Flamel Technologies Announces Second Quarter of Fiscal Year 2014 Results

Company received FDA Approval of Vazculep® on June 30, 2014

Conference call with management to take place at 10:00 am ET on July 29, 2014

Lyon, France – July 29, 2014 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the second quarter of fiscal year 2014. Highlights from the quarter include:

- Received U.S. Food and Drug Administration (FDA) approval of Vazculep® (phenylephrine hydrochloride) in the 1mL single use vials, and 5mL and 10mL pharmacy bulk package vials. Flamel is now the only drug manufacturer offering all three product presentations of phenylephrine hydrochloride injection and will launch before end of the third quarter 2014
- The FDA updated its Drug Shortages website as of June 19, 2014 to reflect that the neostigmine methylsulfate shortage is resolved and cites Éclat Pharmaceuticals as the only listed supplier of the drug
- First-in-Man clinical study of Micropump® technology applied to sodium oxybate identified formulations that demonstrate the potential to eliminate the second nighttime dose for patients suffering from narcolepsy. The Company is expanding the current trial and will test product at higher dosages

"We are pleased that the FDA listed Éclat Pharmaceuticals as the only supplier of neostigmine methylsulfate as of June 19th. We have been in frequent communication with the FDA with regard to Bloxiverz, and look forward to learning more about any specific actions in the near future," said Mike Anderson, Chief Executive Officer of Flamel.

"Additionally, we continue to execute on our strategy with FDA's recent approval of Vazculep," added Mr. Anderson. "Our prompt resubmission of our NDA for Vazculep and the FDA's subsequent approval ahead of the scheduled PDUFA date is an example of the Company's ability to work effectively and positively with the FDA and other third parties in order to execute our business plan."

We continue to make progress on our proprietary pipeline, including the clinical testing of sodium oxybate and other compounds using our Micropump®, LiquiTime®, Trigger Lock™, and Medusa™ drug delivery platforms. Continued prioritization of these programs and investments in our internal infrastructure will facilitate high quality and timely execution on our major proprietary pipeline products throughout 2014 and 2015.

Flamel's Second Quarter Results

Flamel reported total revenues during the second quarter of 2014 of $8.1 million, an increase of $2.5 million in revenues compared to the prior year period. Product sales and services revenues in the second quarter of 2014 of were $4.1 million, compared to $2.2 million in the prior year quarter, principally due to sales of Bloxiverz, which was not launched in the second quarter of 2013. On a sequential basis, second quarter 2014 revenues of $8.1 million were down from $9.2 million in the first quarter of 2014, due to a leveling off of Bloxiverz sales after a spike in sales in the first quarter when two suppliers of unapproved neostigmine methylsulfate were off the market for a portion of the quarter.

Costs of goods and services sold for the second quarter of 2014 were $1.6 million compared to $1.3 million in the second quarter of 2013, principally due to cost of sales of Bloxiverz. Research and development costs in the second quarter of 2014 totaled $6.7 million versus $7.3 million in the prior year period. Selling, general and administrative costs were $4.3 million in the second quarter of 2014 versus $2.7 million in the second quarter of 2013. This increase resulted from the cost of post-marketing studies requested by the FDA and increased legal costs. Amortization of R&D assets associated with the development of Bloxiverz was $2.9 million in the second quarter of 2014.

Total net interest income was $94,000 in the second quarter of 2014 compared to interest expense of $640,000 in the second quarter of 2013. Interest expense was largely eliminated with the Company's repayment of nearly all of its debt and lines of credit with a portion of the net proceeds from its offering of 12.4 million ADSs in mid-March 2014.

Net loss for the second quarter of 2014 was $21.1 million versus net loss of $32.8 million in the year-ago period. Earnings per share (both basic and diluted) was $(0.55) in the second quarter of 2014 versus $(1.29) in the second quarter of 2013.

Adjusted net loss for the second quarter of 2014 was $4.9 million versus an adjusted net loss of $4.5 million in the second quarter of 2013. Adjusted loss per share (both basic and diluted) was $(0.13) in the second quarter of 2014 compared to an adjusted loss per share of $(0.18) in the prior year period.

The Company's cash position as of June 30, 2014 was $77.9 million.

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 and six months ended June 30, 2014 and 2013 (in thousands except per share amounts).

	Three months ended June 30,				Six months ended June 30,			
	2013		2014		2013		2014	
GAAP Net income (loss) and diluted earnings (loss) per share	($32,854)	($1.29)	($21,073)	($0.55)	($41,683)	($1.64)	($47,711)	($1.43)
Fair value remeasurement of acquisition liabilities	28,623		12,607		31,599		27,233	
Fair value remeasurement of royalty agreements	2,015		1,079		2,015		1,235	
Amortization of Intangible R&D Assets	-		2,938		-		5,875	
Accelerated reimbursement of acquisition note	-		-		-		3,013	
Accelerated reimbursement of facility agreements	-		-		-		4,741	
Tax effects of the above items	(2,238)		-		(2,253)		-	
Earn-out acquisition payment payable	-		(383)		(108)		(994)	
Royalty payable	-		(54)		-		(141)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share	($4,454)	($0.18)	($4,886)	($0.13)	($10,430)	($0.41)	($6,750)	($0.20)

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Tuesday, July 29, 2014**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-428-9490 (U.S.) or 1+719-325-2376 (international). The conference ID number is 1681810. 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 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 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, 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.

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

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

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

	Three months ended June 30,		Six months ended June 30,	
	2013	**2014**	**2013**	**2014**
Revenue:				
License and research revenue	$1,650	$2,270	$2,923	$3,703
Product sales and services	2,195	4,128	4,302	10,068
Other revenues	1,696	1,683	3,456	3,485
Total revenue	5,541	8,081	10,681	17,256
Costs and expenses:				
Cost of goods and services sold	(1,283)	(1,636)	(2,278)	(3,588)
Research and development	(7,304)	(6,742)	(15,833)	(13,836)
Amortisation of intangible R&D assets	-	(2,938)	-	(5,875)
Selling, general and administrative	(2,706)	(4,295)	(5,197)	(7,850)
Fair value remeasurement of acquisition liabilities, incl. related parties	(28,623)	(12,607)	(31,599)	(27,233)
Acquisition note expenses, incl. related parties	-	-	-	(3,013)
Total	(39,916)	(28,218)	(54,907)	(61,395)
Profit (loss) from operations	(34,375)	(20,137)	(44,226)	(44,139)
Interest income (Expense) net	(640)	94	(1,069)	(5,414)
Interest expense on debt related to the royalty agreement with related parties	(2,015)	(1,079)	(2,015)	(1,235)
Foreign exchange gain (loss)	(33)	292	(9)	471
Other income (loss)	501	30	466	82
Income (loss) before income taxes	(36,562)	(20,800)	(46,853)	(50,235)
Income tax benefit (expense)	3,708	(273)	5,170	2,524
Net income (loss)	($32,854)	($21,073)	($41,683)	($47,711)
Earnings (loss) per share				
Basic earnings (loss) per ordinary share	($1.29)	($0.55)	($1.64)	($1.43)
Diluted earnings (loss) per share	($1.29)	($0.55)	($1.64)	($1.43)
Weighted average number of shares outstanding (in thousands) :				
Basic	25,421	38,438	25,418	33,403
Diluted	25,421	38,438	25,418	33,403