued double-digit prescription growth for both Trokendi XR and Oxtellar XR,” said Jack Khattar, President and CEO of Supernus Pharmaceuticals. “In addition, we recently reached a key milestone by launching Oxtellar XR, in January 2019, with an expanded indication to include monotherapy for partial seizures, which could be a meaningful long term growth opportunity.”

Progress of Product Pipeline

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

- During December 2018, the Company announced positive topline results from the two pediatric Phase III trials (P301 and P303) and from the first adolescent Phase III trial (P302). All three trials met the primary endpoint with robust statistical significance. Topline data from the second and final adolescent Phase III trial (P304) are expected by the end of the first quarter of 2019.
- The Company continues to expect to submit a New Drug Application (NDA) for SPN-812 in the second half of 2019, and to launch it, pending U.S. Food and Drug Administration (FDA) approval, in the second half of 2020.
- A Phase III program in adult patients is anticipated to start in the second half of 2019.

SPN-810 – Novel treatment of Impulsive Aggression in patients with ADHD

- Enrollment in the Phase III trials (P301 and P302) continues with data from both trials expected in the second half of 2019.

- The Company continues to expect to submit an NDA for SPN-810 in the second half of 2020, and to launch it, pending FDA approval, in the second half of 2021.
- Enrollment in the Open Label Extension (OLE) study continues at 90% or higher. On average, a patient in the OLE study remains on SPN-810 treatment for approximately 10 months, which we believe is an encouraging sign of the tolerability and efficacy of SPN-810.
- Patient dosing continues in the Phase III trial (P503) in adolescent patients.

SPN-604 – Novel treatment of bipolar disorder

- The Company expects to start pivotal Phase III studies for the treatment of bipolar disorder in the second half of 2019.

"We made significant progress in 2018 advancing our late-stage programs through clinical development, including announcing positive topline results from three Phase III trials for SPN-812 for treatment of ADHD," said Jack Khattar. "We are focused in 2019 on submitting the NDA for SPN-812 and completing the Phase III trials for SPN-810, moving us closer to our goal of delivering, in the next several years, two novel products, both addressing billion-dollar market opportunities. In addition, we look forward to starting another Phase III program this year, with SPN-604 for the treatment of bipolar disorder."

Operating Expenses

Fourth Quarter

Research and development expenses in the fourth quarter of 2018 were $29.8 million, as compared to $16.2 million in the same quarter last year. This increase was primarily due to the one-time upfront expense of approximately $14 million in the fourth quarter of 2018 for the acquisition of Biscayne Neurotherapeutics, Inc. (Biscayne).

Selling, general and administrative expenses in the fourth quarter of 2018 were $42.1 million, as compared to $33.8 million in the same quarter last year. This increase was primarily due to the development and production of promotional materials and marketing programs associated with the launch of the monotherapy indication for Oxtellar XR, and an increase in share-based compensation expense.

Full Year

Research and development expenses for the full year 2018 were $89.2 million, as compared to $49.6 million for 2017. This increase was primarily due to the initiation of the four Phase III clinical trials for SPN-812 in the second half of 2017, the OLE trials for SPN-812 and SPN-810, and the one-time upfront expense of approximately $14 million for the acquisition of Biscayne.

Selling, general and administrative expenses for full year 2018 were $159.9 million, as compared to $137.9 million in 2017. This increase was primarily due to the expansion of the salesforce by 40 salespeople, who were fully deployed in the fourth quarter of 2017, increased marketing spend to support Trokendi XR, as well as the factors impacting the fourth quarter as described above.

Operating Earnings and Earnings Per Share

Operating earnings in the fourth quarter of 2018 were $39.9 million, a 16% increase over $34.3 million in the same period the prior year. Operating earnings in full year 2018 were $144.4 million, a 45.1% increase over $99.5 million in 2017. The improvement in operating earnings in both periods was primarily due to increased net product sales, offset by the aforementioned one-time upfront expense of approximately $14 million for the acquisition of Biscayne.

Net earnings (GAAP) in the fourth quarter of 2018 were $25.9 million, or $0.48 per diluted share, an increase of 85% on diluted share amount, as compared to $13.7 million, or $0.26 per diluted share, in the same period last year. Net earnings (GAAP) were $111.0 million in 2018, or $2.05 per diluted share, an increase of 90% on diluted share amount, as compared to $57.3 million, or $1.08 per diluted share, in 2017. In addition to higher operating income for the fourth quarter and full year 2018, net earnings (GAAP) benefited from the reduction in the statutory U.S. Federal income tax rate and, to a lesser extent, from stock option exercises. The reduction in income tax rate had an unfavorable impact of $9.7 million in both the fourth quarter and full year 2017.

Weighted-average diluted common shares outstanding were approximately 54.1 million in the fourth quarter and full year 2018, as compared to approximately 53.5 million and 53.3 million in each of the respective prior year periods.

Balance Sheet Highlights

As of December 31, 2018, the Company had $774.8 million in cash, cash equivalents, marketable securities, and long term marketable securities, compared to $273.7 million at December 31, 2017. This increase reflects net proceeds of $364.9 million from the issuance of convertible senior notes and warrants in March 2018, partially offset by purchases of convertible note hedges, the aforementioned one-time upfront payment of $15 million for the acquisition of Biscayne, and increased cash from operations in 2018.

Financial Guidance

For full year 2019, the Company estimates net product sales, research and development expenses, operating earnings, and an effective tax rate as set forth below. This guidance assumes that the short-term higher levels of wholesaler and pharmacy channel inventory experienced in the fourth quarter of 2018 will revert to historical levels in 2019.

- Net product sales in the range of $435 million to $455 million. Guidance reflects the Company's expectation that wholesaler and pharmacy channel inventory levels will revert to historical 2018 levels, thereby affecting 2019 net product sales by approximately $10 million.
- Research and development expenses in the range of $70 million to $80 million.

- Operating earnings in the range of $160 million to $180 million.
- Effective tax rate of approximately 23% to 25%.

Investor Day

The Company is pleased to announce that it will hold an Investor Day in New York City on April 16, 2019. The management team plans to provide an overview of the Company including a detailed discussion on its clinical programs and an assessment of the associated market opportunities.

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 27, 2019. An accompanying webcast also will be provided.

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:	2170478
Conference Call Name:	Supernus Pharmaceuticals Fourth Quarter and Full Year 2018 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 psychiatry, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients, 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 amounts)

	December 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 192,248	$ 100,304
Marketable securities	163,770	39,736
Accounts receivable, net	102,922	65,586
Inventories, net	25,659	16,304
Prepaid expenses and other current assets	8,888	6,521
Total current assets	493,487	228,451
Long term marketable securities	418,798	133,638
Property and equipment, net	4,095	5,124
Intangible assets, net	31,368	36,019

Deferred income taxes	29,683	20,843
Other assets	380	389
Total assets	$ 977,811	$ 424,464
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,195	$ 6,844
Accrued sales deductions	107,063	68,343
Accrued expenses	36,535	27,305
Income taxes payable	12,377	15,938
Non-recourse liability related to sale of future royalties, current portion	2,183	4,283
Deferred licensing revenue	—	287
Total current liabilities	161,353	123,000
Deferred licensing revenue, net of current portion	—	1,149
Convertible notes, net	329,462	—
Non-recourse liability related to sale of future royalties, long term	22,575	22,258
Other non-current liabilities	11,398	10,577
Total liabilities	524,788	156,984
Stockholders' equity		
Common stock, $0.001 par value, 130,000,000 shares authorized at December 31, 2018 and December 31, 2017; 52,316,583 and 51,314,850 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	52	51
Additional paid-in capital	369,637	294,999
Accumulated other comprehensive loss, net of tax	(3,158)	(747)
Retained earnings (accumulated deficit)	86,492	(26,823)
Total stockholders' equity	453,023	267,480
Total liabilities and stockholders' equity	$ 977,811	$ 424,464

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

	Three Months ended December 31,		**Years Ended December 31,**	
	2018 (unaudited)	**2017**	**2018 (unaudited)**	**2017**
Revenue				
Net product sales	$ 113,494	$ 86,334	$ 399,871	$ 294,097
Royalty revenue	2,440	2,029	8,276	6,367
Licensing revenue	—	72	750	1,774
Total revenue	115,934	88,435	408,897	302,238
Costs and expenses				
Cost of product sales	4,188	4,154	15,356	15,215
Research and development	29,841	16,173	89,209	49,577
Selling, general and administrative	42,050	33,764	159,888	137,905
Total costs and expenses	76,079	54,091	264,453	202,697
Operating earnings	39,855	34,344	144,444	99,541
Other income (expense)				
Interest income	4,512	877	13,843	2,864
Interest expense	(4,425)	—	(13,840)	(134)
Interest expense-nonrecourse liability related to sale of future royalties	(1,175)	(160)	(4,271)	(1,434)
Changes in fair value of derivative liabilities	—	—	—	76
Loss on extinguishment of debt	—	—	—	(295)

Total other income (expense)	(1,088)	717	(4,268)	1,077
Earnings before income taxes	38,767	35,061	140,176	100,618
Income tax expense	12,874	21,403	29,183	43,334
Net earnings	$ 25,893	$ 13,658	$ 110,993	$ 57,284
Earnings per share:				
Basic	$ 0.50	$ 0.27	$ 2.13	$ 1.13
Diluted	$ 0.48	$ 0.26	$ 2.05	$ 1.08
Weighted-average number of common shares outstanding:				
Basic	52,264,504	51,268,465	51,989,824	50,756,603
Diluted	54,104,036	53,534,217	54,098,872	53,301,150

CONTACTS:

Jack A. Khattar, President and CEO
Gregory S. Patrick, Vice President and CFO
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

or

INVESTOR CONTACT:
Peter Vozzo
Westwicke, an ICR Company
Office: (443) 213-0505
Mobile: (443) 377-4767
Email: peter.vozzo@westwicke.com

Source: Supernus Pharmaceuticals, Inc.