



Optimer Reports Fourth Quarter and Fiscal Year 2011 Financial Results

Optimer reports \$145 million in revenues and net income of \$7.8 million

SAN DIEGO, March 7, 2012 /PRNewswire/ -- Optimer Pharmaceuticals, Inc. (NASDAQ: OPTR) announced today financial results for the fourth quarter and fiscal year ended December 31, 2011, and provided an update on the DIFICID® (fidaxomicin) launch for the first two months of 2012.

2011 Financial Highlights

- Total revenues in 2011 were \$145 million, compared to \$1.5 million in 2010
- DIFICID net sales in 2011 were \$21.5 million, compared to no DIFICID sales in 2010
- DIFICID net sales in the fourth quarter were \$11.0 million

"2011 was a highly successful year that saw the FDA approval and U.S. launch of DIFICID as well as European approval. The early launch is highly impactful and we believe interest in DIFICID from physicians, payors and hospitals, coupled with the benefit it can provide patients, will translate into robust growth in product adoption and sales as the launch matures," said Pedro Lichtinger, Optimer's President and CEO. "In 2012 we are starting a series of additional initiatives to support further growth, including a focus on the Long Term Care market, improving access, initiating clinical trials intended to expand our label, and entering new markets including Europe through our collaboration with Astellas and Canada through a direct commercialization effort."

Fourth Quarter and Fiscal Year 2011 Financials:

For the fiscal year 2011 total revenues were \$145 million, compared to \$1.5 million for the fiscal year 2010. Total revenues for the fourth quarter 2011 were \$64.6 million, compared with \$156,000 for the fourth quarter 2010. The increases in revenues were primarily due to an upfront payment received from Astellas Pharma Europe in the first quarter and an EMA approval milestone earned in the fourth quarter in connection with the DIFICID license agreement in Europe, as well as the July 18, 2011 commercial launch of DIFICID in the United States.

DIFICID net product sales were \$21.5 million and \$11 million for the fiscal year 2011 and fourth quarter, respectively. Optimer recognizes product sales of DIFICID upon delivery of product to its wholesalers.

Selling, general and administrative (SG&A) expense for the fiscal year 2011 was \$87.1 million, compared to \$17.6 million for the fiscal year 2010. The increase in 2011 was primarily related to the commercial infrastructure build-up for the launch of DIFICID as well as a significant increase in related marketing expenses. Approximately 100 hospital account managers were hired in mid- 2011 which significantly increased compensation expenses and related personnel costs. In addition, the Company expensed \$6.6 million related to the Cubist service fee as part of its co-promotion agreement. SG&A expense for the fourth quarter of 2011 was \$33.6 million, compared to \$5.7 million for the fourth quarter of 2010. The increase in the fourth quarter was again related to the commercial infrastructure build-up and related marketing expenses, the Cubist service fee, the initial build-up of the Canadian subsidiary's commercial infrastructure, and legal and consulting services related to DIFICID international expansion. In addition, the fourth quarter of 2011 also included \$3.0 million of non-recurring one-time expenses for compensation related matters including \$1.8 million of non-cash stock compensation expense.

R&D expense for the fiscal year 2011 was \$43.1 million, compared to \$32.8 million for 2010. The increase was primarily due to higher health economics and outcomes research, medical affairs, pharmacovigilance, and publication expenses, as well as higher research and development expense by OBI, our Taiwan subsidiary, for its Phase 2/3 breast cancer clinical trial. The increase was partially offset by a \$5.0 million expense in 2010 related to a milestone payment due to Par for the successful completion of the second DIFICID Phase 3 trial. Research and development expense for the fourth quarter of 2011 was \$14.0 million, compared to \$6.9 million for the fourth quarter of 2010. The increase was related to higher health economics and outcomes research as well as medical affairs expenses, DIFICID life cycle management planning, and preparation for a pediatric clinical trial.

For the fiscal year 2011, Optimer reported net income of \$7.8 million, or \$0.17 per share on both a basic and diluted basis, as compared to a net loss for the fiscal year of 2010 of \$47.3 million, or (\$1.25) per share on both a basic and diluted basis.

Net income for the fourth quarter of 2011 was \$13.4 million, or \$0.29 and \$0.28 per share on a basic and diluted basis, respectively, as compared to a net loss for the fourth quarter of 2010 of \$11.9 million, or (\$0.31) per share, on both a basic and diluted basis.

As of December 31, 2011, Optimer held cash, cash equivalents and short-term investments of \$110.6 million and had 46,689,951 shares outstanding.

2012 DIFICID Launch Update

Between January 1, 2012 and February 29, 2012, Optimer estimates approximately \$11.0 million in DIFICID gross sales, representing 3,931 DIFICID treatments shipped to wholesalers.

Additionally, as of February 29, 2012:

- Inventory levels at wholesalers remain within the range of 14 to 28 days of demand
- Approximately 1,400 hospitals had ordered DIFICID
- About 65% of hospitals covered by Optimer have reordered DIFICID
- More than 600 hospitals are estimated to have placed DIFICID on formulary

Optimer 2011 and Recent Highlights

- In December 2011, the EMA granted European marketing approval for DIFICLIR™ (fidaxomicin) tablets.
- In October 2011, Optimer established a Canadian subsidiary and appointed a country manager to support efforts to sell DIFICID directly into Canadian markets, if approved. In addition, the company filed a New Drug Submission to Health Canada for DIFICID for the treatment of CDAD and was granted a priority review from the Canadian authorities.
- In July 2011, Optimer announced the commercial launch of DIFICID tablets for the treatment of CDAD in patients 18 years of age and older.
- In May 2011, the U.S. Food and Drug Administration approved Optimer's antibacterial drug DIFICID® (fidaxomicin) tablets for the treatment of CDAD in adults 18 years of age and older.
- In April 2011, Optimer entered into a co-promotion agreement with Cubist Pharmaceuticals to market DIFICID in the U.S. in an effort to accelerate the DIFICID launch. Cubist's 180 hospital-based sales reps combined with Optimer's 100 sales reps are jointly promoting DIFICID to physicians, hospitals, long-term care facilities and other healthcare institutions.
- In February 2011, Optimer entered into a collaboration agreement with Astellas Pharma Europe Ltd. to develop and commercialize DIFICLIR in Europe and certain other countries in the Middle East, Africa, and the Commonwealth of Independent States. Under the agreement, Optimer is eligible to receive milestone payments of up to approximately \$224 million and of which \$69.2 million was received upfront, and a \$53.6 million milestone was recorded in the fourth quarter related to the EMA approval. The agreement provides Optimer tiered double-digit royalty payments on net sales of DIFICLIR in the Astellas territories.
- In February 2011, DIFICID North American Phase 3 trial results were published in The New England Journal of Medicine in an article titled, "Fidaxomicin versus Vancomycin for *Clostridium difficile* Infection," in the February 3, 2011 issue. In 2011 Optimer also had a series of other publications and presentations at medical and scientific conferences, including the publication of a Subgroup Analysis in the September 1, 2011 issue of Clinical Infectious Diseases demonstrating that DIFICID exhibited higher clinical cure and global cure rates than vancomycin in patients with CDAD receiving concomitant antibiotics.
- In January 2011, Optimer appointed former Chairman and CEO of Pfizer, Hank McKinnell, Ph.D., to Optimer's Board of Directors and in February 2012 he was appointed Lead Independent Director.

Conference Call and Webcast

The Company will host a conference call and webcast to discuss its fourth quarter 2011 and fiscal year 2011 financial results and provide a business overview, including DIFICID® sales, commercialization and development, today at 4:30 p.m. Eastern time (1:30 p.m. Pacific time).

The conference call may be accessed by dialing (877) 280-7280 for domestic callers and +1 (678) 825-8232 for international callers. Please specify to the operator that you would like to join "Optimer's Financial Results Call." The conference call will be webcast live under the "Investors" section of Optimer's website at www.optimerpharma.com, where it will be archived for 30 days following the call.

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a global biopharmaceutical company focused on discovering, developing and commercializing

innovative hospital specialty products that have a positive impact on society. Optimer developed and commercialized DIFICID® (fidaxomicin) tablets, an FDA-approved antibacterial drug for the treatment of adult patients with *Clostridium difficile*-associated diarrhea (CDAD). Optimer has also received marketing authorization for fidaxomicin tablets in the European Union under the trade name DIFICLIR™. The company is seeking marketing authorization for fidaxomicin in Canada and is exploring marketing authorization in other parts of the world where *C. difficile* has emerged as a serious health problem, including Asia. Additional information can be found at <http://www.optimerpharma.com>.

Forward-Looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements, including without limitation statements related to Optimer's expectations of future sales and adoption of DIFICID, projections regarding the results and trends of the DIFICID launch and expected label expansion as a result of new development efforts and clinical trials. Words such as "believes", "would", "anticipates", "plans", "expects", "may", "intend", "will", and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Optimer that any of its plans will be achieved. These forward-looking statements are based on management's expectations on the date of this release. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Optimer's business including, without limitation, risks relating to: Optimer's ability to continue driving adoption and use of DIFICID, the implementation and success of DIFICID growth initiatives and entry into new markets, the ability to expand indications included on DIFICID's label, the ability to successfully complete additional clinical trials and whether such trials will support an expanded label for DIFICID, whether healthcare professionals will prescribe DIFICID, the extent to which DIFICID receives reimbursement coverage from healthcare payers and government agencies, the extent to which DIFICID will be accepted on additional hospital formularies and the timing of hospital formulary decisions, Optimer's ability to successfully coordinate commercialization efforts with Cubist Pharmaceuticals under its co-promotion agreement, whether Optimer will be able to realize expected benefits under its co-promotion agreement with Cubist and its collaboration agreement with Astellas, the fact that past results may not be predictive of future results or performance, the possibility of alternative means of preventing or treating DIFICID impacting adoption and sales of DIFICID, Optimer's ability, through its third party manufacturers and logistics providers, to maintain a sufficient supply of DIFICID to meet demand, and other risks detailed in Optimer's filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date of this release, and Optimer undertakes no obligation to update or revise these statements, except as may be required by law.

Optimer Pharmaceuticals, Inc. Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenues:				
Product revenue, net	\$ 10,959,217	\$ -	\$ 21,511,037	\$ -
Licensing	53,584,000	-	122,749,000	-
Research grants and collaborative agreements	73,139	156,352	718,336	1,480,362
Total revenues	64,616,356	156,352	144,978,373	1,480,362
Operating expenses:				
Cost of product sales	909,843	-	1,525,798	-
Cost of licensing	3,310,821	-	7,584,353	-
Research and development	14,011,059	6,940,564	43,085,307	32,797,672
Selling, general and administrative	33,632,591	5,706,455	87,144,257	17,550,883
Total operating expenses	51,864,314	12,647,019	139,339,715	50,348,555
Income (loss) from operations	12,752,042	(12,490,667)	5,638,658	(48,868,193)
Interest income and other, net	63,337	227,899	290,870	329,290
Consolidated net income (loss)	\$ 12,815,379	\$(12,262,768)	\$ 5,929,528	\$(48,538,903)
Net loss attributable to noncontrolling interest	538,892	316,766	1,892,096	1,199,161
Net income (loss) attributable to Optimer Pharmaceuticals, Inc. common stockholders	\$ 13,354,271	\$(11,946,002)	\$ 7,821,624	\$(47,339,742)
Net income (loss) per share attributable to common stockholders - basic	\$ 0.29	\$ (0.31)	\$ 0.17	\$ (1.25)
Net income (loss) per share attributable to common stockholders - diluted	\$ 0.28	\$ (0.31)	\$ 0.17	\$ (1.25)
Shares used to compute net income (loss) per share attributable to common stockholders - basic	46,668,310	39,140,214	45,622,168	37,830,452
Shares used to compute net income (loss) per share attributable to common stockholders - diluted	47,527,766	39,140,214	46,369,683	37,830,452

Consolidated Balance Sheets

	Year Ended December 31,	
	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,787,512	\$ 19,861,924
Short-term investments	78,791,066	29,553,506
Trade accounts receivable, net	6,563,645	-
Accounts receivable, other	52,289,290	53,552
Inventory	3,947,380	-
Prepaid expenses and other current assets	3,781,830	463,307
Total current assets	177,160,723	49,932,289
Property and equipment, net	2,590,715	697,683
Long-term investments	882,000	882,000
Other assets	1,389,734	508,190
Total assets	<u>\$ 182,023,172</u>	<u>\$ 52,020,162</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,860,462	\$ 2,307,820
Accrued expenses	21,447,544	2,385,046
Total current liabilities	\$ 31,308,006	\$ 4,692,866
Deferred rent	151,141	141,138
Stockholders' equity	150,564,025	47,186,158
Total liabilities and stockholders' equity	<u>\$ 182,023,172</u>	<u>\$ 52,020,162</u>

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