Supernus Announces Third Quarter 2024 Financial Results

November 4, 2024

- Net sales of Qelbree® increased 68% in the third quarter of 2024, compared to the same period in 2023.
  - Net sales of Qelbree of $62.4 million and $166.9 million in the third quarter and first nine months of 2024, respectively.
- Net sales of GOCOVRI® increased 8% in the third quarter of 2024, compared to the same period in 2023.
  - Net sales of GOCOVRI of $35.6 million and $93.9 million in the third quarter and first nine months of 2024, respectively.
- Total revenues were $175.7 million in the third quarter of 2024, an increase of 14% compared to the same period in 2023.
  - Total revenues excluding Trokendi XR® and Oxtellar XR® net product sales (non-GAAP)(1) increased 26% in the third quarter of 2024, compared to the same period in 2023.
- Operating earnings of $40.9 million and $60.3 million in the third quarter and first nine months of 2024, respectively, compared to operating earnings (loss) of $8.1 million and $(4.3) million for the same periods in 2023.
- Adjusted operating earnings (non-GAAP)(1) were $67.7 million and $135.4 million in the third quarter and first nine months of 2024, respectively, compared to $37.3 million and $77.9 million in the same periods in 2023.
- Raising full year 2024 guidance for total revenues and operating earnings (GAAP and Non-GAAP).

ROCKVILLE, Md., Nov. 04, 2024 (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 2024 and associated Company developments.

Business Highlights

- Total IQVIA prescriptions(2) for Qelbree were 194,025 in the third quarter of 2024, an increase of 19% compared to the same period in the prior year.
- On August 16, 2024, the U.S. Food and Drug Administration acknowledged the resubmission of the Company's New Drug Application for the apomorphine infusion device (SPN-830) for the continuous treatment of motor fluctuations ("OFF" episodes) in Parkinson's disease. The resubmission is considered filed, with a user fee goal date (PDUFA date) of February 1, 2025.

"For the third quarter and first nine months of 2024, strong performance from the Company's key growth drivers – Qelbree and GOCOVRI – drove significant operating earnings growth," said Jack Khattar, President and CEO of Supernus. "In addition to strong growth from our key drivers, we continue to advance our product pipeline, announcing positive topline data from our open-label Phase 2a study of SPN-820 in major depressive disorder."

Product Pipeline Update

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

- In October 2024, the Company announced and discussed the data from its exploratory open-label Phase 2a clinical study of SPN-820 in adults with major depressive disorder (MDD). The data were based on 40 enrolled subjects, of which 38 completed the 10-day treatment period. The primary objective of the study was to assess efficacy in MDD, as well as the onset of efficacy. The Phase 2a study demonstrated rapid and substantial decrease in depressive symptoms, and 80% decrease in suicidal ideation. SPN-820 was well-tolerated with few adverse events.
- In addition, the Company presented new data at the 2024 Psych Congress in October 2024 that demonstrate a rapid Montgomery–Asberg Depression Rating Scale (MADRS) response rate (≥50% reduction) and remission (MADRS ≤10), reaching 50.0% and 35.0% of participants, respectively, at 4 hours, with additional improvement to 84.2% and 63.2% of participants by Day 10.
- The Company expects to complete enrollment in the ongoing Phase 2b multi-center randomized double-blind placebo-controlled parallel design study of SPN-820 in adults with treatment-resistant depression in November 2024. The study will examine the efficacy and safety of SPN-820 over a course of five weeks of treatment in approximately 236 patients in approximately 50 clinical sites. The primary outcome measure is the change from baseline to end of treatment period on the MADRS Total Score. Topline data from the Phase 2b trial are expected in the first half of 2025.

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

- The Company is conducting an open label Phase 2a study in patients with treatment-resistant seizures. In May 2024, the Company announced data from a planned interim analysis from the initial stage of the study (Stage A). The Company has

now completed enrollment of Stage A and is reporting topline data from all subjects with focal seizures who received the 3mg and 4mg twice daily doses, completed the maintenance period (n=10), and enrolled in the post-maintenance extension period (n=6).

- Maintenance period:
  - 56% median seizure reduction from baseline.
  - 70% of subjects had 30% or more seizure reduction.
  - 60% of subjects had 50% or more seizure reduction.
  - 30% of subjects had 75% or more seizure reduction.

- Post-maintenance extension period:
  - 66% median seizure reduction from baseline.
  - 83% of subjects had 30% or more seizure reduction.
  - 67% of subjects had 50% or more seizure reduction.
  - 50% of subjects had 75% or more seizure reduction.

- Seizure Freedom:
  - Maintenance period: 1 out of 10 subjects (10%) who completed a post-baseline seizure diary had at least one four-week seizure free period.
  - Post-maintenance extension period: 1 out of 6 subjects (17%) had at least one four-week seizure free period.

- Assessment by EpiTrack®, a validated cognitive screening tool designed for patients with epilepsy, indicated that 75% of 16 subjects was equally split between those who improved and those who had no change in cognitive function.
- SPN-817 was safe and had acceptable tolerability with 2 subjects discontinuing because of treatment related adverse events out of the 26 subjects who entered the maintenance period. Stage B of the study is on-going and includes the concomitant use of an anti-emetic to reduce cholinergic adverse events observed in the study.
- A Phase 2b randomized, double-blind, placebo-controlled study in patients with treatment resistant focal seizures is expected to start by the end of 2024 studying 3mg and 4mg twice daily doses.

SPN-443 – Novel stimulant for ADHD/CNS

- The Company initiated a Phase 1 single dose study in healthy adults in the third quarter of 2024. The primary objective of the study is to assess safety and tolerability.

Financial Highlights

This section includes information on non-GAAP financial measures. See “Non-GAAP Financial Information” section for information on non-GAAP financial measures. In addition, a reconciliation of applicable GAAP to non-GAAP financial information is included at the end of this press release.

Revenues

The following table provides information regarding total revenues (dollars in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change %	2024	2023	Change %
Net product sales						
Qelbree	$ 62.4	$ 37.1	68%	$ 166.9	$ 93.8	78%
GOCOVRI	35.6	32.9	8%	93.9	87.7	7%
Oxtellar XR	29.8	29.6	1%	86.3	82.4	5%
APOKYN	19.9	21.5	(8)%	53.8	56.3	(4)%
Trokendi XR	15.3	20.6	(26)%	48.4	74.7	(35)%
Other[3]	7.3	7.3	— %	22.0	23.0	(4)%
Total net product sales	$ 170.3	$ 149.0	14%	$ 471.3	$ 417.9	13%
Royalty, licensing and other revenues[4]	5.4	4.9	10%	16.4	25.3	(35)%
Total revenues	$ 175.7	$ 153.9	14%	$ 487.7	$ 443.2	10%
Total revenues excluding Trokendi XR and Oxtellar XR net product sales (non-GAAP)[1]	$ 130.6	$ 103.7	26%	$ 353.0	$ 286.1	23%

- Total revenues were $175.7 million and $487.7 million for the three and nine months ended September 30, 2024,

compared to $153.9 million and $443.2 million in the same periods in 2023, respectively.

- Total net product sales were $170.3 million and $471.3 million for the three and nine months ended September 30, 2024, compared to $149.0 million and $417.9 million in the same periods in 2023, respectively. The increase in both periods was primarily due to the increase in net sales of Qelbree and GOCOVRI, partially offset by the decline in net product sales of Trokendi XR due to generic erosion.
- Total revenues excluding Trokendi XR and Oxtellar XR net product sales (non-GAAP) increased 26% and 23% for the three and nine months ended September 30, 2024, compared to the same periods in 2023, respectively.

Other Financial Highlights

- Operating earnings were $40.9 million and $60.3 million for the three and nine months ended September 30, 2024, compared to operating earnings (loss) of $8.1 million and $(4.3) million for the same periods in 2023, respectively. The positive increase in both periods was primarily due to an increase in total net product sales and decreases in cost of goods sold and selling, general and administrative expenses.
- Adjusted operating earnings (non-GAAP) were $67.7 million and $135.4 million for the three and nine months ended September 30, 2024, compared to $37.3 million and $77.9 million for the same periods in 2023, respectively.
- Net earnings and diluted earnings per share were $38.5 million and $0.69 for the three months and $58.5 million and $1.05 for the nine months ended September 30, 2024, respectively, compared to net earnings (loss) and diluted earnings (loss) per share of $(16.0) million and $(0.29) for the three months and $0.1 million and $0.00 for the nine months ended September 30, 2023, respectively.
- At September 30, 2024, cash, cash equivalents, and current and long-term marketable securities were approximately $403.2 million compared to $271.5 million as of December 31, 2023. This increase was primarily due to cash generated from operations.

Full Year 2024 Financial Guidance

For the full year 2024, the Company is increasing prior financial guidance for total revenues and operating earnings (GAAP and Non-GAAP) as set forth below (dollars in millions):

	Current Guidance (as of November 4, 2024)	**Previous Guidance (as of August 6, 2024)**
Total revenues (*includes approximately $155 million of Trokendi XR and Oxtellar XR)*[5][6]	$630 - $650	$600 - $625
Combined R&D and SG&A expenses	$430 - $450	$430 - $460
Operating earnings	$50 - $65	$0 - $20
Adjusted operating earnings (non-GAAP)[1]	$150 - $170	$100 - $125

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 measures 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 adjusted operating earnings on a historical and projected basis adjusts for non-cash share-based compensation expense, depreciation and amortization, intangible asset impairment charges and changes to fair value 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 adjusted operating earnings, we also present total revenues excluding net product sales of Trokendi XR (GAAP) and Oxtellar XR (GAAP), which is a non-GAAP measure and is calculated as total revenues (GAAP) less net product sales of Trokendi XR (GAAP) and Oxtellar XR (GAAP). Beginning in the year a product loses exclusivity due to generic entrants we generally do not expect net product sales of such products 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 2024 financial guidance is also being provided on both a GAAP and a non-GAAP basis.

End Notes

[1] See the section titled "Non-GAAP Financial Information" for information about this non-GAAP financial measure. A reconciliation of each non-GAAP financial measure to the most directly comparable GAAP financial measure is included at the end of this press release.

[2] IQVIA data restatement July 1, 2024.

[3] Includes net product sales of MYOBLOC®, XADAGO® and Osmolex ER®.

[4] Royalty, licensing, and other revenues include royalties on generic Trokendi XR, other licensed products and intellectual property.

(5) Includes net product sales and royalty, licensing, and other revenue.

(6) Reflects continued generic erosion of Trokendi XR and generic erosion of Oxtellar XR beginning in September 2024.

Conference Call Details

Supernus will host a conference call and webcast today, November 4, 2024, 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 in 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 Parkinson's disease (PD), cervical dystonia, chronic sialorrhea, and dyskinesia in PD patients receiving levodopa-based therapy. 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 from its products and the products of its subsidiaries; 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; 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, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 31,673	$ 75,054
Marketable securities	371,537	179,820
Accounts receivable, net	145,408	144,155
Inventories, net	63,981	77,408
Prepaid expenses and other current assets	27,404	16,676
Total current assets	640,003	493,113
Long-term marketable securities	—	16,617
Property and equipment, net	11,876	13,530
Intangible assets, net	540,156	599,889
Goodwill	117,019	117,019
Other assets	33,647	37,505
Total assets	$ 1,342,701	$ 1,277,673

Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 75,803	$ 79,569
Accrued product returns and rebates	169,124	154,274
Contingent consideration, current portion	46,581	52,070
Other current liabilities	—	4,283
Total current liabilities	291,508	290,196
Contingent consideration, long-term	403	1,380
Operating lease liabilities, long-term	28,926	33,196
Deferred income tax liabilities, net	7,364	24,963
Other liabilities	7,350	6,422
Total liabilities	335,551	356,157
Stockholders' equity		
Common stock, $0.001 par value; 130,000,000 shares authorized; 55,219,273 and 54,723,356 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	55	55
Additional paid-in capital	465,919	439,493
Accumulated other comprehensive earnings (loss), net of tax	78	(593)
Retained earnings	541,098	482,561
Total stockholders' equity	1,007,150	921,516
Total liabilities and stockholders' equity	$ 1,342,701	$ 1,277,673

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
	(unaudited)		**(unaudited)**	
Revenues				
Net product sales	$ 170,302	$ 149,004	$ 471,301	$ 417,915
Royalty, licensing and other revenues	5,387	4,876	16,357	25,292
Total revenues	175,689	153,880	487,658	443,207
Costs and expenses				
Cost of goods sold[(a)]	17,583	19,601	51,808	64,152
Research and development	29,036	22,655	80,149	68,246
Selling, general and administrative	69,753	82,700	242,173	255,079
Amortization of intangible assets	19,488	21,242	59,733	61,316
Contingent consideration gain	(1,016)	(456)	(6,466)	(1,313)
Total costs and expenses	134,844	145,742	427,397	447,480
Operating earnings (loss)	40,845	8,138	60,261	(4,273)
Other income (expense)				
Interest and other income, net	4,098	1,751	11,227	8,467
Interest expense	—	—	—	(2,415)
Total other income (expense)	4,098	1,751	11,227	6,052
Earnings before income taxes	44,943	9,889	71,488	1,779
Income tax expense	6,446	25,865	12,951	1,638
Net earnings (loss)	$ 38,497	$ (15,976)	$ 58,537	$ 141
Earnings (loss) per share				
Basic	$ 0.70	$ (0.29)	$ 1.06	$ —

Diluted	$ 0.69	$ (0.29)	$ 1.05	$ —
Weighted average shares outstanding				
Basic	55,149,760	54,608,963	54,977,199	54,498,687
Diluted	56,016,350	54,608,963	55,791,185	55,574,922

(a) Excludes amortization of intangible assets.

Supernus Pharmaceuticals, Inc.
Reconciliations of GAAP to Non-GAAP Financial Information
(Unaudited)

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

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2024	2023	Change %	2024	2023	Change %
Total revenues (GAAP)(1)	$ 175.7	$ 153.9	14%	$ 487.7	$ 443.2	10%
Adjustments:						
Trokendi XR net product sales	(15.3)	(20.6)	(26)%	(48.4)	(74.7)	(35)%
Oxtellar XR net product sales	(29.8)	(29.6)	1%	(86.3)	(82.4)	5%
Total revenues excluding Trokendi XR and Oxtellar XR net product sales (non-GAAP)(1)	$ 130.6	$ 103.7	26%	$ 353.0	$ 286.1	23%

(1) Includes net product sales and royalty, licensing, and other revenues.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating earnings (loss) - As Reported (GAAP)	$ 40.9	$ 8.1	$ 60.3	(4.3)
Adjustments:				
Amortization of intangible assets	19.5	21.2	59.7	61.3
Share-based compensation	7.7	7.9	20.1	20.3
Contingent consideration gain	(1.0)	(0.5)	(6.5)	(1.3)
Depreciation	0.6	0.6	1.8	1.9
Operating earnings - As Adjusted (non-GAAP)	$ 67.7	$ 37.3	$ 135.4	$ 77.9

Non-GAAP adjusted 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.

Reconciliation of Full Year 2024 Financial Guidance - GAAP Operating earnings (loss) to Non-GAAP Adjusted Operating earnings

An itemized reconciliation between projected operating earnings (loss) on a GAAP basis for the full year 2024 and projected adjusted operating earnings on a non-GAAP basis for the full year 2024 is as follows (dollars in millions):

	Current Guidance (as of November 4, 2024)	Previous Guidance (as of August 6, 2024)
Operating earnings (loss) - GAAP	$50 - $65	$0 - $20
Adjustments:		
Amortization of intangible assets	$78 - $80	$78 - $80
Share-based compensation	$27 - $29	$27 - $29
Contingent consideration gain	$(7) - $(7)	$(7) - $(7)
Depreciation	$2 - $3	$2 - $3
Operating earnings - As Adjusted (non-GAAP)	$150 - $170	$100 - $125

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