Flamel Technologies Announces Second Quarter 2013 Results

- ***Bloxiverz® Product Launch Underway***
- ***Second NDA from Éclat Portfolio Resubmitted to FDA***

Lyon, France – July 29, 2013 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the second quarter of 2013. Highlights from the quarter and subsequent period include:

- Flamel received an approval for Bloxiverz®, the first FDA-approved version of neostigmine sulfate, a drug used to reverse neuromuscular blocking drugs in surgical procedures. This is Flamel's first NDA approval
- Product launch for Bloxiverz® has commenced
- Flamel re-submitted its second NDA with the US Food and Drug Administration (FDA) near the end of the second quarter
- 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

"We are excited to receive NDA approval for Bloxiverz® from the FDA on the specified PDUFA action date. We think that speaks to the quality of our team's regulatory skills, and we are applying those skills to our other pipeline products," said Mike Anderson, Chief Executive Officer of Flamel. "Moreover, the marketing organization is intently focused on the product launch for Bloxiverz® and working with clinical staff, hospital risk managers and GPOs to make them aware of availability of an FDA-approved version of neostigmine sulfate for the first time. We are currently taking orders and putting product into the wholesaler channel, which provides distribution services to the hospital community."

"Our team continues to be pleased with our progress in developing products from the acquired Éclat portfolio," added Mr. Anderson. "We resubmitted our second new drug application in the second quarter and look forward to the FDA notification if that NDA will be accepted for filing, which will give us a specific PDUFA action date. We will continue to push forward on additional NDA filings out of the Éclat portfolio and on developing additional, innovative drugs that employ Flamel's proprietary platform of technologies."

Greater research and development spending on these new product efforts is designed to build Flamel's near-term and mid-term pipeline and potential revenues. The Company expects to perform clinical trials on several products from its internal pipeline in the second half of 2013.

Flamel's Second Quarter Results

Flamel reported total revenues during the second quarter of 2013 of $5.5 million, which were 8% lower than revenues of $6.0 million in the second quarter of 2012, primarily due to a decrease in license and research revenue.

Costs of goods and services sold for the second quarter of 2013 were $1.3 million compared to $1.5 million in the second quarter of 2012 primarily due to reduced production costs. Research and development costs in the second quarter of 2013 totaled $7.3 million versus $7.7 million in the prior year period primarily due to the timing of our pre-clinical and clinical studies. Selling, general and administrative expenses for the second quarter of 2013 decreased to $2.7 million compared to $2.9 million in the prior year period primarily due to reduced non-cash stock compensation expenses.

Total costs and expenses in the second quarter of 2013, excluding the remeasurement of acquisition liabilities, decreased by 7.3% to $11.3 million compared to $12.2 million in the second quarter of 2012.

In 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. Because the outlook for the potential value of the Éclat pipeline products owned by Flamel has improved, including the FDA approval of Bloxiverz®, Flamel expects to owe more to the former Éclat shareholders than was estimated previously.

The specific terms of the 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 equal to 20% of the gross profit earned on certain Éclat products that are FDA-approved and launched. In addition, the Company's February 2013 financing of $15 million included a royalty of 1.75% of net sales of certain Éclat products that may be approved and launched. These commitments are revalued and reassessed at each balance sheet date based on information and data available at that time resulting in a non-cash expense of $28.6 million in operating expenses and $2.0 million in financing expenses in the second quarter of 2013 compared to a modest non-cash expense of $0.2 million in the second quarter of 2012. This quarterly re-measurement increased the Company's total costs and expenses by $28.4 million over the prior year period. This change in the remeasurement of acquisition liabilities was the largest source of change in the Company's total costs and expenses, on a GAAP basis, which were $39.9 for the second quarter of 2013 compared to $12.3 million in the prior year period.

Total interest expense of $0.6 million for the second quarter of 2013 includes interest on the additional debt financing completed during the first quarter of 2013. In the second quarter of 2012, the Company had interest income of $0.3 million. Other income of $0.5 million in the second quarter of 2013 reflects the reimbursement of the deductible from a 2007 class action against the Company that was dismissed.

Net loss and loss per share (basic and diluted) for the second quarter of 2013, excluding the impact of the remeasurement of the fair value of acquisition liabilities and royalty, were $2.2 million and $0.09, respectively, compared with $5.7 million and $0.23, respectively, in the prior year period. On a GAAP basis, net loss for the second quarter of 2013 was $32.9 million versus a net loss of $5.9 in the prior year period. Loss per share (both basic and diluted) was $1.29 in the second quarter of 2013 versus $0.24 in the second quarter of 2012.

The Company ended the second quarter with cash and marketable securities of $9.7 million compared to $15.4 million at March 31, 2013, reflecting a decrease of $5.6 million. During the second quarter of each year, Flamel typically receives an annual payment from the French Government in recognition of the research and development conducted by Flamel in France, effectively a research and development tax credit. This year the research and development credit of $6.7 million was delayed to July 3, 2013. Had the payment been received in June, Flamel would have ended the second quarter with a cash balance of $16.4 million.

A conference call to discuss these results and other updates is scheduled for **8:30 AM Eastern Time on Monday, July 29, 2013**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-401-4669 (U.S. and Canada) or 719-457-2648 (international). The conference ID number is 3698213. 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 719-457-0820 (international), with the passcode 3698213. A replay of the webcast will also be archived on Flamel's website for 90 days following the call.

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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 http://www.flamel.com.

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This release contains "forward-looking statements", 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 integration of Éclat Pharmaceuticals may not be successful or that certain payment acceleration events related to the acquisition 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, 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 disclaim any obligation to update or alter our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2012	2013	2012	2013
Revenue:				
License and research revenue	$2,054	$1,650	$4,164	$2,923
Product sales and services	2,053	2,195	5,431	4,302
Other revenues	1,926	1,696	3,798	3,456
Total revenue	6,033	5,541	13,393	10,681
Costs and expenses:				
Cost of goods and services sold	(1,547)	(1,283)	(2,865)	(2,278)
Research and development	(7,722)	(7,304)	(13,707)	(15,833)
Selling, general and administrative	(2,913)	(2,706)	(8,096)	(5,197)
Fair value remeasurement of acquisition liabilities	(182)	(28,623)	4,898	(31,599)
Total	(12,364)	(39,916)	(19,770)	(54,907)
Profit (loss) from operations	(6,331)	(34,375)	(6,377)	(44,226)
Interest income net	250	(640)	416	(1,069)
Fair value remeasurement of royalty agreement	-	(2,015)	-	(2,015)
Foreign exchange gain (loss)	156	(33)	23	(9)
Other income (loss)	9	501	76	466
Income (loss) before income taxes	(5,916)	(36,562)	(5,862)	(46,853)
Income tax benefit (expense)	(1)	3,708	(43)	5,170
Net income (loss)	($5,917)	($32,854)	($5,905)	($41,683)
Earnings (loss) per share				
Basic earnings (loss) per ordinary share	($0.24)	($1.29)	($0.24)	($1.64)
Diluted earnings (loss) per share	($0.24)	($1.29)	($0.24)	($1.64)
Weighted average number of shares outstanding (in thousands) :				
Basic	25,157	25,421	25,085	25,418
Diluted	25,157	25,421	25,085	25,418