



## **Flamel Technologies Announces Second 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 July 30, 2015*

**Lyon, France – July 30, 2015** - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the second quarter of fiscal year 2015. Highlights from the quarter include:

- Product revenues of \$50 million
- Submission of Unapproved Marketed Drug (UMD) #3 to FDA
- Positive results from two pharmacokinetic (PK) studies in healthy volunteers of abuse-deterrent, extended-release, oral hydromorphone product using Trigger Lock™ technology
- Addition of Sandy Hatten as Senior Vice President of Quality and Regulatory Affairs and Gregory J. Davis as its Vice President of Business and Corporate Development

“We are pleased to report that Bloxiverz® remained strong throughout the quarter with approximately 70% average share during the second quarter following the launch of Fresenius Kabi’s competing product early in early April. For the Company’s second approved marketed drug, Vazculep®, Flamel implemented a price increase in the second quarter for both the 5 and 10 mL vial sizes, for which it now supplies virtually the entire market, and continues to gain share in the 1mL vial size,” said Chief Executive Officer, Mike Anderson. “As we look forward for the full year, we are reaffirming product revenue guidance for 2015 of \$170-185 million for both Bloxiverz and Vazculep and will update investors with our third quarter financial report,” added Mr. Anderson.

“The Company continues to focus on expanding its senior management team evident in the appointment of Sandy Hatten to head up Quality and Regulatory Affairs and Greg Davis to focus on Business and Corporate Development, both of whom have outstanding track records in the industry. We submitted our NDA to the FDA for our third unapproved marketed drug in the quarter, consistent with our objective. In our proprietary product pipeline, we were pleased to report positive results from two pilot pharmacokinetic (PK) studies in healthy volunteers of FT227, an abuse-deterrent, extended release oral hydromorphone product using our



proprietary Trigger Lock™ drug delivery platform. These results continue a series of positive clinical trial data announcements by Flamel over the past 15 months,” concluded Mr. Anderson.

### **Flamel’s Second Quarter Results**

Flamel reported total revenues during the second quarter of 2015 of \$49.8 million, an increase of \$45.5 million in revenues compared to the prior year period. Total revenues is comprised of net sales of Bloxiverz of \$45.5 million, Vazculep of \$3.6 million and another product of \$0.6 million. Net sales represent units that have been sold through to the hospitals and where the chargeback can be determined, particularly in a period when product prices may be changing. As of June 30, 2015, the Company had Deferred Revenues of \$19.3 million, comprised of \$17.5 million for Bloxiverz and \$1.8 million for Vazculep, compared to \$30.7 million and \$1.4 million, respectively, in the first quarter of 2015.

Costs of goods and services sold for the second quarter of 2015 were \$2.8 million compared to \$507,000 in the second quarter of 2014. Research and development costs in the second quarter of 2015 totaled \$7.2 million, compared to \$3.6 million in the prior year period, an increase of 100%. A substantial portion of this increase is attributed to costs associated with filing of UMD #3 with the U.S. Food and Drug Administration (FDA) and continued investment in the Company’s pipeline and other proprietary products. Selling, general and administrative costs were \$5.9 million in the second quarter of 2015, an increase of 44% versus \$4.1 million in the second quarter of 2014, due to increased stock compensation expense as a result of higher share price and accelerated vesting and costs associated with hiring new personnel. Amortization of R&D assets associated with the development of Bloxiverz and Vazculep was \$3.1 million in the second quarter of 2015, consistent with the prior sequential quarter.

Total net interest income was \$312,000 in the second quarter of 2015 compared to interest income of \$94,000 in the second quarter of 2014. Interest expense has been 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 second quarter 2015, the Company had foreign exchange loss of (\$3.6) million, compared to a foreign exchange gain of \$292,000 in the prior year period. While our parent company in France uses the Euro as its functional currency, it holds over \$80 million in assets that are U.S. Dollar denominated, which depreciated relative to the Euro over the second quarter.



Operating and net income (loss) includes remeasurement of the fair value of the acquisition liabilities which was an expense of (\$32.0) million for the three months ended June 30, 2015 compared to (\$12.6) 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 loss from Continuing Operations for the second quarter of 2015 was (\$17.4) million versus net loss from Continuing Operations of (\$20.2) million in the year-ago period. Loss per share from Continuing Operations was (\$0.43) on both a basic and diluted level in the second quarter of 2015 versus loss per share from Continuing Operations (both basic and diluted) of (\$0.53) in the second 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 second quarter of 2015 was \$13.9 million versus adjusted net loss (non-GAAP) of (\$5.2) million in the second quarter of 2014. Adjusted earnings



(non-GAAP) per share (diluted) was \$0.34 in the second quarter of 2015 versus adjusted loss (non-GAAP) per share (diluted) of (\$0.13) in the prior year period.

The Company's cash position as of June 30, 2015 was \$116.1 million compared to \$113.2 million as of March 31, 2015.

	Three months ended June 30,		Six months ended June 30,	
	2014	2015	2014	2015
GAAP Net income (loss) and diluted earnings (loss) per share.....	(\$21,073) (\$0.55)	(\$17,400) (\$0.43)	(\$47,711) (\$1.43)	(\$5,753) (\$0.14)
Fair value remeasurement of acquisition liabilities .....	12,607	32,000	27,233	37,254
Fair value remeasurement of royalty agreement.....	1,079	2,726	1,235	2,985
Amortization of Intangible R&D Assets.....	2,938	3,139	5,875	6,282
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.....	(383)	(9,379)	(994)	(15,175)
Royalty payable.....	(54)	(1,270)	(141)	(2,116)
Unrealized foreign exchange (gain)/loss.....	(274)	4,045	(481)	(5,205)
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	(\$5,161) (\$0.13)	\$13,861 \$0.34	(\$9,569) (\$0.29)	\$18,272 \$0.45

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Thursday, July 30, 2015**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-684-1282 (U.S. and Canada) or +1-913-312-1513 (international). The conference ID number is 1557700. The conference call webcast may be accessed at the investors section of [www.flamel.com](http://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. Flamel currently 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](http://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 June 30,		Six months ended June 30,	
	2014	2015	2014	2015
<b>Revenue:</b>				
License and research revenue .....	\$1,819	-	\$2,417	-
Product sales and services .....	\$2,483	49,765	6,443	\$82,476
Other revenues .....	\$16	30	36	45
<b>Total revenue .....</b>	<b>4,318</b>	<b>49,795</b>	<b>8,896</b>	<b>82,521</b>
<b>Costs and expenses:</b>				
Cost of goods and services sold .....	(507)	(2,756)	(1,280)	(6,386)
Research and development .....	(3,600)	(7,204)	(7,544)	(13,226)
Selling, general and administrative .....	(4,065)	(5,873)	(7,581)	(10,336)
Fair value remeasurement of acquisition liabilities, incl. related parties .....	(12,607)	(32,000)	(27,233)	(37,254)
Amortisation of intangible R&D assets .....	(2,938)	(3,139)	(5,875)	(6,282)
Acquisition note expenses, incl. related parties .....	-	-	(3,013)	-
<b>Total .....</b>	<b>(23,717)</b>	<b>(50,972)</b>	<b>(52,526)</b>	<b>(73,484)</b>
<b>Profit (loss) from continuing operations .....</b>	<b>(19,399)</b>	<b>(1,177)</b>	<b>(43,630)</b>	<b>9,037</b>
Interest income .....	94	653	139	1,451
Interest expense .....	-	(341)	(5,552)	(482)
Interest expense on debt related to the royalty agreement with related parties .....	(1,079)	(2,726)	(1,235)	(2,985)
Foreign exchange gain (loss) .....	292	(3,565)	471	7,936
Other income (loss) .....	29	(2)	81	5
<b>Income (loss) before income taxes from continuing operations ...</b>	<b>(20,063)</b>	<b>(7,158)</b>	<b>(49,726)</b>	<b>14,962</b>
Income tax benefit (expense) .....	(137)	(10,242)	2,665	(20,715)
<b>Net income (loss) from continuing operations .....</b>	<b>(\$20,200)</b>	<b>(\$17,400)</b>	<b>(\$47,061)</b>	<b>(\$5,753)</b>
Net income from discontinued operations.....	(\$873)	\$0	(\$650)	\$0
<b>Net income (loss).....</b>	<b>(\$21,073)</b>	<b>(\$17,400)</b>	<b>(\$47,711)</b>	<b>(\$5,753)</b>
<b>Earnings (loss) per ordinary share (Basic):</b>				
Continuing operations.....	(\$0.53)	(\$0.43)	(\$1.41)	(\$0.14)
Discontinued operations.....	(\$0.02)	\$0.00	(\$0.02)	\$0.00
Net income (loss).....	(\$0.55)	(\$0.43)	(\$1.43)	(\$0.14)
<b>Weighted average number of shares outstanding (in thousands) :</b>				
Basic .....	38,438	40,353	33,403	40,281
Diluted .....	38,438	40,353	33,403	40,281