

Cadence Pharmaceuticals Reports Third Quarter 2013 Financial Results

November 5, 2013

SAN DIEGO, Nov. 5, 2013 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (NASDAQ: CADX), a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, today reported financial results for the three and nine months ended September 30, 2013.

Highlights for the third quarter of 2013 included:

- Net product revenue for the third quarter of 2013 was \$29.0 million, representing increases of \$15.1 million, or 109%, from the third quarter of 2012, and \$4.3 million, or 17%, from the second quarter of 2013.
- Gross margin on sales of OFIRMEV was 66% for the third quarter of 2013, compared to 56%, for the third quarter of 2012.
- The number of unique end-user customer accounts that ordered OFIRMEV during the third quarter of 2013 increased 33% as compared to the same period in 2012.
- The average order size per end-user customer increased 22% during the third quarter of 2013 as compared to the third quarter of 2012.
- The average number of orders per end-user customer increased approximately 8% during the third quarter of 2013, as compared to the third quarter of 2012.

"We maintained our strong performance during the third quarter, with OFIRMEV continuing to gain market share and posting year-over-year sales growth of more than 100% in each quarter of 2013," said Ted Schroeder, President and CEO of Cadence. "In addition, our disciplined approach to controlling expenses has enabled us to reduce our cash burn despite the legal expenses we continue to incur to defend the intellectual property covering OFIRMEV."

Financial Results

Cadence's net product revenue for the three months ended September 30, 2013 was \$29.0 million, an increase of 109%, from the \$13.9 million in net product revenue recognized for the three months ended September 30, 2012. For the nine months ended September 30, 2013, Cadence's net product revenue was \$77.2 million, an increase of 134% from the \$33.0 million reported for the same period in 2012.

For the three months ended September 30, 2013, Cadence reported a net loss of \$6.9 million, or \$0.08 per share, compared to a net loss of \$15.9 million, or \$0.19 per share, for the comparable period in 2012. For the nine months ended September 30, 2013, Cadence reported a net loss of \$20.2 million, or \$0.24 per share, compared to \$59.6 million, or \$0.70 per share, for the nine months ended September 30, 2012. Included in the company's net loss for the nine months ended September 30, 2013, was a gain of \$7.7 million recorded with respect to the waiver, termination and sale of Cadence's Incline assets in January 2013, for which the company received cash payments totaling \$14.7 million.

The Company's gross margin on sales of OFIRMEV for the three months ended September 30, 2013, was 66%, compared to 56% for the same period in 2012. For the nine months ended September 30, 2013, Cadence reported a gross margin of 66%, compared to 51% for the same period in 2012. These year-over-year increases were primarily the result of lower freight costs in 2013 and the impact of price increases implemented in 2012 and 2013. Operating expenses, including patent amortization, increased \$2.2 million, or 10%, for the three months ended September 30, 2013, to \$24.8 million, from \$22.6 million for the same period in 2012. This increase was primarily attributable to higher legal expenses related to the company's intellectual property litigation and the timing of marketing programs, partially offset by lower research and development expenses. For the nine months ended September 30, 2013, Cadence reported operating expenses of \$75.4 million, an increase of \$2.1 million, or 3%, as compared to \$73.3 million for the same period in 2012. This increase was primarily attributable to higher legal expenses and corporate development activities, partially offset by lower selling and research and development expenses.

As of September 30, 2013, Cadence held cash, cash equivalents and short-term investments of \$54.3 million, a decrease of \$2.5 million from \$56.8 million at June 30, 2013, and \$7.8 million from \$62.1 million at December 31, 2012. Net accounts receivable at September 30, 2013, was \$8.7 million, representing less than 30 days of sales outstanding.

Guidance

As of November 5, 2013, Cadence expects that net product revenue from sales of OFIRMEV for the twelve months ending December 31, 2013, will range between \$107.0 million and \$109.0 million. This change represents an increase from the company's prior guidance range of net product revenue between \$103.0 million to \$105.0 million.

Conference Call and Webcast on November 5, 2013, at 1:30 p.m. Pacific Time (4:30 p.m. Eastern Time)

Cadence will host a conference call on November 5, 2013, at 1:30 p.m. Pacific Time (4:30 p.m. Eastern Time) and interested investors may participate in the conference call by dialing (877) 303-9145 (domestic) or (760) 536-5203 (international). To access the webcast, please visit the company's website at <u>www.cadencepharm.com</u> and go to the Investors page. A replay of the webcast will be available approximately two hours after the call and remain available on the company's website until the next quarterly financial results call. Cadence uses the Investors portion of its website as one

means of disclosing material non-public information, and investors are encouraged to monitor Cadence's website in addition to following the company's press releases, SEC filings and public conference calls and webcasts.

About OFIRMEV[®] (Acetaminophen) Injection

OFIRMEV (acetaminophen) injection (1000 mg / 100 mL, 10 mg / mL; for intravenous use only), Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen, is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. The FDA approval of OFIRMEV was based on data from clinical trials in approximately 1,020 adult and 355 pediatric patients. These trials included two studies evaluating the safety and effectiveness of OFIRMEV in the treatment of pain, and one study evaluating OFIRMEV in the treatment of fever. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age.

Important Safety Information

RISK OF MEDICATION ERRORS AND HEPATOTOXICITY

Take care when prescribing, preparing, and administering OFIRMEV injection to avoid dosing errors which could result in accidental overdose and death.

OFIRMEV contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment. Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur, or at the first appearance of skin rash. Do not use in patients with acetaminophen allergy.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. The antipyretic effects of OFIRMEV may mask fever in patients treated with postsurgical pain. OFIRMEV is approved for use in patients \geq 2 years of age. Do not exceed the recommended maximum daily dose of OFIRMEV. OFIRMEV should be administered only as a 15-minute infusion.

For more information, please see the full OFIRMEV Prescribing Information, including the complete boxed warning, which is available at <u>www.OFIRMEV.com</u> or <u>www.cadencepharm.com</u>.

About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. The current version of Cadence Pharmaceuticals' corporate overview may be viewed on the Investors page of www.cadencepharm.com under "Events & Presentations" by selecting "Corporate Overview."

Forward-Looking Statements

Statements included in this press release and Cadence's conference call that are not a description of historical facts are forward-looking statements. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements, and are based on Cadence's current beliefs and expectations. Such statements include, without limitation, statements regarding: Cadence's belief that OFIRMEV is continuing to gain market share; the company's ongoing intellectual property litigation and related expenses; and the company's guidance regarding anticipated net product revenue from sales of OFIRMEV for the twelve months ending December 31, 2013. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cadence's actual future results may differ materially from Cadence's current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence's dependence on the successful commercialization of OFIRMEV, which is the company's only product; Cadence's ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; Cadence's dependence on its contract manufacturers and its ability to ensure an adequate and continued supply of OFIRMEV to meet market demand; Cadence's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including in current intellectual property litigation with the parties that have submitted new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that Cadence may be required to continue intellectual property litigation for substantial lengths of time or file additional lawsuits to defend its patent rights from challenges by companies that have submitted NDAs or ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential introduction of generic competition to OFIRMEV in the event Cadence is unsuccessful in current or future intellectual property litigation, and the impact it may have on the sales and pricing of the product; Cadence's dependence on its licensors for the maintenance and enforcement of its intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products Cadence may in-license or acquire; Cadence's ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to its commercial activities; public concern regarding the safety of drug products such as OFIRMEV, and the potential implementation by regulatory agencies of new requirements to include unfavorable information in the labeling for OFIRMEV; the risk that Cadence may not be able to raise sufficient capital when needed, or at all; and other risks detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are gualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

Cadence[®] and $OFIRMEV^{®}$ are trademarks of Cadence Pharmaceuticals, Inc.

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CADENCE PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months EndedNine Months Ended					
	September 30,		September 30,			
	2013	2012	2013	2012		
Revenues:						
Product revenue, net	\$ 28,957	\$ 13,898	\$ 77,243	\$ 32,977		
License revenue	-	-	-	33		
Total revenues	28,957	13,898	77,243	33,010		
Costs and expenses:						
Cost of product sales	9,964	6,076	26,425	16,078		
Amortization of patent license	336	336	1,008	1,008		
Research and development	1,655	2,235	4,698	5,446		
Selling, general and administrative	22,928	20,039	70,261	66,811		
Other	(107)	13	(602)	14		
Total costs and expenses	34,776	28,699	101,790	89,357		
Loss from operations	(5,819)	(14,801)	(24,547)	(56,347)		
Other (expense) income, net	(1,119)	(1,089)	4,371	(3,205)		
Net loss	\$ (6,938)	\$ (15,890)	\$ (20,176)\$ (59,552)		
Basic and diluted net loss per share	e\$ (0.08)	\$ (0.19)	\$ (0.24)	\$ (0.70)		
Shares used to compute basic and						
diluted net loss per share	86,044	85,560	85,841	85,544		

CADENCE PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30,December 31,					
	2013	2012				
	(unaudited)					
Assets						
Current assets:						
Cash, cash equivalents and short-term investment	s\$ 54,306	\$ 62,072				
Restricted cash	548	640				
Accounts receivable, net	8,711	6,152				
Inventory	6,094	6,498				
Prepaid expenses and other current assets	1,307	1,154				
Total current assets	70,966	76,516				
Property and equipment, net	1,801	1,967				
Intangible assets, net	11,082	12,090				
Other assets	175	7,106				
Total assets	\$ 84,024	\$ 97,679				
Liabilities and Stockholders' Equity						
Current liabilities:						
Accounts payable	\$ 4,473	\$ 5,796				
Accrued liabilities	15,379	12,969				
Deferred revenue	-	2,234				
Current portion of long-term debt, less discount	7,937	-				
Total current liabilities	27,789	20,999				
Other liabilities	604	51				
Long-term debt, less discount	21,251	28,818				
Total stockholders' equity	34,380	47,811				
Total liabilities and stockholders' equity	\$ 84,024	\$ 97,679				

SOURCE Cadence Pharmaceuticals, Inc.

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