



Flamel Technologies Reports Third Quarter 2015 Results

Reaffirmed product revenue guidance for 2015 of \$170-\$185 million

Licensed LiquiTime® to Perrigo for the U.S. OTC market

Lyon, France – November 12, 2015 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the third quarter of fiscal year 2015. Highlights included:

- Total revenue for third quarter was \$47.3 million, compared to \$2.9 million during the same period last year.
- GAAP net loss was (\$29.7) million, or (\$0.73) per diluted share, compared to (\$10.0) million, or (\$0.26) per diluted share, during the same period last year. Adjusted net income, which excludes certain items described below, was \$11.5 million, or \$0.28 per diluted share, compared to an adjusted net loss of (\$6.0) million, or (\$0.16) per diluted share, during the same period last year.
- Cash on hand at September 30, 2015 was \$128.4 million, compared to \$116.1 million at June 30, 2015.
- Received acceptance of a New Drug Application (NDA) for the Company's third Unapproved Marketed Drug (UMD), Éclat #3, by the U.S. Food and Drug Administration (FDA).
- Licensed exclusive rights for the Company's LiquiTime® drug delivery platform to Perrigo for the U.S. Over-the-Counter (OTC) drug market.

Michael Anderson, Chief Executive Officer of Flamel, commented, "The third quarter of 2015 marked another consecutive period of strong revenues and cash flow generated by Flamel's marketed products, Bloxiverz® and Vazculep®, allowing the Company to reiterate its yearly revenue guidance of \$170-\$185 million. As expected, Bloxiverz maintained its market share during the quarter averaging approximately 60%. In addition to strong revenue generation, the Company received acceptance from the FDA for its third NDA for Éclat #3 and a PDUFA date of April 30, 2016."

Mr. Anderson continued, "Near the end of the third quarter, Flamel licensed its proprietary LiquiTime drug delivery platform to Perrigo for the U.S. Over-the-Counter (OTC) drug market."



Flamel received an upfront payment of \$6 million and will be eligible for a minimum of \$50 million in approval and launch milestone payments for at least seven products, in addition to receiving mid-single digit royalties on net sales of these products. The OTC cough/cold market is estimated to be in the range of \$6.5 billion per year, and we believe the need for extended release liquid oral therapies is widely recognized. Both Flamel and Perrigo believe that the commercial potential for mono and combination therapies using our LiquiTime drug delivery platform is robust. This agreement with Perrigo is a significant milestone for Flamel as we successfully out-licensed our technology to a leading OTC player and believe Perrigo is well positioned to maximize the commercial potential of LiquiTime.”

Third Quarter Results

Flamel reported total revenues during the third quarter of 2015 of \$47.3 million, an increase of \$44.4 million compared to the prior year period. Total revenues included revenue from Bloxiverz of \$41.2 million and from Vazculep of \$5.6 million.

Adjusted net income for the third quarter of 2015 was \$11.5 million, compared to adjusted net loss of (\$6.0) million in the third quarter of 2014. Adjusted earnings per diluted share was \$0.28 in the third quarter of 2015, versus adjusted loss per diluted share of (\$0.16) in the prior year period. The Bloxiverz and Vazculep revenue streams drove the increase in adjusted net income enabling continued investment and spending for the Company’s opportunistic UMD strategy and further development of its proprietary pipeline of pharmaceutical products, which will contribute to its product portfolio in the medium term.

Net loss from Continuing Operations for the third quarter of 2015 was (\$29.7) million, versus net loss of (\$10.0) million in the year-ago period. Loss per diluted share from Continuing Operations was (\$0.73) in the third quarter of 2015, versus loss per diluted share from Continuing Operations of (\$0.26) in the third quarter of 2014. The increase in net loss from continuing operations when compared to the same period last year primarily resulted from higher charges associated with fair value remeasurements of certain acquisition and royalty liabilities which increased by \$36.9 million and \$5.2 million, respectively, and a decrease in foreign exchange gain of \$7.9 million from the third quarter of 2014 that did not repeat in the third quarter of 2015. These items were partially offset by higher net income resulting from greater revenue levels in the third quarter of 2015, compared to the third quarter of 2014.



Flamel discloses certain non-GAAP financial measures, including adjusted net income and loss and adjusted net income and loss per diluted share, as management believes that a comparison of its current and historical results would be difficult if the disclosures were limited to financial measures prepared only in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to reporting its financial results in accordance with GAAP, Flamel reports 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, but includes the 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. The following table reconciles GAAP net income and loss and diluted earnings or loss per share to the corresponding adjusted amounts.

	Three months ended September 30,				Nine months ended September 30,			
	2014		2015		2014		2015	
GAAP Net income (loss) and diluted earnings (loss) per share.....	(\$10,046)	(\$0.26)	(\$29,685)	(\$0.73)	(\$57,757)	(\$1.64)	(\$35,438)	(\$0.88)
Fair value remeasurement of acquisition liabilities	7,865		44,782		35,098		82,036	
Fair value remeasurement of royalty agreement.....	1,486		6,644		2,721		9,629	
Amortization of Intangible R&D Assets.....	2,937		3,141		8,812		9,423	
Accelerated reimbursement of acquisition note.....	-		-		3,013		-	
Accelerated reimbursement of facility agreements.....	-		-		4,741		-	
Earn-out acquisition payment payable.....	(361)		(9,028)		(1,356)		(24,203)	
Royalty payable.....	(58)		(1,211)		(204)		(3,326)	
Unrealized foreign exchange (gain)/loss.....	(7,856)		(32)		(8,337)		(4,814)	
Tax effects of the above items.....	-		(3,089)		(2,338)		(4,080)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	(\$6,033)	(\$0.16)	\$11,522	\$0.28	(\$15,607)	(\$0.44)	\$29,227	\$0.72

A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Thursday, November 12, 2015. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-811-5408 (U.S. and Canada) or +1-913-312-1486 (international). The conference ID number is 776094.



Interested parties may access a live audio webcast of the conference call via the investor section of the Company website, www.flamel.com. The archived webcast of the conference call will be available for 90 days on Flamel's website.

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, and recently announced FDA acceptance of its third NDA filing with an FDA-assigned PDUFA date of April 30, 2016. Flamel also has several products in development utilizing Micropump[®] (oral sustained release microparticles platform) along with its tangent 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 (such as hydromorphone). 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 may include "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 amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; 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 September 30,		Nine months ended September 30,	
	2014	2015	2014	2015
Revenue:				
License and research revenue	\$335	-	\$2,752	-
Product sales and services	2,570	47,314	9,013	\$129,790
Other revenues	8	6	44	51
Total revenue	<u>2,913</u>	<u>47,320</u>	<u>11,809</u>	<u>129,841</u>
Costs and expenses:				
Cost of goods and services sold	(707)	(2,087)	(1,987)	(8,473)
Research and development	(4,118)	(7,221)	(11,662)	(20,447)
Selling, general and administrative	(4,025)	(4,568)	(11,606)	(14,904)
Fair value remeasurement of acquisition liabilities, incl. related parties	(7,865)	(44,782)	(35,098)	(82,036)
Amortisation of intangible R&D assets	(2,937)	(3,141)	(8,812)	(9,423)
Acquisition note expenses, incl. related parties	-	-	(3,013)	-
Total	<u>(19,652)</u>	<u>(61,799)</u>	<u>(72,178)</u>	<u>(135,283)</u>
Operating profit (loss) from continuing operations	(16,739)	(14,479)	(60,369)	(5,442)
Interest income	86	407	225	1,858
Interest expense	-	(237)	(5,552)	(719)
Interest expense on debt related to the royalty agreement with related parties	(1,486)	(6,644)	(2,721)	(9,629)
Foreign exchange gain (loss)	8,074	160	8,545	8,096
Other income (loss)	71	27	152	32
Income (loss) before income taxes from continuing operations	<u>(9,994)</u>	<u>(20,766)</u>	<u>(59,720)</u>	<u>(5,804)</u>
Income tax benefit (expense)	14	(8,919)	2,679	(29,634)
Net income (loss) from continuing operations	<u>(\$9,980)</u>	<u>(\$29,685)</u>	<u>(\$57,041)</u>	<u>(\$35,438)</u>
Net income from discontinued operations.....	(\$66)	\$0	(\$716)	\$0
Net income (loss).....	<u>(\$10,046)</u>	<u>(\$29,685)</u>	<u>(\$57,757)</u>	<u>(\$35,438)</u>
Earnings (loss) per ordinary share (Basic):				
Continuing operations	(\$0.26)	(\$0.73)	(\$1.62)	(\$0.88)
Discontinued operations.....	(\$0.00)	\$0.00	(\$0.02)	\$0.00
Net income (loss).....	(\$0.26)	(\$0.73)	(\$1.64)	(\$0.88)
Earnings (loss) per share (Diluted):				
Continuing operations	(\$0.26)	(\$0.73)	(\$1.62)	(\$0.88)
Discontinued operations.....	(\$0.00)	\$0.00	(\$0.02)	\$0.00
Net income (loss).....	(\$0.26)	(\$0.73)	(\$1.64)	(\$0.88)
Weighted average number of shares outstanding (in thousands) :				
Basic	38,767	40,625	35,201	40,397
Diluted	38,767	40,625	35,201	40,397