

Flamel Technologies Announces First Quarter 2013 Results

Conference call with management to take place at 8:30 AM ET on May 7, 2013

Lyon, France – May 7, 2013 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the first quarter of 2013. Highlights from the quarter and subsequent period include:

- Management continues to focus on development and advancement of internal near term projects as well as mid-term pipeline opportunities that employ Flamel's proprietary drug delivery technologies.
- Flamel has filed a second NDA with the US Food and Drug Administration (FDA) in the first quarter.
- Management continues to pursue selective external business development opportunities.
- Flamel had \$15.4 million of cash and marketable securities as of March 31, 2013, subsequent to the debt financing.

"We continue to be pleased with our progress in developing products from the acquired Éclat portfolio and are excited about the expected approval and launch of our first product in the summer of 2013," said Mike Anderson, Chief Executive Officer of Flamel. "We are still working to submit additional new drug applications as soon as possible and filed a second NDA in the quarter. For this second NDA, we have received a 'refusal to file' letter from the FDA, citing our need to reformat parts of certain datasets in the application. The letter does not comment on the approvability of our product and we will continue to work closely with the agency to provide the information requested for resubmission of this application as quickly as possible. While this is disappointing, given the limited nature of the deficiency, we have confidence in being able to resubmit our filing shortly in accordance with FDA requirements. Moreover, we continue to push forward developing additional, innovative drugs that employ Flamel's proprietary platform of technologies."

Greater research and development spending on these efforts is designed to build Flamel's near-term and mid-term pipeline and revenues and to build the company's shareholder value. The company expects to perform clinical trials on two internal pipeline products in the second half of 2013. Additionally, Flamel announced the dismissal of a 2007 class action law suit during the first quarter, resulting in the reimbursement of the \$0.5 million deductible.

"We continue to execute on our strategy to strike a balance between our own pipeline products, where we control decisions on development, regulatory submission and marketing, while continuing our commitment to enter into significant partnerships that

employ Flamel's proprietary drug delivery platforms," said Mr. Anderson. "In the near term, our new strategy of funding and developing our own products could lower partner-derived revenue, but will provide a much larger revenue base in the mid and long terms. We believe we have evolved the company into an organization that now has three distinctive ways to create revenue: commercializing the Éclat projects in the shorter term, pursuing our self-funded internal projects in the mid-term, and continuing to seek meaningful partnerships with other companies to supplement the other initiatives."

Flamel's First Quarter Results

Flamel reported total revenues during the first quarter of 2013 of \$5.1 million versus \$7.4 million in the first quarter of 2012. For the first quarter of 2013, a decrease of \$1.3 million in product sales and services was the primary driver of lower revenues versus the prior year period. License and research revenues were \$1.3 million during the first quarter of 2013 compared to \$2.1 million in the prior year quarter, reflecting the absence of new contracts. Product sales were \$2.1 million in the first quarter of 2013 compared to \$3.4 million in the prior year period. The decline is primarily due to the timing of demand from GlaxoSmithKline ("GSK") and recognition in the first quarter of 2012 of the remaining \$0.9 million of indemnity payments due to the Company following the signature of a new supply agreement in 2011. Other revenues, consisting primarily of royalty income from GSK on the sales of Coreg CR, were \$1.8 million in the first quarter of 2013 versus \$1.9 million in the prior year quarter.

Total costs and expenses during the first quarter of 2013 increased to \$15.0 million versus \$7.4 million in the prior year period. The total costs and expenses for the first quarter of 2013 increased due to several items. First, the Company incurred Éclat expenses for the full first quarter of 2013 compared to March 13- 31, 2012 in the prior year period, resulting in an increase of \$1.4 million in expenses (excluding the filing fee mentioned below) included in both R&D and SG&A expenses. Second, Flamel incurred a \$2 million filing fee for its second new drug application NDA filed with the FDA, offset by reduced SG&A costs. Third, the value of the warrants issued for the acquisition of Éclat has increased over the quarter as a result of our share price, resulting in an accounting non-cash expense of \$3.0 million in the first quarter of 2013 compared with a favorable adjustment of \$5.1 million in the first quarter of 2012.

Costs of goods and services sold for the first quarter of 2013 were \$1.0 million compared to \$1.3 million in the first quarter of 2012 due to lower product sales. Research and development costs in the first quarter of 2013 totaled \$8.5 million versus \$6.0 million in the prior year period primarily due to the Company's expanding portfolio of new internal pipeline products in development, including the \$2 million filing fee. Selling, general and administrative expenses for the first quarter of 2013 decreased to \$2.5 million compared to

\$5.2 million in the year-prior period due to severance costs incurred in the first quarter of 2012 upon the departure of the Company's previous Chief Executive Officer and legal costs associated with the acquisition of Éclat.

The terms of acquisition of Éclat in March 2012 included the issuance of a \$12 million note, whose repayment is tied to the approval and net sales of certain Éclat products, 3.3 million warrants, and earn-out payments based on the gross profit achieved on the Éclat products. These commitments are revalued and reassessed at each balance sheet date based on information and data available at that time, including financial projections related to the potential of the Éclat products, the share price and interest rates in so far as they influence the value of the warrants. An unfavorable \$3.0 million adjustment was realized in the first quarter of 2013 from the updated fair-value measurement of these liabilities, compared to a favorable adjustment of \$5.1 million in the prior year period. Excluding these adjustments, operating expenses in the first quarter of 2013 decreased to \$12.0 million compared to \$12.5 million in the first quarter of 2012.

Total interest expense of \$0.4 million for the first quarter of 2013 includes interest on the debt financing completed during the quarter. In the first quarter of 2012, the Company had interest income of \$0.2 million.

Net loss for the first quarter of 2013 was \$8.8 million versus net income of \$12,000 in the year-ago period. Earnings per share (both basic and diluted) was \$(0.35) in the first quarter of 2013 versus \$0.00 in the first quarter of 2012. Net loss and loss per share (basic and diluted) for the first quarter of 2013, excluding the impact of the re-measurement of the fair value of acquisition liabilities, was \$5.9 million and \$0.23, respectively compared with \$5.1 million and \$0.20 respectively in the prior year period.

A conference call to discuss these results and other updates is scheduled for **8:30 AM Eastern Time on Tuesday, May 7, 2013**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-428-9473 (U.S. and Canada) or +1-719-325-2315 (international). The conference ID number is 8200950. The conference call webcast may be accessed at www.flamel.com. A replay of the call will be available for 14 days, within a few hours after the call ends. Investors may listen to the replay of the call by dialing 888-203-1112 (U.S. and Canada) or +1-719-457-0820 (international), with the passcode 8200950. A replay of the webcast will also 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 acquisition of Éclat Pharmaceuticals may not be successfully integrated or that certain payment acceleration events may be triggered; the new hospital-based product under FDA review may not be approved or such approval may be delayed; the reacquisition of the exclusive rights to develop and commercialize IFN-β XL worldwide and identification of an alternative strategic partner for the program may not be successful; the identified opportunities will not result in shorter-term, high value results; clinical trial results may not be positive or our partners may decide not to move forward; management transition may be disruptive or not succeed as planned; 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, 2011 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 March 31,

	<u>2012</u>	<u>2013</u>
Revenue:		
License and research revenue	\$2,110	\$1,273
Product sales and services	3,378	2,107
Other revenues	1,872	1,760
Total revenue	<u>7,360</u>	<u>5,140</u>
Costs and expenses:		
Cost of goods and services sold	(1,318)	(995)
Research and development	(5,985)	(8,529)
Selling, general and administrative	(5,183)	(2,491)
Remeasurement of acquisition liabilities	5,080	(2,976)
Total	<u>(7,406)</u>	<u>(14,991)</u>
Profit (loss) from operations	(46)	(9,851)
Interest income (loss) net	166	(429)
Foreign exchange gain (loss)	(133)	24
Other income (loss)	67	(35)
Income (loss) before income taxes	<u>54</u>	<u>(10,291)</u>
Income tax benefit (expense).....	(42)	1,462
Net Income (loss)	<u>\$12</u>	<u>(\$8,829)</u>
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	\$0.00	(\$0.35)
Diluted earnings (loss) per share	\$0.00	(\$0.35)
Weighted average number of shares outstanding (in thousands) :		
Basic	25,012	25,415
Diluted	25,012	25,415