# Flamel Technologies Announces Third Quarter 2013 Results

- ***Second NDA from Éclat Portfolio Accepted for FDA Review***
- ***Preclinical Studies with Medusa hGH XL Completed***

**Lyon, France – October 31, 2013** - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the third quarter of 2013. Highlights from the quarter include:

- Flamel's second NDA has been accepted for review by the US Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) date of April 28, 2014
- Flamel continues its work on the launch of Bloxiverz®, the first FDA-approved version of neostigmine sulfate
- Flamel completed preclinical studies with its proprietary extended-release Medusa hGH XL product, a customized version of recombinant human growth hormone (rhGH) based upon Flamel's proprietary Medusa Technology

"We are pleased that the FDA has accepted for review our second NDA from the Éclat product portfolio and we look forward to the April 28, 2014 PDUFA date," said Mike Anderson, Chief Executive Officer of Flamel. "For competitive reasons we are not identifying the product at this time, but this adds to Flamel's pipeline of new products that we believe will become increasingly more visible to our investors in 2014."

"For Bloxiverz, the marketing organization is working to place product into the marketplace and informing clinical staff, hospital risk managers and Group Purchasing Organizations (GPOs) to make them aware of availability of the first FDA-approved version of neostigmine sulfate", added Mr. Anderson. "Since our approval, we have signed contracts with nearly all of the major GPOs in the US and sold product to the major drug wholesalers, which distributes the product to the hospital community. Additionally, we have provided information to the FDA on our Bloxiverz production levels and the inventory in the wholesale channel in order to demonstrate that Flamel can satisfy the entire U.S. demand for neostigmine sulfate."

"We will continue to push forward on additional NDA filings out of the Éclat portfolio and on development of 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 report clinical data on several products from its internal pipeline in the first half of 2014."

**Medusa hGH XL Update**

As a part of its R&D program, Flamel has completed preclinical studies with its proprietary extended release Medusa hGH XL product which utilizes Flamel's Medusa technology applied to recombinant human growth hormone (rhGH). The Medusa technology is an innovative and safe depot formulation for the delivery of a broad range of injectable biological and chemical drugs. The study was conducted on hypophysectomized ("hypoX") rats, e.g. animals that have had their pituitary glands removed. This animal model is relevant for assessing efficacy evaluation in the condition of growth hormone deficiency. Flamel's study data provided significant evidence to move this proprietary drug forward into a human clinical trial in 2014 with once weekly dosing. The table below summarizes the key data:

| **AT DAY 14** | Placebo | Low dose IR* | High dose IR* | Medusa hGH XL |
|---|---|---|---|---|
| Number of animals | 10 | 10 | 10 | 10 |
| Body Weight Gain (g) | -2±4 | 16±4 | 36±8 | 22±7 |
| Tibia Length (mm) | 27.0±0.7 | 27.7±0.5 | 28.7±1.1 | 28.4±0.6 |

*Immediate Release

The data demonstrates that hypoX rats treated with Medusa hGH XL showed a comparable increase in body weight gain as compared to the immediate release drug. The dose of Medusa over 14 days in the study did not exceed the high dose of the immediate release rhGH over 14 days. There were no adverse events in any arms of the study attributed to rhGH or Medusa polymer.

**Flamel's Third Quarter Results**

Flamel reported total revenues during the third quarter of 2013 of $5.6 million, compared with $5.4 million in the third quarter of 2012, primarily due to an increase in product sales and services offset partially by a decrease in license and research revenue.

Costs of goods and services sold for the third quarter of 2013 were $1.7 million compared to $1.5 million in the third quarter of 2012. Research and development costs in the third quarter of 2013 totaled $6.7 million versus $6.2 million in the prior year period primarily due to the timing of our development and regulatory activities on our internal pipeline products. Selling, general and administrative expenses for the third quarter of 2013 decreased to $2.9 million compared to $3.1 million in the prior year period.

Total costs and expenses in the third quarter of 2013 were $12.4 million compared with $11.9 million in the prior year period. Excluding approximately $1 million related to the remeasurement of acquisition liabilities in both periods, as discussed below, total costs and expenses increased by 4.5% to $11.3 million in the third quarter of 2013 compared to $10.9 million in the third 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. 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 $1.0 million in operating expenses in the third quarter of 2013 consistent with the non-cash expense of $1.1 million in the third quarter of 2012.

Total interest expense was $0.7 million for the third quarter of 2013, which includes interest on the additional debt financing completed during the first quarter of 2013, compared to $0.1 million in interest income in the prior year period.

Net loss for the third quarter of 2013 was $6.4 million versus a net loss of $6.4 million in the prior year period. Loss per share (both basic and diluted) was $0.25 in the third quarter of 2013 versus $0.26 in the third quarter of 2012. Adjusted net loss for the third quarter of 2013 was $5.6 million versus an adjusted net loss of $5.5 million in the third quarter of 2012. Adjusted loss per share (both basic and diluted) was $0.22 in the third quarter of 2013 compared to an adjusted loss per share of $0.22 in the prior year period. A reconciliation of adjusted net loss is included below.

The Company ended the third quarter with cash and marketable securities of $9.3 million compared to $9.7 million at June 30, 2013, reflecting a decrease of $0.4 million. However, on July 3, 2013, the Company received payment of $6.7 million from the French Government in recognition of the research and development conducted by Flamel in France, effectively a R&D tax credit. Had the R&D credit been received in June, then the company would have ended the second quarter with a cash balance of $16.4 million and the decrease in cash during the third quarter would have been $7.1 million. The reduction in cash during the third quarter principally reflects continued investment in the Company's product pipeline, payment of expenses related to the launch of Bloxiverz, including the working capital investment required to build an inventory position, and the slow uptake of Bloxiverz in the quarter due to the FDA not having removed unapproved neostigmine products from the market as of this point. Flamel is working actively to expedite this process.

After the close of the third quarter, Flamel entered into a term sheet for a $15 million secured line of credit. Flamel believes it is prudent to put the line of credit into place now as we continue to anticipate that Bloxiverz sales will begin to ramp, primarily tied to the FDA's rulings and other proactive steps taken by the Company. The final documentation for the line of credit should be completed in November 2013, although there are be no assurances that documentation will be completed and the line of credit will be available to the Company.

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 and amortization expense directly associated with the acquisition and include items such as operating cash flows associated with the acquisition liabilities and Royalty Agreement, 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 and nine months ended September 30, 2013 and 2012 (in thousands except per share amounts).

| | Three months ended September | | | | Nine months ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2012 | | 2013 | | 2012 | | 2013 | |
| GAAP Net income (loss) and diluted earnings (loss) per share | ($6,425) | ($0.26) | ($6,369) | ($0.25) | ($12,330) | ($0.49) | ($48,052) | ($1.89) |
| Fair value remeasurement of acquisition liabilities | 1,060 | | 1,043 | | (3,963) | | 32,642 | |
| Fair value remeasurement of Royalty Agreement | - | | 13 | | - | | 2,028 | |
| Tax effects of the above items | (111) | | (89) | | (236) | | (2,342) | |
| Earn-out acquisition payment payable | (73) | | (167) | | (75) | | (275) | |
| Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share | ($5,549) | ($0.22) | ($5,569) | ($0.22) | ($16,604) | ($0.66) | ($15,999) | ($0.63) |

A conference call to discuss these results and other updates is scheduled for **10:00AM Eastern Time on Thursday, October 31, 2013**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-471-3843 (U.S. and Canada) or 719-325-2494 (international). The conference ID number is 9636511. 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 9636511. 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.

*******

**Contact:** **Michael S. Anderson**
Phone: 33 (0) 4 72 78 34 34
Fax: 33 (0) 4 72 78 34 35
E-mail: anderson@flamel.com

**Investor Relations**
**Bob Yedid**
**ICR Inc**.
Phone: 646-277-1250
Email: bob.yedid@icrinc.com

*******

*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 continued integration of Éclat Pharmaceuticals may not be successful or that certain payment acceleration events may be triggered; 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; 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2012 | 2013 | 2012 | 2013 |
| Revenue: | | | | |
| License and research revenue | $1,710 | $1,192 | $5,874 | $4,115 |
| Product sales and services | 2,063 | 2,500 | 7,494 | 6,802 |
| Other revenues | 1,625 | 1,891 | 5,423 | 5,347 |
| Total revenue | 5,398 | 5,583 | 18,791 | 16,264 |
| Costs and expenses: | | | | |
| Cost of goods and services sold | (1,500) | (1,736) | (4,365) | (4,014) |
| Research and development | (6,246) | (6,680) | (19,953) | (22,513) |
| Selling, general and administrative | (3,107) | (2,925) | (11,203) | (8,122) |
| Fair value remeasurement of acquisition liabilities (1) | (1,060) | (1,043) | 3,963 | (32,642) |
| Total | (11,913) | (12,384) | (31,558) | (67,291) |
| Profit (loss) from operations | (6,515) | (6,801) | (12,767) | (51,027) |
| Interest income (expense), net | 122 | (688) | 413 | (1,757) |
| Fair value remeasurement of royalty agreement | - | (13) | - | (2,028) |
| Foreign exchange gain (loss) | (95) | (161) | (72) | (170) |
| Other income (loss) | 15 | 66 | 91 | 532 |
| Income (loss) before income taxes | (6,473) | (7,597) | (12,335) | (54,450) |
| Income tax benefit (expense) | 48 | 1,228 | 5 | 6,398 |
| Net income (loss) | ($6,425) | ($6,369) | ($12,330) | ($48,052) |
| Earnings (loss) per share | | | | |
| Basic earnings (loss) per ordinary share | ($0.26) | ($0.25) | ($0.49) | ($1.89) |
| Diluted earnings (loss) per share | ($0.26) | ($0.25) | ($0.49) | ($1.89) |
| Weighted average number of shares outstanding (in thousands) : | | | | |
| Basic | 25,157 | 25,465 | 25,109 | 25,434 |
| Diluted | 25,157 | 25,465 | 25,109 | 25,434 |

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