Flamel Technologies Announces First Quarter of Fiscal Year 2014 Results

Company recognized revenue from initial sales of FDA-approved Bloxiverz™

Conference call with management to take place at 10:00 AM ET on May 12, 2014

Lyon, France – May 12, 2014 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the first quarter of fiscal year 2014. Highlights from the quarter include:

- Recognized revenue from its first-FDA approved Éclat product, Bloxiverz™, the first FDA-approved version of neostigmine methylsulfate
- Announced positive results from First-in-Man clinical study using Micropump® technology applied to sodium oxybate for narcolepsy patients
- The Company closed the sale of 12.4 million American Depositary Shares (ADSs) for approximately $113 million of net proceeds in March 2014. After repayment of virtually all outstanding debt and credit lines, and the first quarter cash needs, the Company had $83.5 million of cash and marketable securities as of March 31, 2014

"We are pleased to report growth in our revenues due to the recognition of revenue from Bloxiverz for the first time in the first quarter of 2014. Bloxiverz is the company's first NDA approval from our line of products acquired from Éclat, and is the first FDA-approved version of neostigmine currently available in the marketplace," said Mike Anderson, Chief Executive Officer of Flamel. "We will continue to work with the FDA as they consider removing the currently available unapproved versions of neostigmine from the marketplace."

In addition to the first quarter 2014 results, the Company last month announced positive results from its First-in-Man (FIM) clinical study in healthy volunteers using its proprietary Micropump technology applied to sodium oxybate. The study identified formulations that demonstrate the potential to eliminate the second nighttime dose for patients suffering from narcolepsy and instead administer only a single dose before bedtime.

"The results from our First-in-Man trial using Micropump sodium oxybate are an important accomplishment for us. We will look to complete the extension phase of our first trial which will test two formulations at doses above 6 grams as well as begin a new clinical study before year-end 2014. This new study will be in a larger number of patients to further evaluate these formulations as well as certain pharmacodynamic endpoints in patients suffering from narcolepsy. We plan to meet with regulatory authorities prior to embarking upon studies required for registration, which we expect to begin before the end of 2015.

On April 28th, the FDA issued Flamel a complete response letter (CRL) for the Company's second New Drug Application (NDA) from the Éclat portfolio. In the CRL, the FDA cited issues related to the active pharmaceutical ingredient (API) supplier. "While we are disappointed having received this CRL for our second product candidate in the Éclat portfolio, we will work diligently with the FDA and our API supplier to satisfy the issue that was raised in the CRL. At this moment, based upon the information available to us, we expect to submit our response to the CRL prior to the end of 2014." said Mr. Anderson.

Flamel's First Quarter Results

Flamel reported total revenues during the first quarter of 2014 of $9.2 million, which reflected the initial recognition of sales of Bloxiverz, compared to $5.1 million in the first quarter of 2013, an increase of 78.5% compared to the year-ago period. Product sales and services revenues in the first quarter of 2014 of were $5.9 million, compared to $2.1 million in the prior year quarter as the Company continues its successful transition from a drug delivery company to a self-funded specialty pharmaceutical company.

Costs of goods and services sold for the first quarter of 2014 were $2.0 million compared to $995,000 in the first quarter of 2013, principally due to initial sales of Bloxiverz and the corresponding costs of inventory. Research and development costs in the first quarter of 2014 totaled $7.1 million versus $8.5 million in the prior year period because the Company paid an NDA filing fee in the first quarter of 2013 that did not recur this quarter. Selling, general and administrative costs were $3.6 million in the first quarter of 2014 versus $2.5 million in the first quarter of 2013. This increase resulted from additional selling and marketing costs to support the launch of Bloxiverz, the cost of post-marketing studies requested by the FDA, and increased legal costs. For the first time, amortization of R&D assets associated with the development of Bloxiverz was accounted for in the first quarter of 2014 for a total of $2.9 million.

Total interest expense was $5.5 million in the first quarter of 2014 compared to interest expense of $429,000 in the first quarter of 2013. Virtually all of the company's debt and lines of credit, which totaled $32 million, were repaid as of March 24, 2014 using the proceeds from the offering of ADSs.

Net loss for the first quarter of 2014 was $26.6 million versus net loss of $8.8 million in the year-ago period. Earnings per share (both basic and diluted) was $(0.94) in the first quarter of 2014 versus $(0.35) in the first quarter of 2013.

Adjusted net loss for the first quarter of 2014 was $4.2 million versus an adjusted net loss of $5.9 million in the first quarter of 2013. Adjusted loss per share (both basic and diluted) was

$(0.15) in the first quarter of 2014 compared to an adjusted loss per share of $(0.23) in the prior year period.

The Company's cash position as of March 31, 2014 was $83.5 million, which includes the net proceeds from the sale of 12.4 million ADSs less the repayment of debt and lines of credit.

Flamel is disclosing non-GAAP financial measures when providing financial results, including adjusted net loss. 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 in accordance with GAAP, Flamel is disclosing certain non-GAAP results that exclude fair value remeasurements, impairment of intangible assets, amortization expense of intangible assets and effects of accelerated reimbursement of certain debt instruments and include 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 ended March 31, 2014 and 2013 (in thousands except per share amounts).

	Three months ended March 31,			
	2013		2014	
GAAP Net income (loss) and diluted earnings (loss) per share.....	($8,829)	($0.35)	($26,638)	($0.94)
Fair value remeasurement of acquisition liabilities*	2,976		14,626	
Fair value remeasurement of royalty agreements	-		156	
Amortization of Intangible R&D Assets.....	-		2,937	
Accelerated reimbursement of acquisition note	-		3,013	
Accelerated reimbursement of facility agreements	-		4,741	
Tax effects of the above items	(15)		(2,338)	
Earn-out acquisition payment payable	(9)		(611)	
Royalty payable	-		(92)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	($5,876)	($0.23)	($4,206)	($0.15)

**Earn out due and warrants issued in relation to the Éclat acquisition.*

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Monday, May 12, 2014**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-542-1086 (U.S.) or 1+719-325-2109 (international). The conference ID number is 9667665. 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.

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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 markets Bloxiverz™ (neostigmine methylsulfate) in the USA and manufactures Micropump-based microparticles under FDA-audited GMP guidelines for Coreg CR® (carvedilol phosphate), marketed in the USA by GlaxoSmithKline. 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 pipeline includes chemical and biological drugs formulated with its Micropump® (and its applications to the development of liquid formulations, i.e. LiquiTime® and of abuse-deterrent formulations Trigger Lock™) and Medusa™ proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. 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 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; we may not be able to quickly resolve the issue raised in the CRL issued by the FDA; 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, 2013 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,	
	2013	**2014**
Revenue:		
License and research revenue	$1,273	$1,433
Product sales and services	2,107	5,940
Other revenues	1,760	1,802
Total revenue	5,140	9,175
Costs and expenses:		
Cost of goods and services sold	(995)	(1,952)
Research and development	(8,529)	(7,094)
Amortisation of intangible R&D assets	-	(2,937)
Selling, general and administrative	(2,491)	(3,555)
Fair value remeasurement of acquisition liabilities	(2,976)	(14,626)
Reimbursement of acquisition Note	-	(3,013)
Total	(14,991)	(33,177)
Profit (loss) from operations	(9,851)	(24,002)
Interest income (expense), net	(429)	(5,508)
Interest expense on the debt related to the royalty agreement	-	(156)
Foreign exchange gain (loss)	24	179
Other income (loss)	(35)	52
Income (loss) before income taxes	(10,291)	(29,435)
Income tax benefit (expense)	1,462	2,797
Net income (loss)	($8,829)	($26,638)
Earnings (loss) per share		
Basic earnings (loss) per ordinary share	($0.35)	($0.94)
Diluted earnings (loss) per share	($0.35)	($0.94)
Weighted average number of shares outstanding (in thousands) :		
Basic	25,415	28,312
Diluted	25,415	28,312