Supernus Announces Third Quarter 2023 Financial Results

November 8, 2023

- Raises full year 2023 adjusted operating earnings (non-GAAP)[1] guidance range to $95 million to $110 million from previous range of $75 million to $100 million
- Total revenues (GAAP) of $153.9 million in the third quarter of 2023; total revenues excluding Trokendi XR® net product sales (non-GAAP)[2], increased by 24% in the third quarter of 2023, compared to the same period in 2022
- Qelbree® net product sales of $37.1 million in the third quarter of 2023, a 103% increase compared to the third quarter of 2022 and a 20% increase compared to the second quarter of 2023
- GOCOVRI® net product sales of $32.9 million in the third quarter of 2023, an 18% increase compared to the third quarter of 2022 and a 14% increase compared to the second quarter of 2023
- Operating earnings (GAAP) of $8.1 million in the third quarter of 2023, compared to an operating loss (GAAP) of ($1.5) million in the third quarter of 2022
- Adjusted operating earnings (non-GAAP) of $37.3 million in the third quarter of 2023, an increase of 47% compared to the third quarter of 2022
- SPN-830 (apomorphine infusion device) NDA resubmission accepted for review by FDA; PDUFA date of April 5, 2024

ROCKVILLE, Md., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Supernus Pharmaceuticals, Inc. (Nasdaq: SUPN), a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases, today announced financial results for the third quarter of 2023, and associated Company developments.

“Our third-quarter performance underscores the strength of our growth products, with combined Qelbree and GOCOVRI net product sales increasing 52% in the third quarter of 2023 compared to the same period last year,” said Jack Khattar, President and CEO of Supernus. “In addition to our strong commercial execution, during our R&D Day in October 2023, we highlighted our pipeline of first-in-class differentiated CNS product candidates that have the potential to bolster future growth.”

Qelbree Update

- Total IQVIA prescriptions were 163,344 in the third quarter of 2023, an increase of 73% compared to the same period last year and 12% compared to the second quarter of 2023.
- Qelbree continues to expand its base of prescribers, with approximately 24,189 prescribers in the third quarter of 2023, up from 21,291 prescribers in the second quarter of 2023.
- The Company presented new data at Psych Congress 2023 in September showing improved efficacy in children ages 6 years and older with attention-deficit hyperactivity disorder (ADHD) when Qelbree is administered with stimulants, as well as in adults with ADHD who undergo long-term treatment with Qelbree.

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(1) Adjusted Operating Earnings is a non-GAAP measure and is calculated as Operating Earnings (Loss) (GAAP) plus amortization of intangible assets, share-based compensation, contingent consideration expense (gain) and depreciation. A reconciliation of the full year 2023 financial guidance for Operating Loss (GAAP) to Adjusted Operating Earnings (non-GAAP) is included under the heading “Full Year 2023 Financial Guidance – GAAP to Non-GAAP Adjustments.”

(2) Total revenues, excluding Trokendi XR net product sales is a non-GAAP measure and is calculated as total revenues (GAAP) less net product sales of Trokendi XR (GAAP). A reconciliation of this measure to Total revenues (GAAP) is included under the heading “Reconciliation of GAAP Total revenues to Non-GAAP Total revenues excluding Trokendi XR net product sales.”

Product Pipeline Update

The Company hosted a successful Research & Development (R&D) Day in October 2023 highlighting clinical and R&D progress and its emerging pipeline of novel CNS product candidates. During the R&D Day the Company provided a product pipeline update as set forth below:

SPN-830 (apomorphine infusion device) for treatment of PD

- In November 2023, the FDA accepted the resubmission of the New Drug Application (NDA) for SPN-830 for continuous treatment of motor fluctuations ("off" episodes) in Parkinson's disease (PD). The resubmission is now considered filed, with a user fee goal date (PDUFA date) of April 5, 2024.

SPN-820 – Novel first-in-class molecule that increases mTORC1 mediated synaptic function for depression

- The Phase IIb multi-center randomized double-blind placebo-controlled parallel design study of SPN-820 in adults with treatment-resistant depression is ongoing. The study will examine the efficacy and safety of SPN-820 over a course of five weeks of treatment in approximately 268 patients in up to 50 clinical sites. The primary outcome measure is the change from baseline to end of treatment period on the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score. Topline data from the Phase IIb trial is expected in 2025.

- The Company plans to initiate a Phase II open-label study in approximately 40 subjects with major depressive disorder (MDD) before year-end 2023. The primary objective of the study is to assess efficacy in MDD, as well as onset of efficacy.

SPN-817 – Novel first-in-class highly selective AChE inhibitor for epilepsy

- An open-label Phase IIa clinical study of SPN-817 for treatment-resistant seizures is ongoing. The study is examining the safety and tolerability of SPN-817 as adjunctive therapy in adult patients with treatment-resistant seizures, as well as assessing efficacy. The Company expects topline results from the Phase IIa study in the first half of 2024.

- The Company expects to initiate a Phase IIb randomized, double-blind, placebo-controlled study in approximately 436 patients with treatment-resistant focal seizures in the first half of 2024. The primary endpoint is change from baseline in focal seizure frequency per 28 days. Topline results from the Phase IIb study are expected in 2026.

SPN-443 – Novel stimulant for ADHD/CNS

- The Company is planning in 2024 to initiate a Phase I single dose study in approximately 24 healthy adults following submission of an Investigational New Drug (IND) application. The primary objective of the study is to assess safety and tolerability.

Financial Highlights

Total revenues (GAAP and non-GAAP)

For the three months ended September 30, 2023, total revenues and total net product sales (GAAP) were $153.9 million and $149.0 million, respectively, compared to total revenues and total net product sales of $177.4 million and $172.7 million for the same period in 2022. For the nine months ended September 30, 2023, total revenues and total net product sales were $443.2 million and $417.9 million, respectively, compared to total revenues and total net product sales of $499.9 million and $485.6 million for the same period in 2022. The decrease in net product sales in both periods was primarily due to the decline in net product sales of Trokendi XR. This decline in net product sales of Trokendi XR was partially offset by an increase in net product sales of Qelbree, GOCOVRI and APOKYN for the three months ended September 30, 2023, and an increase in net product sales of Qelbree and GOCOVRI for the nine months ended September 30, 2023.

Total revenues excluding Trokendi XR net product sales (non-GAAP) for the three and nine months ended September 30, 2023, increased 24% and 25%, respectively, compared to the same periods in 2022.

The following table provides information regarding total revenues during the three and nine months ended September 30, 2023 and 2022 (unaudited, dollars in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Change %	2023	2022	Change %
Total net product sales	$ 149.0	$ 172.7	(14)%	$ 417.9	$ 485.6	(14)%
Royalty revenues[(1)]	4.9	4.7	4%	25.3	14.3	77%
Total revenues (GAAP)	$ 153.9	$ 177.4	(13)%	$ 443.2	$ 499.9	(11)%
Total revenues excluding Trokendi XR net product sales (non-GAAP)	$ 133.3	$ 107.8	24%	$ 368.5	$ 295.9	25%

(1) Royalty revenues include royalties on generic Trokendi XR, other licensed products and intellectual property.

The following table provides information regarding total net product sales during the three and nine months ended September 30, 2023 and 2022 (unaudited, dollars in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		

	2023	2022	Change %	2023	2022	Change %
Net product sales						
Qelbree	$ 37.1	$ 18.3	103%	$ 93.8	$ 37.7	149%
GOCOVRI	32.9	27.9	18%	87.7	75.2	17%
Oxtellar XR®	29.6	30.5	(3)%	82.4	88.0	(6)%
Trokendi XR	20.6	69.6	(70)%	74.7	204.0	(63)%
APOKYN®	21.5	18.3	17%	56.3	57.2	(2)%
Other(1)	7.3	8.1	(10)%	23.0	23.5	(2)%
Total net product sales	$ 149.0	$ 172.7	(14)%	$ 417.9	$ 485.6	(14)%

(1) Includes net product sales of MYOBLOC®, XADAGO® and Osmolex ER®.

Operating earnings (loss) (GAAP and non-GAAP)

For the three months ended September 30, 2023, operating earnings (GAAP) was $8.1 million, compared to operating loss (GAAP) of ($1.5) million for the same period in 2022. For the nine months ended September 30, 2023, operating loss (GAAP) was ($4.3) million, compared to operating earnings (GAAP) of $11.8 million for the same period in 2022. The increase in operating earnings (GAAP) in the third quarter of 2023 was due primarily to lower selling and marketing expenses compared to the third quarter of 2022 due to the launch of Qelbree to the adult population and the Qelbree direct-to-consumer campaign, which substantially occurred in the third quarter of 2022. The operating loss (GAAP) in the nine months ended September 30, 2023 was primarily due to a decrease in net product sales of Trokendi XR, partially offset by growth in net product sales of Qelbree and GOCOVRI, and a decrease in operating expenses.

For the three months ended September 30, 2023, adjusted operating earnings (non-GAAP) were $37.3 million, compared to $25.4 million for the same period in 2022. For the nine months ended September 30, 2023, adjusted operating earnings (non-GAAP) were $77.9 million, compared to $91.1 million for the same period in 2022.

Reconciliation of GAAP Operating earnings (loss) to Non-GAAP Operating earnings

An itemized reconciliation between operating earnings (loss) on a GAAP basis and operating earnings on a non-GAAP basis is as follows (unaudited, dollars in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating earnings (loss) - As Reported (GAAP)	$ 8.1	$ (1.5)	$ (4.3)	$ 11.8
Adjustments:				
Amortization of intangible assets	21.2	20.6	61.3	61.9
Share-based compensation	7.9	5.0	20.3	13.3
Contingent consideration expense (gain)	(0.5)	0.5	(1.3)	1.9
Depreciation	0.6	0.8	1.9	2.2
Operating earnings - As Adjusted (non-GAAP)	$ 37.3	$ 25.4	$ 77.9	$ 91.1

Non-GAAP operating earnings adjusts for non-cash items including amortization of intangible assets, share-based compensation expense, change in fair value of contingent consideration, and depreciation.

Net earnings (loss) (GAAP)

For the three months ended September 30, 2023, net earnings (loss) (GAAP) and diluted earnings (loss) per share (GAAP) were ($16.0) million and ($0.29), respectively, as compared to $1.7 million and $0.03, in the same period in 2022. For the nine months ended September 30, 2023, net earnings (GAAP) and diluted earnings per share (GAAP) were $0.1 million and $0.00, respectively, as compared to $35.2 million and $0.62 in the same period in 2022.

Balance sheet

At September 30, 2023, the Company's cash, cash equivalents, and current and long-term marketable securities were approximately $225.3 million, compared to $555.2 million as of December 31, 2022. This decrease was primarily due to repayment of the Company's $402.5 million 0.625% Convertible Senior Notes due 2023 (2023 Notes), partially offset by cash generated from operations.

Full Year 2023 Financial Guidance (GAAP)

The Company is revising its full-year 2023 financial guidance as set forth below (dollars in millions).

	Current (as of November 8, 2023)	Previous (as of August 8, 2023)
Total revenues(1)(2)	$590 - $610	$580 - $620
Combined R&D and SG&A expenses	$420 - $440	$450 - $480
Operating loss(3)	($15) - ($5)	($30) - ($10)

(1) Includes net product sales and royalty revenue, and approximately $90 million of Trokendi XR.

(2) Reflects Trokendi XR generic erosion in 2023.

(3) Includes amortization of intangible assets and contingent consideration expense (gain).

Full Year 2023 Financial Guidance - GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected operating loss on a GAAP basis and projected operating earnings on a non-GAAP basis is as follows (dollars in millions):

	Current (as of November 8, 2023)	Previous (as of August 8, 2023)
Operating loss - GAAP	($15) - ($5)	($30) - ($10)
Adjustments:		
Amortization of intangible assets	$83	$83
Share-based compensation	$25 - $29	$20 - $24
Contingent consideration	$0 - $1	$0 - $1
Depreciation	$2	$2
Operating earnings - non-GAAP	$95 - $110	$75 - $100

Non-GAAP Financial Information

This press release contains financial measures that present financial information which do not comply with United States generally accepted accounting principles (GAAP). The non-GAAP financial measure should be considered in addition to, not as a substitute for or in isolation from, or superior to measures prepared in accordance with GAAP. Non-GAAP operating earnings adjusts for non-cash share-based compensation expense, depreciation and amortization, and accretion of contingent consideration, and for factors that are unusual, non-recurring or unpredictable, and excludes those costs, expenses, and other specified items presented in the reconciliation tables in this press release. In addition to non-GAAP operating earnings, we also present total revenues excluding net product sales of Trokendi XR which is a non-GAAP measure and is calculated as total revenues (GAAP) less net product sales of Trokendi XR (GAAP). With the loss of exclusivity due to generic entrants, we do not expect net product sales of Trokendi XR to constitute a significant part of our revenue in the future. We believe that the use of non-GAAP financial measures provides useful supplemental information to management, investors, analysts and others regarding the Company's revenue and results of operations and assist management, investors, analysts, and others in understanding and evaluating our revenue growth and the performance of the business.

There are limitations associated with the use of non-GAAP financial measures and therefore comparability may be limited. These limitations include: non-GAAP financial measures that may not be entirely comparable to similarly titled measures used by other companies; these may not reflect all items of income and expense, as applicable, that affect our operations; there may be potential differences among calculation methodologies; these may differ from the non-GAAP information used by other companies, including peer companies. We mitigate these limitations by reconciling the non-GAAP financial measure to the most comparable GAAP financial measure. Investors are encouraged to review the reconciliation. The Company's 2023 financial guidance is also being provided on both a reported and a non-GAAP basis.

Reconciliation of GAAP Total revenues to Non-GAAP Total revenues excluding Trokendi XR net product sales

An itemized reconciliation between total revenues on a GAAP basis and Total revenues excluding Trokendi XR net product sales, a non-GAAP measure, is as follows (unaudited, dollars in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Change %	2023	2022	Change %
Total revenues (GAAP)(1)	$153.9	$177.4	(13)%	$443.2	$499.9	(11)%
Less: Trokendi XR net product sales	20.6	69.6	(70)%	74.7	204.0	(63)%
Total revenues excluding Trokendi XR net product sales (Non-GAAP)	$133.3	$107.8	24%	$368.5	$295.9	25%

(1) Includes net product sales and royalty revenue.

Conference Call Details

Supernus will host a conference call and webcast today, November 8, 2023, at 4:30 p.m. Eastern Time to discuss these results. A live webcast will be available in the Events & Presentations section of the Company's Investor Relations website www.supernus.com/investors.

Participants may also pre-register any time before the call here. Once registration is completed, participants will be provided a dial-in number with a personalized conference code to access the call. Please dial 15 minutes prior to the start time.

Following the live call, a replay will be available on the Company's Investor Relations website www.supernus.com/investors. The webcast will be available on the Company's website for 60 days following the live call.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases.

Our diverse neuroscience portfolio includes approved treatments for epilepsy, migraine, ADHD, hypomobility in PD, cervical dystonia, chronic

sialorrhea, dyskinesia in PD patients receiving levodopa-based therapy, and drug-induced extrapyramidal reactions in adult patients. We are developing a broad range of novel CNS product candidates including new potential treatments for hypomobility in PD, epilepsy, depression, and other CNS disorders.

For more information, please visit www.supernus.com.

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 and the products of its subsidiaries; the Company's ability to increase its net revenue; the Company's ability to commercialize its products and the products of its subsidiaries; 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 the intellectual property of its subsidiaries 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; the Company's ability to increase the number of prescriptions written for each of its products and the products of its subsidiaries; the Company's ability to increase its net revenue from its products and the products of its subsidiaries; 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 94,985	$ 93,120
Marketable securities	105,204	368,214
Accounts receivable, net	141,764	165,497
Inventories, net	83,480	91,541
Prepaid expenses and other current assets	23,927	15,779
Total current assets	449,360	734,151
Long-term marketable securities	25,125	93,896
Property and equipment, net	13,688	15,173
Intangible assets, net	641,147	702,463
Goodwill	117,019	117,019
Other assets	38,821	39,806
Total assets	$ 1,285,160	$ 1,702,508
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 78,471	$ 96,342
Accrued product returns and rebates	162,473	151,665
Convertible notes, net	—	401,968
Contingent consideration, current portion	45,880	21,120
Other current liabilities	710	16,863
Total current liabilities	287,534	687,958
Contingent consideration, long-term	7,774	33,847
Operating lease liabilities, long-term	33,841	35,998
Deferred income tax liabilities, net	35,224	49,809
Other liabilities	8,596	8,692
Total liabilities	372,969	816,304
Stockholders' equity		

Common stock, $0.001 par value; 130,000,000 shares authorized; 54,630,758 and 54,253,796 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	55	54
Additional paid-in capital	431,956	408,115
Accumulated other comprehensive loss, net of tax	(1,206)	(3,210)
Retained earnings	481,386	481,245
Total stockholders' equity	912,191	886,204
Total liabilities and stockholders' equity	$ 1,285,160	$ 1,702,508

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Revenues				
Net product sales	$ 149,004	$ 172,724	$ 417,915	$ 485,647
Royalty revenues	4,876	4,629	25,292	14,263
Total revenues	153,880	177,353	443,207	499,910
Costs and expenses				
Cost of goods sold	19,601	25,878	64,152	64,267
Research and development	22,655	19,554	68,246	56,778
Selling, general and administrative	82,700	112,314	255,079	303,249
Amortization of intangible assets	21,242	20,644	61,316	61,932
Contingent consideration expense (gain)	(456)	486	(1,313)	1,894
Total costs and expenses	145,742	178,876	447,480	488,120
Operating earnings (loss)	8,138	(1,523)	(4,273)	11,790
Other income (expense)				
Interest expense	—	(1,724)	(2,415)	(5,476)
Interest and other income, net	1,751	2,803	8,467	19,289
Total other income (expense)	1,751	1,079	6,052	13,813
Earnings (loss) before income taxes	9,889	(444)	1,779	25,603
Income tax expense (benefit)	25,865	(2,193)	1,638	(9,627)
Net earnings (loss)	$ (15,976)	$ 1,749	$ 141	$ 35,230
Earnings (loss) per share				
Basic	$ (0.29)	$ 0.03	$ 0.00	$ 0.66
Diluted	$ (0.29)	$ 0.03	$ 0.00	$ 0.62
Weighted average shares outstanding				
Basic	54,608,963	53,789,674	54,498,687	53,517,838
Diluted	54,608,963	55,034,838	55,574,922	61,543,121

CONTACTS:

Jack A. Khattar, President and CEO
Timothy C. Dec, Senior Vice President and CFO
Supernus Pharmaceuticals, Inc.
Tel: (301) 838-2591

or

INVESTOR CONTACT:
Peter Vozzo
ICR Westwicke
Office: (443) 213-0505

Email: peter.vozzo@westwicke.com

Source: Supernus Pharmaceuticals, Inc.