



November 8, 2012

Affymax Reports Third Quarter 2012 Financial Results

PALO ALTO, Calif.--(BUSINESS WIRE)-- Affymax, Inc. (NASDAQ: AFFY) today reported financial results for the third quarter ended September 30, 2012. The net loss for the third quarter of 2012 was \$24.6 million (or (\$0.68) per share) compared to a net loss of \$9.8 million (or (\$0.28) per share) for the third quarter of 2011.

Affymax recognized total revenue for the quarter ended September 30, 2012, of \$13.6 million compared to \$13.2 million for the quarter ended September 30, 2011. Revenue for the quarter ended September 30, 2012 primarily consisted of a \$10.4 million profit equalization payment earned from its partner, Takeda Pharmaceutical Company Limited (Takeda) related to OMONTYS[®] (peginesatide) Injection product sales during the period. OMONTYS net product sales, as provided by Takeda, were \$15.0 million for the quarter. In addition, Affymax earned a \$2.25 million milestone payment from Takeda during the quarter as a result of the commercial progress achieved with OMONTYS during its product launch. Revenue for the quarter ended September 30, 2011 consisted of a \$10 million regulatory milestone payment from Takeda and pre-approval research and development and commercialization expenses reimbursable by Takeda.

Research and development expenses for the quarter ended September 30, 2012, were \$11.4 million compared to \$14.9 million for the quarter ended September 30, 2011. The decrease was primarily due to reduced consultant and personnel-related costs as a result of the completion of both the filing of the OMONTYS New Drug Application with the U.S. Food and Drug Administration (FDA) in May 2011 and the preparation for an FDA advisory committee meeting which occurred in December 2011. These decreases were partially offset by clinical trial activity for the company's Phase 3b trial during the current quarter.

Selling, general and administrative expenses for the quarter ended September 30, 2012, were \$26.2 million compared to \$8.2 million for the quarter ended September 30, 2011. The increase was primarily due to increases in commercial and medical affairs costs, including personnel-related costs associated with the establishment of its commercial and medical affairs field organizations, as the company continues to execute on the launch and commercialization of OMONTYS.

The company had cash and investments of \$100.0 million as of September 30, 2012.

Updated Financial Guidance

Affymax is updating its financial guidance for 2012. With respect to collaboration revenue, Affymax has earned milestone payments of \$60.3 million and is not expecting additional milestone payments in 2012, consistent with its previously issued guidance. Affymax is not providing profit equalization payment or OMONTYS net product sales guidance for 2012.

With respect to operating expenses, Affymax now expects to incur \$130 million to \$135 million in total operating expenses for 2012, excluding stock based compensation. This reduction from the previously issued operating expense guidance of \$135 million to \$145 million for 2012 is primarily driven by lower than expected increases in selling, general and administrative expenses as a result of cost savings.

"We continue to be pleased with our commercial progress since the launch of OMONTYS in the second quarter of this year," said John Orwin, chief executive officer of Affymax. "A number of dialysis providers are evaluating the conversion process and experience with OMONTYS, including a key large dialysis organization and four medium dialysis organizations, while some of the smaller dialysis providers have completely converted centers to the once-monthly drug."

Conference Call with Management Today

Management will host a teleconference and webcast to provide a general business overview, as well as to discuss third quarter 2012 financial results today, November 8, 2012, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time).

Interested parties can listen to the live teleconference by dialing (866) 393-1565 from the U.S. or +1 (973) 409-9608 for international callers. Individuals may access the live audio webcast by visiting: <http://www.investors.affymax.com/events.cfm>. A replay of the webcast will be available on the Company's website for 30 days following the live event.

About Affymax, Inc.

Affymax, Inc. is a biopharmaceutical company based in Palo Alto, California. Affymax's mission is to discover, develop and deliver innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening

illnesses.

The company's first marketed product, OMONTYS® (peginesatide) Injection, was approved by the U.S. Food and Drug Administration (FDA) in March 2012. For additional information, please visit www.affymax.com.

This release contains forward-looking statements, including statements regarding financial projections and condition, the continuation and success of the Company's collaboration with Takeda and the commercialization of OMONTYS. The Company's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties, including risks relating to factors affecting the commercial potential of OMONTYS, the continued safety and efficacy of OMONTYS, industry and competitive environment, regulatory requirements by the FDA or other regulatory authorities, including post-marketing studies, trials and Risk Evaluation and Mitigation Strategy, potential for disruptions to supply, financing requirements and ability to access capital, and other matters that are described in Affymax's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to update any forward-looking statement in this press release.

AFFYMAX, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2012	December 31, 2011
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 89,169	\$ 54,339
Short-term investments	9,684	44,165
Receivable from Takeda	9,710	6,937
Inventory	2,040	—
Deferred tax assets	351	351
Prepaid expenses and other current assets	7,267	1,828
Total current assets	118,221	107,620
Property and equipment, net	3,024	3,013
Restricted cash	1,135	1,135
Deferred tax assets, net of current	6,888	6,888
Other assets	3,481	339
Total assets	<u>\$ 132,749</u>	<u>\$ 118,995</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 3,766	\$ 941
Accrued liabilities	17,749	13,733
Accrued clinical trial expenses	2,500	3,365
Deposit from Takeda	559	1,998
Notes payable, current	2,766	—
Total current liabilities	27,340	20,037
Long-term income tax liability	10,513	10,411
Advance from Takeda	9,310	6,121
Deferred revenue	12,386	5,174
Notes payable, net of current	7,234	—
Other long-term liabilities	810	1,255
Total liabilities	67,593	42,998
Commitments and contingencies	—	—
Stockholders' equity		
Common stock: \$0.001 par value, 100,000,000 shares authorized, 36,663,946 and 35,733,181 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	37	36
Additional paid-in capital	540,560	526,244
Accumulated deficit	(475,442)	(450,301)
Accumulated other comprehensive income	1	18

Total stockholders' equity	65,156	75,997
Total liabilities and stockholders' equity	<u>\$ 132,749</u>	<u>\$ 118,995</u>

AFFYMAX, INC.
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share data)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Revenue:				
Collaboration revenue	\$ 13,603	\$ 13,204	\$ 79,562	\$ 44,029
License and royalty revenue	4	5	9	14
Total revenue	<u>13,607</u>	<u>13,209</u>	<u>79,571</u>	<u>44,043</u>
Operating expenses:				
Research and development	11,416	14,863	40,486	51,606
Selling, general and administrative	26,181	8,172	62,936	24,426
Total operating expenses	<u>37,597</u>	<u>23,035</u>	<u>103,422</u>	<u>76,032</u>
Loss from operations	(23,990)	(9,826)	(23,851)	(31,989)
Interest income	23	45	56	136
Interest expense	(668)	(38)	(1,316)	(111)
Other income (expense), net	(3)	3	(29)	39
Net loss before provision for income taxes	<u>(24,638)</u>	<u>(9,816)</u>	<u>(25,140)</u>	<u>(31,925)</u>
Provision for income taxes	—	—	(1)	(1)
Net loss	<u>\$ (24,638)</u>	<u>\$ (9,816)</u>	<u>\$ (25,141)</u>	<u>\$ (31,926)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.68)</u>	<u>\$ (0.28)</u>	<u>\$ (0.70)</u>	<u>\$ (0.98)</u>
Weighted-average number of shares used in computing basic and diluted net loss per share	<u>36,350</u>	<u>35,578</u>	<u>36,067</u>	<u>32,474</u>
Total comprehensive loss	<u>\$ (24,641)</u>	<u>\$ (9,844)</u>	<u>\$ (25,158)</u>	<u>\$ (31,915)</u>

AFFYMAX, INC.
COLLABORATION REVENUE
(in thousands)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
OMONTYS net product sales (as provided by Takeda)	\$ 15,008	\$ —	\$ 15,008	\$ —
Total Collaboration costs & expenses (1)	<u>23,406</u>	<u>—</u>	<u>42,920</u>	<u>—</u>
OMONTYS collaboration profit (loss)	<u>(8,398)</u>	<u>—</u>	<u>(27,912)</u>	<u>—</u>
Affymax share of collaboration profit (loss)	(4,199)	—	(13,956)	—
Net reimbursement of Affymax costs & expenses	<u>14,576</u>	<u>—</u>	<u>27,004</u>	<u>—</u>
Profit equalization payment earned by Affymax (2)	10,377	—	13,048	—
Milestone payments	2,250	10,000	60,250	10,000
Revenue previously deferred related to API	441	—	441	—
Revenue recognized under CAPM (3)	—	—	—	26,606
Net expense reimbursement after CAPM (4)	<u>535</u>	<u>3,204</u>	<u>5,823</u>	<u>7,423</u>
Total collaboration revenue	<u>\$ 13,603</u>	<u>\$ 13,204</u>	<u>\$ 79,562</u>	<u>\$ 44,029</u>

(1) Total Collaboration costs and expenses include costs incurred by Affymax and Takeda including amounts provided to us by Takeda.

- (2) Profit equalization payment earned is comprised of Affymax's share of collaboration profit or loss as well as net reimbursement for commercialization costs and certain post-marketing development costs incurred subsequent to the launch of OMONTYS on March 27, 2012.
- (3) Revenue recognized under CAPM (Contingency Adjusted Performance Model) includes amounts received related to upfront payments, development milestones, purchase of active pharmaceutical ingredient, or API, and reimbursement of development expenses. Under CAPM, revenue for these amounts was recognized ratably over the expected development period, which ended in May 2011 with the submission of the NDA for OMONTYS to the FDA.
- (4) Net expense reimbursement after CAPM is comprised of two components: (i) net reimbursement of commercialization expenses and certain post-marketing development costs incurred subsequent to the submission of the NDA for OMONTYS in May 2011 and prior to the launch of OMONTYS on March 27, 2012, after which such costs are incorporated into the profit equalization payment and (ii) the reimbursement of those development expenses that fall under the 70/30 expense split in our collaboration agreement with Takeda subsequent to the submission of the NDA for OMONTYS in May 2011.

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Source: Affymax, Inc.

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