



Flamel Technologies Announces Fourth Quarter and Full Year 2013 Results

Company closes sale of 12.4 million American Depositary Shares for \$113 million of net proceeds in first quarter of 2014

Conference call with management to take place at 10:00 AM EST on March 25, 2014

Lyon, France – March 25, 2014 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the fourth quarter and full year 2013. Highlights from the quarter include:

- Established a \$15.0 million secured line of credit with Broadfin Capital, a current Flamel shareholder, allowing the Company to continue its investment in R&D projects and the launch of its first-NDA approved product, Bloxiverz™
- Flamel had \$7.0 million of cash and marketable securities as of December 31, 2013
- Flamel continued to advance the work on its technology-based portfolio of niche proprietary drugs

In addition to these fourth quarter and full year 2013 results, the Company announced on March 7, 2014 the sale of 12.4 million American Depositary Shares (ADSs) for approximately \$113 million of net proceeds to the Company. Flamel intends to use the net proceeds from the offering for the repayment of amounts under the Deerfield Debt Financing, a \$15.0 million principal amount which bears an interest rate of 12.5% and the Broadfin secured line of credit, of which \$5.0 million was drawn and bears an interest rate of 12.5%. The Company intends to use the remaining net proceeds for the continued development of its product pipeline, including possible clinical trials, and general corporate purposes, including working capital.

“We are excited to have completed this major equity financing for Flamel in the first quarter of 2014. This is an important milestone for us as we look to expand our development pipeline, repay outstanding debt and conduct additional clinical trials. The improved sales trend of Bloxiverz is another highlight for this first quarter. While no sales were recognized in the fourth quarter of 2013 given minimal pull through to the hospitals and US GAAP requirements, we have seen an increase in sales of Bloxiverz in the first quarter of 2014. With one manufacturer of the unapproved version of neostigmine having withdrawn from the marketplace and two manufacturers on back-order status during parts of the first quarter, we are encouraged by our recent sales level to the end-users. We anticipate generating solid revenue growth from Bloxiverz through 2014 and look forward to updating



investors on Bloxiverz specifics when we discuss our financial results for the first quarter of 2014,” said Mike Anderson, Chief Executive Officer of Flamel.

“We were also pleased to announce the \$15.0 million secured line of credit we established with Broadfin Capital in December. Flamel drew down the initial \$5 million tranche from the line of credit in December, which allowed us to support the launch of Bloxiverz, the advancement of our R&D pipeline and new drug submissions. Subsequently, we are pleased that Flamel was able to complete an equity financing which allows the Company to repay our debt and to strengthen Flamel’s balance sheet for future growth,” Mr. Anderson added.

Flamel’s Fourth Quarter Results

Flamel reported total revenues during the fourth quarter of 2013 of \$6.2 million versus \$7.3 million in the fourth quarter of 2012. The decrease was primarily driven by lower license and research revenue of \$2.4 million in the fourth quarter of 2013, compared to \$3.5 million in the prior year quarter, due to impact of the termination of its agreement with Merck-Serono in the fourth quarter of 2012 when the company recognized the remaining upfront license fee. Product sales and services revenues in the fourth quarter of 2013 of \$2.2 million were comparable to the fourth quarter of 2012. This decline in external revenue correlates with the company’s transition from a drug delivery company to a self-funded specialty pharma company.

Costs of goods and services sold for the fourth quarter of 2013 were \$335,000 compared to \$1.5 million in the fourth quarter of 2012. This reduction was due to optimized production scheduling and release of payroll accruals due to a change in the Company’s compensation policy. Research and development costs in the fourth quarter of 2013 totaled \$4.2 million versus \$6.2 million in the prior year period. R&D expense was impacted equally by the release of payroll accruals and timing in development costs for the Company’s internal portfolio. Selling, general and administrative costs were \$5.2 million in the fourth quarter of 2013, versus \$3.0 million in the fourth quarter of 2012, impacted by contractual severance indemnities the Company was required to accrue and includes employer’s French social charges, where applicable.

With the acquisition of Éclat, Flamel acquired several pipeline products that management believed could be commercially attractive. As part of the acquisition, Flamel has incurred obligations owed to the former Éclat shareholders that are contingent on the approval and market potential for those products. These commitments are revalued and reassessed at each balance sheet date based on information and data available at that time, resulting in non-cash income of \$4.5 million and \$14.9 million in the fourth quarters of 2013 and 2012, respectively.



Total interest expense was \$600,000 for the fourth quarter of 2013 due to additional debt incurred in January 2013 and the initial tranche of the line of credit. In the fourth quarter of 2012, the Company had interest income of \$98,000.

Net income for the fourth quarter of 2013 was \$5.1 million versus net income of \$9.1 million in the year-ago period. Earnings per share (both basic and diluted) was \$0.20 in the fourth quarter of 2013 versus \$0.36 in the fourth quarter of 2012.

Adjusted net loss for the fourth quarter of 2013 was \$0.1 million versus an adjusted net loss of \$1.2 million in the fourth quarter of 2012. Adjusted loss per share (both basic and diluted) was \$0.00 in the fourth quarter of 2013 compared to an adjusted loss per share of \$0.05 in the prior year period. For the full year periods, adjusted net loss for 2013 was \$16.1 million versus an adjusted net loss of \$17.7 million for 2012. Adjusted loss per share (both basic and diluted) was \$0.63 for the full year 2013 compared to an adjusted loss per share of \$0.70 in the prior year. A reconciliation of adjusted net loss is included below.

The Company's cash position as of December 31, 2013 was \$7.0 million, which includes \$5.0 million drawn from the line of credit in the fourth quarter. The Company continues to generate considerable tax benefit from operating losses that management expects to be able to offset against future profits.

Flamel is disclosing non-GAAP financial measures when providing financial results, including adjusted net income. Flamel believes that an evaluation of its ongoing operations (and comparison of current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to disclosing its financial results determined in accordance with GAAP, Flamel is disclosing certain non-GAAP results that exclude items such as fair value remeasurements, impairment of intangible assets and amortization expense directly associated with the acquisition and include items such as operating cash flows associated with the acquisition liabilities and Royalty Agreements, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. The Company's management uses these non-GAAP measures internally for forecasting, budgeting and measuring its operating performance. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most closely applicable GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP.

Below is a reconciliation of GAAP net losses attributable to Flamel and diluted GAAP losses per share to adjusted net losses attributable to Flamel and adjusted diluted losses per share



for the three months and year ended December 31, 2013 and 2012 (in thousands except per share amounts).

	Three months ended December 31,				Twelve months ended December 31,			
	2012		2013		2012		2013	
GAAP Net income (loss) and diluted earnings (loss) per share.....	\$9,102	\$0.36	\$5,126	\$0.20	(\$3,228)	(\$0.13)	(\$42,925)	(\$1.69)
Fair value remeasurement of acquisition liabilities	(14,871)		(4,507)		(18,834)		28,135	
Fair value remeasurement of royalty agreements	-		(38)		-		1,990	
Tax effects of the above items.....	295		(74)		258		(2,416)	
Asset Impairment net of tax effects.....	4,302				4,302			
Earn-out acquisition payment payable.....	(66)		(565)		(160)		(840)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	(\$1,238)	(\$0.05)	(\$58)	(\$0.00)	(\$17,661)	(\$0.70)	(\$16,057)	(\$0.63)

A conference call to discuss these results and other updates is scheduled for **10:00 AM Eastern Standard Time on Tuesday, March 25, 2014**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-437-9445 (U.S.) or 719-325-2354 (international). The conference ID number is 1187173. The conference call webcast may be accessed at www.flamel.com. A replay of the webcast will be archived on Flamel's website for 90 days following the call.

About Flamel Technologies. Flamel Technologies SA's (NASDAQ: FLML) business model is to blend high-value internally developed products with its leading drug delivery capabilities. The Company has a proprietary pipeline of niche specialty pharmaceutical products, while its drug delivery platforms are focused on the goal of developing safer, more efficacious formulations of drugs to address unmet medical needs. Its partnered pipeline includes biological and chemical drugs formulated with its Medusa™ and Micropump® (and its applications to the development of liquid formulations, i.e. LiquiTime® and of abuse-deterrent formulations Trigger Lock™) proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. The Company has developed products and manufactures Micropump-based microparticles under FDA-audited GMP guidelines. Flamel Technologies has collaborations with a number of leading pharmaceutical and biotechnology companies, including GlaxoSmithKline (Coreg CR®, carvedilol phosphate). The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and manufacturing facilities in Pessac, France. Additional information may be found at www.flamel.com.

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This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including certain plans, expectations, goals and projections regarding financial results, product developments and technology platforms. All statements that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and similar expressions are generally intended to identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond our control that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that the launch of Bloxiverz will not be as successful as anticipated; our ability to bring other R&D projects of the former Éclat Pharmaceuticals to market may be unsuccessful; FDA may not take action on the status of unapproved versions of neostigmine still on the market; clinical trial results may not be positive or our partners may decide not to move forward; products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements; products in development may not achieve market acceptance; competitive products and pricing may hinder our commercial opportunities; we may not be successful in identifying and pursuing opportunities to develop our own product portfolio using Flamel's technology; and the risks associated with our reliance on outside parties and key strategic alliances. These and other risks are described more fully in Flamel's Annual Report on Form 20-F for the year ended December 31, 2012 that has been filed with the Securities and Exchange Commission (SEC). All forward-looking statements included in this release are based on information available at the time of the release. We undertake no obligation to update or alter our forward-looking statements as a result of new information, future events or otherwise.

Condensed Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2012	2013	2012	2013
Revenue:				
License and research revenue	\$3,450	\$2,434	\$9,324	\$6,549
Product sales and services	2,163	2,150	9,657	8,952
Other revenues	1,697	1,595	7,120	6,942
Total revenue	<u>7,310</u>	<u>6,178</u>	<u>26,101</u>	<u>22,443</u>
Costs and expenses:				
Cost of goods and services sold	(1,495)	(335)	(5,860)	(4,349)
Research and development	(6,162)	(4,173)	(26,115)	(26,686)
Selling, general and administrative	(2,950)	(5,184)	(14,153)	(13,306)
Fair value remeasurement of acquisition liabilities (1)...	14,871	4,507	18,834	(28,135)
Impairment of assets.....	(7,170)		(7,170)	
Total	<u>(2,906)</u>	<u>(5,185)</u>	<u>(34,464)</u>	<u>(72,476)</u>
Profit (loss) from operations	4,404	993	(8,363)	(50,033)
Interest income (expense), net	98	(600)	511	(2,357)
Interest expense on the debt related to the royalty agreements.....	-	38	-	(1,990)
Foreign exchange gain (loss)	(108)	(118)	(180)	(288)
Other income (loss)	11	41	102	573
Income (loss) before income taxes	<u>4,405</u>	<u>354</u>	<u>(7,930)</u>	<u>(54,095)</u>
Income tax benefit (expense)	4,697	4,772	4,702	11,170
Net income (loss)	<u>\$9,102</u>	<u>\$5,126</u>	<u>(\$3,228)</u>	<u>(\$42,925)</u>
Earnings (loss) per share				
Basic earnings (loss) per ordinary share	\$0.36	\$0.20	(\$0.13)	(\$1.69)
Diluted earnings (loss) per share	\$0.36	\$0.20	(\$0.13)	(\$1.69)
Weighted average number of shares outstanding (in thousands) :				
Basic	25,213	25,496	25,135	25,449
Diluted	25,314	25,824	25,135	25,449

(1) Includes impact of passage of time on valuation of acquisition liabilities, which was classified in interest expense in prior period.