Vanda Pharmaceuticals Reports Second Quarter 2019 Financial Results

July 31, 2019

- Q2 2019 Total net product sales of $59.1 million, a 25% increase year over year
- Q2 2019 Hetlioz® net product sales grew to $37.8 million, a 35% increase year over year
- Vanda reiterates 2019 net product sales guidance of $215 million to $225 million

WASHINGTON, July 31, 2019 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced financial and operational results for the second quarter ended June 30, 2019.

"The exceptional commercial performance of HETLIOZ and Fanapt positions Vanda to continue on its path of growth and long term value creation," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO. "The recently announced positive results from the tradipitant motion sickness study further enhance the potentially broad therapeutic utility of tradipitant as a treatment option for the millions of patients with gastroparesis, motion sickness and atopic dermatitis."

Key Financial Highlights:

- Total net product sales from HETLIOZ® and Fanapt® were $59.1 million in the second quarter of 2019, a 24% increase compared to $47.7 million in the first quarter of 2019 and a 25% increase compared to $47.4 million in the second quarter of 2018.
- HETLIOZ® net product sales were $37.8 million in the second quarter of 2019, a 31% increase compared to $29.0 million in the first quarter of 2019 and a 35% increase compared to $28.0 million in the second quarter of 2018.
- Fanapt® net product sales were $21.2 million in the second quarter of 2019, a 13% increase compared to $18.8 million in the first quarter of 2019 and a 10% increase compared to $19.3 million in the second quarter of 2018.
- Cash, cash equivalents and marketable securities (Cash) were $292.7 million as of June 30, 2019, representing an increase to Cash of $24.8 million as compared to March 31, 2019.

Key Research and Development Highlights:

Tradipitant

- In July 2019, Vanda announced positive results from a Phase II clinical study (Motion Sifnos) of tradipitant in motion sickness. Patients with a prior history of motion sickness were treated with tradipitant or placebo prior to a chartered trip on the Pacific Ocean. In this setting, significantly fewer patients on tradipitant vomited than those on placebo. Vanda intends to initiate a Phase III program in motion sickness in 2019 with a plan to file for marketing authorization in 2020.
- After meeting with the U.S. Food and Drug Administration (FDA) in May 2019 to discuss the Phase III program, Vanda initiated a Phase III clinical study of tradipitant in gastroparesis in the second quarter of 2019 and plans to begin randomizing patients in the third quarter of 2019.
- Enrollment in the Phase III clinical study (EPIONE) of tradipitant in atopic dermatitis is ongoing. Results are expected in the first half of 2020. A second Phase III clinical study is expected to begin in the first quarter of 2020.

HETLIOZ® (tasimelteon)

- The FDA's review of the supplemental New Drug Application (sNDA) of HETLIOZ® for the treatment of jet lag disorder is ongoing with a Prescription Drug User Fee Act (PDUFA) target date of August 16, 2019. On July 19, 2019, Vanda received a "Deficiencies Preclude Discussion" letter from the FDA. The letter does not specify any deficiencies in the file at this time. Vanda will await the PDUFA action and work expeditiously to resolve any potential deficiencies.
- Vanda expects to file a sNDA for HETLIOZ® for the treatment of Smith-Magenis Syndrome in the third quarter of 2019.
- Vanda plans in the third quarter of 2019 to initiate a Phase II clinical study of HETLIOZ® in delayed sleep phase disorder (DSPD) in patients who have a mutation in the CRY1 gene, which is believed to be causative in a subset of patients with DSPD.

Fanapt® (iloperidone)

- Enrollment is ongoing in a pharmacokinetic study for the once-a-month long acting injectable (LAI) formulation of Fanapt®.
- A randomized study of Fanapt® in bipolar disorder is planned to begin in 2019.

VTR-297 (histone deactetylase (HDAC) inhibitor)

- Enrollment is ongoing in a Phase I clinical study (1101) of VTR-297 in hematologic malignancies.

Non-GAAP Financial Results

Non-GAAP net income was $15.0 million for the second quarter of 2019, or $0.28 per share, compared to a Non-GAAP net income of $7.7 million, or $0.15 per share, for the second quarter of 2018.

Vanda provides Non-GAAP financial information, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP figures. Refer to the sections of this press release entitled "Non-GAAP Financial Information" and "Reconciliation of GAAP to Non-GAAP Financial Information" for more detailed information regarding Non-GAAP financial information.

2019 Financial Guidance

Vanda reiterates its prior 2019 net product sales guidance and provides an update to Year-end 2019 Cash and expects to achieve the following financial objectives in 2019:

Full Year 2019 Financial Objectives	Full Year 2019 Guidance
Combined net product sales from both HETLIOZ® and Fanapt®	$215 to $225 million
HETLIOZ® net product sales	$137 to $143 million
Fanapt® net product sales	$78 to $82 million
Year-end 2019 Cash	Greater than $275 million as compared to prior guidance of Greater than $260 million

Conference Call

Vanda has scheduled a conference call for today, Wednesday, July 31, 2019, at 4:30 PM ET. During the call, Vanda's management will discuss the second quarter 2019 financial results and other corporate activities. Investors can call 1-866-688-9426 (domestic) or 1-409-216-0816 (international) and use passcode 2589983. A replay of the call will be available on Wednesday, July 31, 2019, beginning at 7:30 PM ET and will be accessible until Wednesday, August 7, 2019, at 7:30 PM ET. The replay call-in number is 1-855-859-2056 for domestic callers and 1-404-537-3406 for international callers. The passcode number is 2589983.

The conference call will be broadcast simultaneously on Vanda's website, www.vandapharma.com. Investors should click on the Investor Relations tab and are advised to go to the website at least 15 minutes early to register, download, and install any necessary software or presentations. The call will also be archived on Vanda's website for a period of 30 days.

Non-GAAP Financial Information

Vanda believes that the Non-GAAP financial information provided in this press release can assist investors in understanding and assessing the ongoing economics of Vanda's business and reflect how it manages the business internally and sets operational goals. Vanda's "Non-GAAP Selling, general and administrative expenses" and "Non-GAAP Research and development expenses" exclude stock-based compensation. Vanda's "Non-GAAP Net income," "Non-GAAP Net income per share" and "Non-GAAP Operating expenses excluding Cost of goods sold" exclude stock-based compensation and intangible asset amortization.

Vanda believes that excluding the impact of these items better reflects the recurring economic characteristics of its business, as well as Vanda's use of financial resources and its long-term performance.

These Non-GAAP financial measures, as presented, may not be comparable to similarly titled measures reported by other companies since not all companies may calculate these measures in an identical manner and, therefore, they are not necessarily an accurate measure of comparison between companies.

The presentation of these Non-GAAP financial measures is not intended to be considered in isolation or as a substitute for guidance prepared in accordance with GAAP. The principal limitation of these Non-GAAP financial measures is that they exclude significant elements that are required by GAAP to be recorded in Vanda's financial statements. In addition, they are subject to inherent limitations as they reflect the exercise of judgments by management in determining these Non-GAAP financial measures. In order to compensate for these limitations, Vanda presents its Non-GAAP financial guidance in connection with its GAAP guidance. Investors are encouraged to review the reconciliation of our Non-GAAP financial measures to their most directly comparable GAAP financial measure.

About Vanda Pharmaceuticals Inc.

Vanda is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release, including, but not limited to, the guidance provided under "2019 Financial Guidance" above, are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's assumptions regarding its ability to continue to grow its business in the U.S., Vanda's ability to complete the clinical development and obtain regulatory approval of tradipitant for the treatment of motion sickness, gastroparesis and/or chronic pruritus in atopic dermatitis, the outcome of the lawsuit initiated by Vanda against the FDA relating to tradipitant, Vanda's discussion and potential resolution of the deficiencies that the FDA believes are contained in the sNDA for HETLIOZ® for the treatment of jet lag disorder and Vanda's ability to obtain marketing approval for the use of HETLIOZ® in the treatment of jet lag disorder following any such resolution, Vanda's ability to complete the clinical development, submit an sNDA and obtain regulatory approval of tasimelteon for the treatment of sleep disorders in patients with SMS and other

factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2018 and quarterly report on Form 10-Q for the quarter ended March 31, 2019, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's quarterly report on Form 10-Q for the quarter ended June 30, 2019, to be filed with the SEC in the third quarter of 2019. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30 2019	June 30 2018	June 30 2019	June 30 2018
Revenues:				
HETLIOZ® product sales, net	$ 37,835	$ 28,045	$ 66,792	$ 53,468
Fanapt® product sales, net	21,225	19,305	39,981	37,474
Total revenues	59,060	47,350	106,773	90,942
Operating expenses:				
Cost of goods sold excluding amortization	6,368	5,213	11,481	9,773
Research and development	10,950	9,866	24,228	19,282
Selling, general and administrative	31,468	27,960	62,497	54,782
Intangible asset amortization	379	398	759	750
Total operating expenses	49,165	43,437	98,965	84,587
Income from operations	9,895	3,913	7,808	6,355
Other income	1,649	788	3,134	1,410
Income before income taxes	11,544	4,701	10,942	7,765
Provision for income taxes	18	90	28	88
Net income	$ 11,526	$ 4,611	$ 10,914	$ 7,677
Net income per share, basic	$ 0.22	$ 0.09	$ 0.21	$ 0.16
Net income per share, diluted	$ 0.21	$ 0.09	$ 0.20	$ 0.15
Weighted average shares outstanding, basic	53,101,499	52,172,982	52,928,101	49,270,829
Weighted average shares outstanding, diluted	54,579,982	53,945,640	54,932,932	51,101,464

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30 2019 (1)	December 31 2018 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,543	$ 61,005
Marketable securities	233,618	196,355
Accounts receivable, net	23,890	28,780
Inventory	1,057	994
Prepaid expenses and other current assets	10,694	11,998
Total current assets	315,802	299,132
Marketable securities, non-current	12,517	-

Property and equipment, net	4,240	4,417
Operating lease right-of-use assets	11,718	-
Intangible assets, net	23,783	24,542
Non-current inventory and other	4,423	4,039
Total assets	$ 372,483	$ 332,130

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued liabilities	$ 29,307	$ 21,584
Product revenue allowances	33,269	31,231
Milestone obligations under license agreements	-	200
Total current liabilities	62,576	53,015
Operating lease non-current liabilities	12,992	-
Other non-current liabilities	221	3,693
Total liabilities	75,789	56,708
Stockholders' equity:		
Common stock	53	52
Additional paid-in capital	621,559	611,587
Accumulated other comprehensive income	386	1
Accumulated deficit	(325,304)	(336,218)
Total stockholders' equity	296,694	275,422
Total liabilities and stockholders' equity	$ 372,483	$ 332,130

(1)With the adoption of Accounting Standards Codification Subtopic ASC 842, Leases, on January 1, 2019, Vanda recognized operating lease liabilities and right-of-use assets. Prior period financial statements were not recast for the new leasing standard. Please refer to footnote 2 in the quarterly report on Form 10-Q for the quarter ended June 30, 2019, to be filed in the third quarter of 2019, for more information.

VANDA PHARMACEUTICALS INC.
Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except for share and per share amounts)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30 2019	June 30 2018	June 30 2019	June 30 2018
Net income	$ 11,526	$ 4,611	$ 10,914	$ 7,677
Adjustments:				
Stock-based compensation	3,101	2,721	6,383	5,872
Intangible asset amortization	379	398	759	750
Non-GAAP Net income	$ 15,006	$ 7,730	$ 18,056	$ 14,299
Non-GAAP Net income per share, basic	$ 0.28	$ 0.15	$ 0.34	$ 0.29
Weighted average shares outstanding, basic	53,101,499	52,172,982	52,928,101	49,270,829
Operating expenses	$ 49,165	$ 43,437	$ 98,965	$ 84,587
Adjustments:				
Cost of goods sold excluding amortization	(6,368)	(5,213)	(11,481)	(9,773)
Stock-based compensation	(3,101)	(2,721)	(6,383)	(5,872)
Intangible asset amortization	(379)	(398)	(759)	(750)
Non-GAAP Operating expenses excluding Cost of goods sold	$ 39,317	$ 35,105	$ 80,342	$ 68,192
Research and development	$ 10,950	$ 9,866	$ 24,228	$ 19,282
Adjustment:				
Stock-based compensation	(756)	(316)	(1,484)	(637)
Non-GAAP Research and development	$ 10,194	$ 9,550	$ 22,744	$ 18,645
Selling, general and administrative	$ 31,468	$ 27,960	$ 62,497	$ 54,782
Adjustment:				
Stock-based compensation	(2,345)	(2,405)	(4,899)	(5,235)
Non-GAAP Selling, general and administrative	$ 29,123	$ 25,555	$ 57,598	$ 49,547

COMPANY CONTACT:
Jim Kelly
Executive Vice President & Chief Financial Officer
Vanda Pharmaceuticals Inc.
(202) 734-3428
jim.kelly@vandapharma.com

View original content:http://www.prnewswire.com/news-releases/vanda-pharmaceuticals-reports-second-quarter-2019-financial-results-300894361.html

SOURCE Vanda Pharmaceuticals Inc.