

# Cadence Pharmaceuticals Reports Fourth Quarter and Full Year 2012 Financial Results

March 7, 2013

#### -- 2012 Net Product Revenue Exceeds \$50 Million --

SAN DIEGO, March 7, 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 fourth quarter and full year ended December 31, 2012.

For the fourth quarter of 2012, Cadence reported net product revenue from sales of OFIRMEV<sup>®</sup> (acetaminophen) injection of \$17.1 million, nearly three times the amount reported for the fourth quarter of 2011. Additionally, during the fourth quarter of 2012, the company entered into an agreement to terminate its option to purchase Incline Therapeutics, Inc., in connection with the sale of Incline to a third party. As a result, Cadence received a payment of \$13.1 million for the waiver of its option plus an additional \$1.5 million for the shares of Incline stock held by the company in connection with the closing of the transaction in January 2013. Other recent highlights include the following:

- Net product revenue for the fourth quarter of 2012 was \$17.1 million, an increase of \$3.2 million, or 23%, from the \$13.9 million in net product revenue received during the third quarter of 2012.
- Net product revenue for the twelve months ended December 31, 2012, was \$50.1 million, more than four times the \$11.5 million in net product revenue reported for 2011.
- The company had over 3,750 unique customer accounts as of December 31, 2012, an increase of 8% from the third guarter of 2012, and 66% from the fourth guarter of 2011.
- The average number of orders per customer increased more than 16% for the fourth quarter of 2012 as compared to the fourth quarter of 2011. Further, the average order size during the same period increased approximately 40%.
- The gross margin on sales of OFIRMEV was 58% for the fourth quarter of 2012, an improvement of 200 basis points from the third quarter of 2012.
- An amendment to the company's credit facility in December 2012 delayed the commencement of principal payments by one year, from January 1, 2013, to January 1, 2014, deferring approximately \$11.0 million in principal payments originally scheduled for 2013
- On February 28, 2013, Cadence announced an extension of its existing supply agreement for OFIRMEV with Lawrence Laboratories, a member of the Bristol-Myers Squibb Company group of companies, from April 2014 to December 2018.
- On March 4, 2013, the company entered into an agreement with Laboratorios Grifols, S.A., for the development,
  manufacture and supply of commercial quantities of OFIRMEV in flexible plastic bags. Grifols has supplied intravenous
  acetaminophen to BMS in flexible plastic bags for distribution in certain markets outside of the U.S. and Canada since
  2010. Cadence plans to submit a supplemental NDA to the FDA in the second half of 2013 seeking approval of the
  product to be manufactured by Grifols.
- On March 6, 2013, Cadence and Baxter Healthcare Corporation announced the termination of the development and supply
  agreement for OFIRMEV between the two companies.

Ted Schroeder, President and CEO of Cadence, stated, "Our fourth quarter 2012 revenue exceeded our guidance as we ended the year with strong sales growth and momentum. We continue to expand our customer base and drive higher OFIRMEV utilization rates as physicians increasingly recognize that a balanced, multimodal approach to perioperative analgesia can reduce opioid consumption. We believe that OFIRMEV has a compelling position in such a multimodal strategy."

Mr. Schroeder continued, "Along with our strong sales performance during the year, the monetization of our investment in Incline and the amendment of our credit facility helped to further strengthen our balance sheet as we achieve steady progress toward cash flow breakeven."

#### **Financial Results**

For the three months ended December 31, 2012, Cadence reported net product revenue of \$17.1 million, an increase of \$11.2 million from the \$5.9 million of net product revenue reported for the three months ended December 31, 2011. For the twelve months ended December 31, 2012, the company reported net product revenue of \$50.1 million, an increase of \$38.6 million from the \$11.5 million of net product revenue reported for 2011. Additionally, the company reported \$0.1 million in licensing revenue during 2012, as compared to \$5.2 million reported for 2011, primarily related to Cadence's data license agreement with Terumo Corporation, which intends to seek regulatory approval in Japan for the same intravenous formulation of acetaminophen as OFIRMEV.

For the three months ended December 31, 2012, Cadence reported a net loss of \$21.4 million, or \$0.25 per share, compared to a net loss of \$27.6

million, or \$0.37 per share, for the comparable period in 2011. For the twelve months ended December 31, 2012, the company's net loss was \$81.0 million, or \$0.95 per share, compared to a net loss of \$93.0 million, or \$1.41 per share, for the comparable period in 2011.

The net loss for each of the three and twelve months ended December 31, 2012, includes impairment charges and a loss on the sale of equipment totaling \$8.6 million pertaining to certain assets involved with the manufacture of OFIRMEV under the terminated development and supply agreement with Baxter. Additionally, the Company recognized disposal costs of \$0.3 million during the fourth quarter of 2012 for the inventory held as part of its manufacturing suspension at Baxter. Excluding these one-time charges, the company's net loss would have been \$12.5 million, or \$0.15 per share, for the three months ended December 31, 2012, and \$72.1 million, or \$0.84 per share, for the twelve months ended December 31, 2012.

The cost of product sales, as a percentage of sales, for the three and twelve months ended December 31, 2012, was 42% and 46%, respectively. The reduction in costs for the fourth quarter of 2012 as compared to the full year was primarily attributable to expedited freight costs and an inventory write-down that occurred during the first quarter of 2012. In 2012, the company also improved efficiencies as a result of increased production volumes and a higher net product selling price resulting from a price increase that was implemented in July 2012. The company's cost of product sales during 2012 was negatively impacted by unabsorbed manufacturing costs incurred as a result of idle manufacturing assets held at Baxter.

Research and development expenses for the three months ended December 31, 2012, decreased by \$0.8 million to \$1.1 million, from \$1.9 million for the comparable period in 2011. This reduction was primarily attributable to a workforce restructuring implemented in the fourth quarter of 2011, partially offset by clinical trial expenses incurred during this period in 2012 that were not incurred during 2011. For the twelve months ended December 31, 2012, research and development expenses decreased by \$2.4 million to \$6.5 million, from \$8.9 million for 2011. This reduction was primarily attributable to a workforce restructuring implemented in the fourth quarter of 2011, partially offset by clinical trial expenses incurred in 2012 that were not incurred during 2011, as well as severance obligations related to the departure of two of the company's officers in the third quarter of 2012.

Selling, general and administrative costs for the three months ended December 31, 2012, were \$20.0 million compared to \$20.5 million for the comparable period in 2011. This reduction was primarily a result of lower sales and marketing expenses incurred during the fourth quarter of 2012, as compared to the same period 2011, and was partially offset by higher legal fees incurred during the fourth quarter of 2012 as compared to the same period in 2011. For the twelve months ended December 31, 2012, selling, general and administrative expenses increased by \$5.3 million to \$86.8 million, from \$81.5 million for 2011. This increase was mostly attributable to additional legal costs incurred in 2012 related to the company's ongoing intellectual property litigation, increased commissions earned by Cadence's hospital sales specialists as a result of higher sales levels, and additional costs incurred in connection with product distribution and related services. These increases were partially offset by lower medical affairs and marketing costs.

As of December 31, 2012, Cadence reported cash, cash equivalents and short-term investments of \$62.1 million. This figure does not include the \$14.6 million of cash received by the company in early January 2013 in connection with the waiver of its option to acquire Incline and the sale of its shares of Incline stock. Net accounts receivable at December 31, 2012, was \$6.2 million.

## Guidance

As of March 7, 2013, Cadence expects that net product revenue from sales of OFIRMEV for the twelve months ending December 31, 2013, will range from \$94.0 million to \$100.0 million.

#### Conference Call and Webcast on March 7, 2013 at 5:30 a.m. Pacific Time (8:30 a.m. Eastern Time)

Cadence management will host a conference call on March 7, 2013, at 5:30 a.m. Pacific Time (8:30 a.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 <a href="https://www.cadencepharm.com">www.cadencepharm.com</a> 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

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. 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. OFIRMEV should be administered only as a 15-minute intravenous infusion. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. 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 for post-surgical pain.

For more information, please see the complete OFIRMEV Prescribing Information, available at www.OFIRMEV.com or www.cadencepharm.com.

# **Non-GAAP Financial Measures**

This press release provides financial measures for net loss and basic and diluted loss per share that exclude specifically identified non-routine items,

and are therefore not calculated in accordance with accounting principles generally accepted in the United States ("GAAP"). Management believes that these non-GAAP financial measures provide meaningful supplemental information regarding its performance that enhances management's and investors' ability to evaluate Cadence's operating results.

These non-GAAP financial measures are not intended to be used in isolation and should not be considered a substitute for any other performance measure determined in accordance with GAAP. Investors and potential investors are cautioned that there are material limitations associated with the use of non-GAAP financial measures as an analytical tool, including that other companies may calculate similar non-GAAP financial measures differently than Cadence, limiting their usefulness as a comparative tool. Cadence compensates for these limitations by providing specific information regarding the GAAP amount excluded from the non-GAAP financial measures. Cadence further compensates for the limitations of its use of non-GAAP financial measures by presenting comparable GAAP measures more prominently. Investors and potential investors are encouraged to review the calculation of non-GAAP financial measures contained within this press release with Cadence's GAAP net income and basic and diluted loss per share.

### 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 <a href="https://www.cadencepharm.com">www.cadencepharm.com</a> 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 plan to submit a supplemental new drug application for OFIRMEV in flexible plastic bags in the second half of 2013; the company's belief that it will continue to expand its customer base and drive higher OFIRMEV utilization rates; Cadence's progress toward cash flow breakeven; and the company's guidance regarding 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 patent litigation with the parties that have submitted abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that Cadence may be required to continue patent litigation for substantial lengths of time or file additional lawsuits to defend its patent rights from challenges by companies that have submitted 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 patent litigation; 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, which could result in the 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 qualified 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.

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# CADENCE PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Revenue:				
Product revenue, net	\$ 17,089	\$ 5,889	\$ 50,066	\$ 11,486
License revenues	85		118	5,210
Total revenues	17,174	5,889	50,184	16,696
Costs and synances				
Costs and expenses:  Cost of product sales	7.178	8,818	23,256	12,406
Amortization of patent license	335	335	23,236 1.343	
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Research and development	1,073	1,883	6,519	8,885
Selling, general and administrative	20,032	20,501	86,843	81,504
Impairment of long-lived assets	7,723	-	7,723	-

Other	1,160	1,077	1,174	1,076
Total costs and expenses	37,501	32,614	126,858	105,438
Loss from operations	(20,327)	(26,725)	(76,674)	(88,742)
Other expense, net	(1,094)	(881)	(4,299)	(4,279)
Net loss	\$ (21,421)	\$ (27,606)	\$ (80,973)	\$ (93,021)
Basic and diluted net loss per share <sup>(1)</sup>	\$ (0.25)	\$ (0.37)	\$ (0.95)	\$ (1.41)
Shares used to compute basic and diluted net loss per share <sup>(1)</sup>	85,591	73,982	85,556	66,075

<sup>(1)</sup> There is a lack of comparability in the per share amounts between the periods presented as a result of the issuance of 21,800,000 shares of common stock pursuant to a public offering in November 2011.

CADENCE PHARMACEUTICALS, INC.

## CADENCE PHARMACEUTICALS, INC CONDENSED BALANCE SHEETS (in thousands)

	December 31, 2012	December 31, 2011
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 62,072	\$ 127,227
Restricted cash	640	450
Accounts receivable, net	6,152	2,208
Inventory	6,498	1,388
Prepaid expenses and other current assets	1,154	1,161
Total current assets	76,516	132,434
Property and equipment, net	1,967	10,569
Intangible assets, net	12,090	13,433
Restricted cash	-	190
Other assets	7,106	7,039
Total assets	\$ 97,679	\$ 163,665
Liabilities and Stockholders' Equity		
Current liabilities:	Ф. Г. <b>7</b> 00	<b>#</b> 0.004
Accounts payable	\$ 5,796	\$ 3,801
Accrued liabilities	12,969	10,450
Deferred revenue	2,234	1,291
Total current liabilities	20,999	15,542
Other liabilities	51	117
Long-term debt, less discount	28,818	28,696
Total stockholders' equity	47,811	119,310
Total liabilities and stockholders' equity	\$ 97,679	\$ 163,665
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