



Flamel Technologies Announces First Quarter Results of Fiscal Year 2015

Product revenue guidance for 2015 of \$170-\$185 million reaffirmed

Conference call with management to take place at 10:00 am ET on May 15, 2015

Lyon, France – May 15, 2015 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the first quarter of fiscal year 2015. Highlights from the quarter include:

- Bloxiverz's increased market share and price increase drives record revenue of \$28.6 million
- Vazculep™, the Company's second marketed product, reaches higher than expected product sales
- Data from first-in-man trial with LiquiTime® guaifenesin announced; plans in place to begin a pivotal trial of LiquiTime® ibuprofen in the second half of 2015

"We are pleased to announce that Bloxiverz® accounted for 100% of the neostigmine methylsulfate market by February of this year, which coincided with the Company's price increase. Although Fresenius Kabi entered the neostigmine market at the start of the second quarter, Flamel was able to enjoy a period as the sole supplier to the market at a higher price, which allows the Company to maintain product revenue guidance for 2015 of \$170-185 million for combined product sales," said Chief Executive Officer, Mike Anderson.

"In addition, Flamel has been able to recognize revenues for Vazculep, which are higher than initially expected. Following an earlier than expected exit of the market by the unapproved manufacturer, Flamel now supplies the entire market in the 5 and 10 mL vial sizes and continues to gain share in the 1mL vial size," added Mr. Anderson.

"Revenues from Bloxiverz and Vazculep have made Flamel cash flow positive from operations, increasing our cash balance to over \$110 million. Additionally, we anticipate announcing data for Trigger Lock™ controlled release, abuse-resistant technology for opioids in the first half of 2015. We look forward to achieving other milestones in the second half of 2015, including beginning pivotal trials for LiquiTime ibuprofen for the substantial Over-The-Counter (OTC)



market as well as our Micropump® Sodium Oxybate formulation before year end,” concluded Mr. Anderson.

Flamel’s First Quarter Results

Flamel reported total revenues during the first quarter of 2015 of \$32.7 million, an increase of \$28.1 million in revenues compared to the prior year period. As of March 31, 2015, the Company had Deferred Revenues of \$32.1 million, comprised of \$30.7 million for Bloxiverz and \$1.4 million for Vazculep, compared to \$7.0 million and \$2.7 million, respectively, in the fourth quarter of 2014. We anticipate the majority of these product sales will be recognized in the second quarter of 2015. The increase in Deferred Revenue is largely attributed to the increase in the selling price of Bloxiverz and the increase in inventory held by wholesalers. The Company believes that wholesalers were selling Bloxiverz at contracted prices based on the higher Wholesale Acquisition Cost (WAC) as of mid-February. 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 first quarter of 2015 were \$3.6 million compared to \$0.8 million in the first quarter of 2014. Research and development costs in the first quarter of 2015 totaled \$6.0 million, compared to \$3.9 million in the prior year period. This increase is attributed to the Company’s continued investment in its pipeline and other proprietary products. Selling, general and administrative costs were \$4.5 million in the first quarter of 2015 versus \$3.5 million in the first quarter of 2014. Amortization of R&D assets associated with the development of Bloxiverz and Vazculep was \$3.1 million in the first quarter of 2015, modestly above recent quarters.

Total net interest income was \$657,000 in the first quarter of 2015 compared to interest expense of \$5.5 million in the first quarter of 2014. 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.

In the first quarter 2015, the Company had total foreign exchange gain of \$11.5 million, of which \$2.2 million was realized, 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, it 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 (\$5.3) million for the three months ended March 31, 2015 compared to (\$14.6) 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).

Net income from Continuing Operations for the first quarter of 2015 was \$11.6 million versus net loss from Continuing Operations of (\$26.9) million in the year-ago period. Earnings per share from Continuing Operations was \$0.29 (basic) and \$0.27 (diluted) in the first quarter of 2015 versus loss per share from Continuing Operations (both basic and diluted) of (\$0.95) in the first quarter of 2014.

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.



Adjusted net income (non-GAAP) for the first quarter of 2015 was \$4.4 million versus adjusted net loss (non-GAAP) of (\$4.4) million in the first quarter of 2014. Adjusted earnings (non-GAAP) per share (diluted) was \$0.10 in the first quarter of 2015 versus adjusted loss (non-GAAP) per share (diluted) of (\$0.16) in the prior year period.

The Company's cash position as of March 31, 2015 was \$113.2 million compared to \$92.8 million as of December 31, 2014.

	Three months ended March 31,			
	2014		2015	
GAAP Net income (loss) and diluted earnings (loss) per share.....	(\$26,638)	(\$0.95)	\$11,647	\$0.27
Fair value remeasurement of acquisition liabilities	14,626		5,254	
Fair value remeasurement of royalty agreement.....	156		259	
Amortization of Intangible R&D Assets.....	2,937		3,143	
Accelerated reimbursement of acquisition note.....	3,013		-	
Accelerated reimbursement of facility agreements.....	4,741		-	
Tax effects of the above items.....	(2,338)		-	
Earn-out acquisition payment payable.....	(611)		(5,796)	
Royalty payable.....	(92)		(845)	
Unrealized foreign exchange (gain)/loss.....	(207)		(9,250)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	(\$4,413)	(\$0.16)	\$4,411	\$0.10

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Friday, May 15, 2015**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 877-856-1969 (U.S.) or 1+ 719-325-4818 (international). The conference ID number is 2363276. 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 (NASDAQ: FLML) is a specialty pharmaceutical company utilizing its core competencies in formulation development and drug delivery to develop safer and more efficacious pharmaceutical products, addressing unmet medical needs and/or reducing overall healthcare costs. Flamel currently has approvals for and markets two previously Unapproved Marketed Drugs ("UMDs") in the USA, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep™ (phenylephrine hydrochloride injection). The Company intends to add to this branded business by creating additional products, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. Flamel currently has several products in development utilizing Micropump® (oral sustained release microparticles platform) along with its related technologies, LiquiTime® and Trigger Lock™. The



lead project for Micropump is Sodium Oxybate. LiquiTime allows for the extended-release of liquid medicines (such as Ibuprofen and Guaifenesin) and Trigger Lock is an abuse-resistant iteration of Micropump, designed specifically for long-acting opioids. Additionally, the Company has developed a long acting injectable platform, Medusa™, a hydrogel depot technology currently being studied with Exenatide. Flamel's products are targeting high-value molecules and will utilize either the 505(b)(2) approval process for NDAs or biosimilar pathways ultimately approved by FDA and other regulatory authorities. 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 includes statements concerning our operating results (including product sales), financial condition and product development milestones, which are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words “anticipate,” “assume,” “believe,” “expect,” “estimate,” “plan,” “will,” “may,” and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Flamel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz® and Vazculep™ products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for the two pipeline products we are evaluating for potential application to the FDA pursuant to our “unapproved-to-approved” strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; our dependence on key personnel to execute our business plan; the possibility that we may cease to qualify as a foreign private issuer, which would increase the costs and expenses we incur to comply with U.S. securities laws; and the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 20-F for the year ended December 31, 2014, all of which filings are also available on the Company's website.



Flamel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.

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

	Three months ended March	
	31,	
	2014	2015
Revenue:		
License and research revenue	\$598	(\$38)
Product sales and services	3,960	32,711
Other revenues	20	53
Total revenue	<u>4,578</u>	<u>32,726</u>
Costs and expenses:		
Cost of goods and services sold	(773)	(3,630)
Research and development	(3,944)	(6,022)
Selling, general and administrative	(3,516)	(4,463)
Fair value remeasurement of acquisition liabilities, incl. related parties	(14,626)	(5,254)
Amortisation of intangible R&D assets	(2,937)	(3,143)
Acquisition note expenses, incl. related parties	(3,013)	-
Total	<u>(28,809)</u>	<u>(22,512)</u>
Profit (loss) from continuing operations	(24,231)	10,214
Interest income (expense) net	(5,507)	657
Interest expense on debt related to the royalty agreement with related parties.....	(156)	(259)
Foreign exchange gain (loss)	179	11,501
Other income (loss)	52	7
Income (loss) before income taxes from continuing operations ...	<u>(29,663)</u>	<u>22,120</u>
Income tax benefit (expense)	2,802	(10,473)
Net income (loss) from continuing operations	<u>(\$26,861)</u>	<u>\$11,647</u>
Net income from discontinued operations.....	\$223	\$0
Net income (loss).....	<u><u>(\$26,638)</u></u>	<u><u>\$11,647</u></u>
Earnings (loss) per ordinary share (Basic):		
Continuing operations.....	(\$0.95)	\$0.29
Discontinued operations.....	\$0.01	\$0.00
Net income (loss).....	(\$0.94)	\$0.29
Earnings (loss) per share (Diluted):		
Continuing operations.....	(\$0.95)	\$0.27
Discontinued operations.....	\$0.01	\$0.00
Net income (loss).....	(\$0.94)	\$0.27
Weighted average number of shares outstanding (in thousands) :		
Basic	28,312	40,207
Diluted	28,312	42,834