Flamel Technologies Announces Fourth Quarter and Full Year Results of Fiscal Year 2014

Bloxiverz™ increases market share in the neostigmine market
Product revenue guidance for 2015 of $170-$185 million reaffirmed

Conference call with management to take place at 10:00 am ET on March 19, 2015

Lyon, France – March 19, 2015 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the fourth quarter of fiscal year 2014. Highlights from the quarter include:

- Flamel announced positive results of a second clinical trial with the company's proprietary Micropump® Sodium Oxybate, reconfirming potential elimination of the 'middle-of-the-night' dose that is required with the currently available drug for treating narcolepsy
- Flamel's intellectual property, including patents on its drug delivery platform technologies, clinical data sets and other intangible assets related to its pipeline of proprietary products in development, has been relocated to the Company's Irish-based subsidiary
- Sale of Flamel's development and manufacturing facility in Pessac, France to Recipharm AB

"We are very pleased to announce that the market share of Bloxiverz™ increased significantly in recent months as compared to the fourth quarter of 2014, and the Company is currently providing 100% of the neostigmine market. The higher market share allows Flamel to reaffirm our product revenue guidance for 2015 of $170 to $185 million for combined sales of Bloxiverz and Vazculep™," said Mike Anderson, Chief Executive Officer of Flamel.

"In addition, Flamel has experienced greater success than initially anticipated with Vazculep and is now leading the phenylephrine hydrochloride market in the 10mL vial size, and continues to gain share in both the 5mL and 1mL vial sizes. We are in regular communication with the FDA about Vazculep and we continue to supply them with the information they need to evaluate steps to remove the unapproved manufacturer of 5 and 10 mL sizes of phenylephrine from the market," added Mr. Anderson.

Mr. Anderson also commented, “The positive data from our second clinical trial of Micropump Sodium Oxybate in healthy volunteers is very encouraging for the Company, as it achieved the objective of a single dose before bedtime for patients suffering from narcolepsy, reconfirming the results of our first-in-man clinical study with Sodium Oxybate. The potential to eliminate a ‘middle-of-the-night dose’ will drastically improve the standard of care for people suffering from narcolepsy. Subject to meeting with the FDA on the clinical trial program for Micropump Sodium Oxybate, we look forward to beginning a pivotal trial with Sodium Oxybate by year end 2015.”

“Flamel continues to move forward with the development of our other proprietary pipeline products, which along with Micropump Sodium Oxybate, represent valuable assets for our Company. We anticipate announcing clinical data in the second quarter on products using our LiquiTime® extended release liquid technology and Trigger Lock™ controlled release, abuse-resistant technology for opioids,” concluded Mr. Anderson.

Flamel’s Fourth Quarter Results

As announced, Flamel closed the sale of its development and manufacturing facility located in Pessac, France, to Recipharm AB on December 1, 2014 for a purchase price of EUR 10.6 million. Concurrently with the purchase of Flamel’s Pessac facility, Recipharm made an investment of EUR 10.5 million in Flamel's stock. The “License and research services revenues” and “Other revenues” related to the development and manufacturing facility are classified as Discontinued Operations for the three month and twelve month periods ended December 31, 2014 and 2013.

Flamel reported total revenues during the fourth quarter of 2014 of $3.0 million, an increase of $2.0 million in revenues compared to the prior year period. Product sales and services revenues in the fourth quarter of 2014 were $2.9 million compared to $108,000 in the prior year quarter due to sales of Bloxiverz. As of December 31, 2014, the Company had Deferred Revenues of $9.7 million, comprised of $7.0 million for Bloxiverz and $2.7 million for Vazculep. We anticipate those sales will be recognized in the first quarter of 2015. Revenue recognition under GAAP requires the price on the product to be determinable. In Flamel’s view, price is determinable when the product is sold through to the hospital and the chargeback can be determined, particularly in a period when product prices may be changing. Therefore, the Company’s product revenue is recognized on this “sales-through” methodology.

Costs of goods and services sold for the fourth quarter of 2014 were $1.4 million compared to $50,000 in the fourth quarter of 2013. Research and development costs in the fourth quarter of 2014 totaled $5.6 million, compared to $2.0 million in the prior year period. This increase is attributed to the Company's continued investment in its pipeline and other proprietary products and because R&D expenses were reduced in the prior year period due to one-off reversal of payroll accruals due to changes in employee compensation plans. Selling, general and administrative costs were $4.1 million in the fourth quarter of 2014 versus $5.2 million in the fourth quarter of 2013. Amortization of R&D assets associated with the development of Bloxiverz was $2.9 million in the fourth quarter of 2014, consistent with recent quarters, and this charge will be incurred quarterly through the end of 2016.

Total net interest income was $543,000 in the fourth quarter of 2014 compared to interest expense of $598,000 in the fourth 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 for net proceeds of approximately $113 million.

In the fourth quarter 2014, the Company had total unrealized foreign exchange gain of $3.3 million due to the strengthening of the U.S. Dollar to the Euro. While our parent company in France uses the Euro as its functional currency, Flamel holds over $95 million in assets that are U.S. Dollar denominated which appreciated relative to the Euro.

Operating and net income (loss) includes remeasurement of the fair value of the acquisition liabilities which was an expense of ($22.4) million for the three months ended December 31, 2014 compared to a gain of $4.5 million for the prior year period. These liabilities were incurred as a part of Flamel's acquisition of Éclat Pharmaceuticals in March 2012 and are tied to commercial sales of FDA-approved products as well as other factors described in our Form 20-F. Changes in the fair value of the acquisition liabilities, which are remeasured at each balance sheet date, are recognized in the Company's reported income (loss). In addition, the Company incurred amortization expense of intangible assets of $2.9 million in the third quarter of 2014.

Net loss for the fourth quarter of 2014 was $(27.1) million versus net income of $5.1 million in the year-ago period. Loss per share (both basic and diluted) was $(0.69) in the fourth quarter of 2014 versus earnings per share of $0.20 in the fourth quarter of 2013.

Net loss from Continuing Operations for the fourth quarter of 2014 was $(31.9) million versus net income from Continuing Operations of $2.5 million in the year-ago period. Loss per share from Continuing Operations (both basic and diluted) was $(0.81) in the fourth quarter of 2014 versus earnings per share from Continuing Operations (both basic and diluted) of $0.10 in the fourth quarter of 2013.

Adjusted net loss (non-GAAP) for the fourth quarter of 2014 was $(4.7) million versus net income of $154,000 in the fourth quarter of 2013. Adjusted loss per share (both basic and diluted) was $(0.12) in the fourth quarter of 2014 versus adjusted earnings per share (both basic and diluted) of $0.01 in the prior year period.

The Company's cash position as of December 31, 2014 was $92.8 million compared to $76.4 million as of September 30, 2014. The increase of cash during the fourth quarter principally reflects the facility sale and investment by Recipharm in Flamel's stock.

Flamel's Full Year 2014 Results

Flamel reported total revenues during the twelve months ended December 31, 2014 of $14.8 million, an increase of 253% as compared to total revenues of $4.2 million in the twelve months ended December 31, 2013. Product sales and services revenues in the full year 2014 were $11.9 million compared to $1.0 million in the prior year due to sales of Bloxiverz being recognized for the first time in 2014.

Operating and net income (loss) includes remeasurement of the fair value of the acquisition liabilities which was an expense of $57.5 million for the full year 2014 compared to $28.1 million for the prior year, a net increase of $29.4 million. Flamel also incurred amortization expense of intangible assets of $11.7 million in the full year 2014 while there was no comparable amortization expense in the prior year.

Net loss for the full year 2014 was $(84.9) million versus $(42.9) million for the full year 2013. Loss per share (both basic and diluted) was $(2.34) in 2014 versus $(1.69) in 2013.

Net loss from Continuing Operations for 2014 was $(88.9) million versus net loss of $(46.5) million for 2013. Loss per share from Continuing Operations (both basic and diluted) was $(2.46) in 2014 versus $(1.83) in 2013.

Adjusted net loss (non-GAAP) for 2014 was $(20.3) million versus $(15.7) million for 2013. Adjusted loss per share (both basic and diluted) was $(0.56) in 2014 versus $(0.62) in 2013.

Flamel is disclosing non-GAAP financial measures when providing financial results, including adjusted net loss and adjusted loss per share. 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; effects of accelerated reimbursement of certain debt instruments and unrealized foreign exchange gains and losses on assets and liabilities denominated in foreign currency 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 twelve months ended December 31, 2014 and 2013 (in thousands except per share amounts).

	Three months ended December 31,				Twelve months ended December 31,			
	2013		2014		2013		2014	
GAAP Net income (loss) and diluted earnings (loss) per share	$5,127	$0.10	($27,149)	($0.81)	($42,925)	($1.83)	($84,906)	($2.46)
Fair value remeasurement of acquisition liabilities	(4,507)		22,393		28,135		57,491	
Fair value remeasurement of royalty agreement	(38)		804		1,990		3,525	
Amortization of Intangible R&D Assets	-		2,937		-		11,749	
Accelerated reimbursement of acquisition note	-		-		-		3,013	
Accelerated reimbursement of facility agreements	-		-		-		4,741	
Tax effects of the above items	(74)		-		(2,416)		(2,338)	
Earn-out acquisition payment payable	(565)		(323)		(840)		(1,678)	
Royalty payable			(58)		-		(249)	
Unrealized foreign exchange (gain)/loss	211		(3,330)		363		(11,667)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share,	$154	$0.01	($4,726)	($0.12)	($15,694)	($0.62)	($20,319)	($0.56)

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Thursday, March 19, 2015.** A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-259-8724 (U.S.) or 1+ 913-312-1471 (international). The conference ID number is 1595960. 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.

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) and Vazculep™ (phenylephrine hydrochloride) in the US and licenses the Micropump-based microparticles technology to Recipharm AB for application to the manufacturing under FDA-audited GMP guidelines of 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 Dublin, Ireland. Additional information may be found at www.flamel.com.

Safe Harbor: *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™ and Vazculep™ 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; 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

FLAMEL technologies

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

	Three months ended Dec 31,		Twelve months ended Dec 31,	
	2013	2014	2013	2014
Revenue:				
License and research revenue	$811	$30	$3,026	$2,782
Product sales and services	108	2,907	983	11,920
Other revenues	49	29	170	73
Total revenue	968	2,966	4,179	14,775
Costs and expenses:				
Cost of goods and services sold	(50)	(1,396)	(562)	(3,383)
Research and development	(1,951)	(5,636)	(15,966)	(17,298)
Selling, general and administrative	(5,184)	(4,093)	(13,216)	(15,698)
Fair value remeasurement of acquisition liabilities, incl. related parties	4,507	(22,393)	(28,135)	(57,491)
Amortisation of intangible R&D assets	-	(2,937)	-	(11,749)
Acquisition note expenses, incl. related parties	-	-	-	(3,013)
Total	(2,678)	(36,455)	(57,879)	(108,632)
Profit (loss) from continuing operations	(1,710)	(33,489)	(53,700)	(93,857)
Interest income (Expense) net	(598)	543	(2,348)	(4,784)
Interest expense on debt related to the royalty agreement with related parties	38	(804)	(1,990)	(3,525)
Foreign exchange gain (loss)	(118)	3,326	(288)	11,871
Other income (loss)	41	(188)	573	(36)
Income (loss) before income taxes from continuing operations	(2,347)	(30,612)	(57,753)	(90,331)
Income tax benefit (expense)	4,819	(1,272)	11,244	1,407
Net income (loss) from continuing operations	$2,472	($31,884)	($46,509)	($88,924)
Net income from discontinued operations	$2,655	$4,735	$3,584	$4,018
Net income (loss)	$5,127	($27,149)	($42,925)	($84,906)
Earnings (loss) per ordinary share (Basic):				
Continuing operations	$0.10	($0.81)	($1.83)	($2.46)
Discontinued operations	$0.10	$0.12	$0.14	$0.11
Net income (loss)	$0.20	($0.69)	($1.69)	($2.34)
Earnings (loss) per share (Diluted):				
Continuing operations	$0.10	($0.81)	($1.83)	($2.46)
Discontinued operations	$0.10	$0.12	$0.14	$0.11
Net income (loss)	$0.20	($0.69)	($1.69)	($2.34)
Weighted average number of shares outstanding (in thousands) :				
Basic	25,496	39,208	25,450	36,211
Diluted	25,824	39,208	25,450	36,211