



## **Flamel Technologies Announces Third Quarter Results of Fiscal Year 2014**

***Vazculep™ is now shipping to hospitals in all three vial sizes***

***David Monteith joins as Vice President, Research and Development***

***Conference call with management to take place at 10:00 am ET on October 31, 2014***

**Lyon, France – October 31, 2014** - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the third quarter of fiscal year 2014. Highlights from the quarter include:

- Vazculep™ (phenylephrine hydrochloride) was shipped in the third quarter, reaching hospital shelves in early October. The company is distributing 1ml single use vials, as well as 5ml and 10ml pharmacy bulk package vials. Flamel is now the only drug manufacturer offering FDA-approved versions of all three product presentations of phenylephrine hydrochloride injection.
- Flamel announced data from a First-in-Man clinical study of its proprietary LiquiTime® drug delivery platform applied to ibuprofen, a broadly used medication for pain relief and fever. LiquiTime® is designed to provide a controlled, extended release of oral liquids. A BID (twice daily) formulation of LiquiTime® ibuprofen was shown to be bioequivalent to an immediate release ibuprofen oral suspension. There were no safety or tolerability issues detected.
- David Monteith joined Flamel in mid-October as Vice President, Research and Development.

“We are very pleased that both Bloxiverz® and Vazculep™ are now available to hospital pharmacists, GPOs and distributors. As we believe that the unapproved versions of neostigmine inventory are being depleted in the market, we are confident that Flamel’s market share of neostigmine will rise in the fourth quarter of 2014,” said Mike Anderson, Chief Executive Officer of Flamel.

“In addition, Flamel’s Vazculep™ is the only FDA-approved version of phenylephrine hydrochloride that is available to the market in all three vial sizes. We are excited about this launch and believe that the availability of all three vial sizes from a single manufacturer is preferred by hospital pharmacists for simplified ordering. Even in early distribution, we have seen some uptake from hospitals around the country.



“For our LiquiTime<sup>®</sup> extended release liquid technology, the initial First-in-Man data is promising,” added Mr. Anderson. “It shows the early potential of another of Flamel’s four drug delivery platforms to deliver a commercially promising drug to the market.

“Also, we are excited to welcome David Monteith to Flamel as Vice President, Research and Development. He joins the Company with 25 years of pharmaceutical industry experience, most recently at Merck. David is an important addition to the team and will play a key role in executing on our product pipeline and leveraging Flamel’s drug delivery platforms and formulation expertise.”

### **Flamel’s Third Quarter Results**

Flamel reported total revenues during the third quarter of 2014 of \$7.0 million, an increase of \$1.4 million in revenues compared to the prior year period. Product sales and services revenues in the third quarter of 2014 of were \$4.7 million compared to \$2.5 million in the prior year quarter, principally due to higher sales of Bloxiverz<sup>®</sup> which had just started its commercial launch in the third quarter of 2013. On a sequential basis, third quarter 2014 revenues of \$7.0 million were down from \$8.1 million in the second quarter of 2014 due to a decline in license and research revenue. The lower license and research revenue reflects the Company’s strategic focus on proprietary products which have more attractive potential returns as compared to partnered products.

Costs of goods and services sold for the third quarter of 2014 were \$1.9 million compared to \$1.7 million in the third quarter of 2013. Research and development costs in the third quarter of 2014 totaled \$7.0 million, compared to \$6.7 million in the prior year period. Selling, general and administrative costs were \$4.1 million in the third quarter of 2014 versus \$2.9 million in the third quarter of 2013. This increase resulted from the increase in FDA product fees following the approval of Vazculep<sup>™</sup> and increased legal costs. Amortization of R&D assets associated with the development of Bloxiverz<sup>®</sup> was \$2.9 million in the third quarter of 2014, consistent with recent quarters, and this charge will be incurred quarterly through the end of 2016.

Total net interest income was \$86,000 in the third quarter of 2014 compared to interest expense of \$688,000 in the third 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.

In the third quarter 2014, the Company had total unrealized foreign exchange gain of \$8.1 million due to the strengthening of the U.S. Dollar to the Euro. While our parent company in France uses the Euro as our functional currency, Flamel holds approximately \$70 million in assets that are U.S. Dollar denominated which appreciated relative to the Euro.



Net loss for the third quarter of 2014 was \$10.0 million versus net loss of \$6.4 million in the year-ago period. Earnings per share (both basic and diluted) was \$(0.26) in the third quarter of 2014 versus \$(0.25) in the third quarter of 2013.

Adjusted net loss (non-GAAP) for the third quarter of 2014 was \$6.0 million versus \$5.4 million in the third quarter of 2013. Adjusted loss per share (both basic and diluted) was \$(0.16) in the third quarter of 2014 versus \$(0.21) in the prior year period.

The Company's cash position as of September 30, 2014 was \$76.4 million compared to \$77.9 million as of June 30, 2014. During the quarter, Flamel received a payment of \$5.7 million from the French Government in recognition of the research and development conducted by Flamel in France, effectively an R&D tax credit. The use of cash during the third quarter principally reflects continued investment in the Company's product pipeline, preparation for the launch of Vazculep™, including the working capital investment required to build an inventory position, and other general and administrative costs related to the growth of the company.

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

	Three months ended September 30,		Nine months ended September 30,	
	2013	2014	2013	2014
GAAP Net income (loss) and diluted earnings (loss) per share.....	(\$6,369) (\$0.25)	(\$10,046) (\$0.26)	(\$48,052) (\$1.89)	(\$57,757) (\$1.64)
Fair value remeasurement of acquisition liabilities .....	1,043	7,865	32,642	35,098
Fair value remeasurement of royalty agreements .....	13	1,486	2,028	2,721
Amortization of Intangible R&D Assets.....	-	2,937	-	8,812
Accelerated reimbursement of acquisition note.....	-	-	-	3,013
Accelerated reimbursement of facility agreements.....	-	-	-	4,741
Tax effects of the above items .....	(89)	-	(2,342)	(2,338)
Earn-out acquisition payment payable.....	(167)	(361)	(275)	(1,356)
Royalty payable.....	-	(58)	-	(196)
Unrealized foreign exchange (gain)/loss.....	140	(7,856)	152	(8,337)
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share.....	(\$5,428) (\$0.21)	(\$6,033) (\$0.16)	(\$15,847) (\$0.62)	(\$15,599) (\$0.44)

A conference call to discuss these results and other updates is scheduled for **10:00 AM ET on Friday, October 31, 2014**. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-504-7963 (U.S.) or 1+ 719-457-2648 (international). The conference ID number is 1529553. The conference call webcast may be accessed at [www.flamel.com](http://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) and Vazculep™ (phenylephrine hydrochloride) in the US 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](http://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® 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.*

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

	Three months ended Sept 30,		Nine months ended Sept 30,	
	2013	2014	2013	2014
<b>Revenue:</b>				
License and research revenue .....	\$1,192	\$681	\$4,115	\$4,384
Product sales and services .....	2,500	4,747	6,802	14,815
Other revenues .....	1,891	1,600	5,347	5,086
Total revenue .....	<u>5,583</u>	<u>7,028</u>	<u>16,264</u>	<u>24,285</u>
<b>Costs and expenses:</b>				
Cost of goods and services sold .....	(1,736)	(1,913)	(4,014)	(5,501)
Research and development .....	(6,680)	(7,028)	(22,513)	(20,864)
Selling, general and administrative .....	(2,925)	(4,105)	(8,122)	(11,955)
Fair value remeasurement of acquisition liabilities, incl. related parties .....	(1,043)	(7,865)	(32,642)	(35,098)
Amortisation of intangible R&D assets .....	-	(2,937)	-	(8,812)
Acquisition note expenses, incl. related parties .....	-	-	-	(3,013)
Total .....	<u>(12,384)</u>	<u>(23,848)</u>	<u>(67,291)</u>	<u>(85,243)</u>
Profit (loss) from operations .....	(6,801)	(16,820)	(51,027)	(60,958)
Interest income (Expense) net .....	(688)	86	(1,757)	(5,328)
Interest expense on debt related to the royalty agreement with related parties .....	(13)	(1,486)	(2,028)	(2,721)
Foreign exchange gain (loss) .....	(161)	8,074	(170)	8,545
Other income (loss) .....	66	71	532	152
Income (loss) before income taxes .....	(7,597)	(10,075)	(54,450)	(60,310)
Income tax benefit (expense) .....	1,228	29	6,398	2,553
Net Income (loss) .....	<u>(\$6,369)</u>	<u>(\$10,046)</u>	<u>(\$48,052)</u>	<u>(\$57,757)</u>
<b>Earnings (loss) per share</b>				
Basic earnings (loss) per ordinary share .....	(\$0.25)	(\$0.26)	(\$1.89)	(\$1.64)
Diluted earnings (loss) per share .....	(\$0.25)	(\$0.26)	(\$1.89)	(\$1.64)
<b>Weighted average number of shares outstanding (in thousands) :</b>				
Basic .....	25,465	38,767	25,434	35,201
Diluted .....	25,465	38,767	25,434	35,201