



Flamel Technologies Reports Fourth Quarter and Full Year 2015 Results

Full year product revenues of \$173.2 million and diluted EPS of \$0.93

Reaffirms 2016 revenue guidance of \$110 million to \$130 million

Lyon, France – March 10, 2016 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the fourth quarter and full year of 2015.

Fourth Quarter Highlights Include:

- Total revenue for fourth quarter 2015 was \$43.4 million, compared to \$3.0 million during the same period last year.
- GAAP net income for the fourth quarter was \$76.1 million, or \$1.75 per diluted share, compared to a GAAP net loss of (\$27.1) million, or (\$0.69) per diluted share, for the same period last year.
- Adjusted net income* for the fourth quarter was \$13.9 million, or \$0.32 per diluted share, compared to an adjusted net loss* of (\$9.7) million, or (\$0.25) per diluted share, during the same period last year.
- Cash and marketable securities at December 31, 2015 were \$144.8 million, compared to \$128.4 million at September 30, 2015 and \$92.8 million at December 31, 2014.
- Acquisition of FSC Pediatrics in February 2016 provides four new commercial stage products and established commercial infrastructure.

** Non-GAAP financial measure. Descriptions of Flamel's non-GAAP financial measures are included under the caption "Non-GAAP Disclosures and Adjustments" included within this document and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the "Supplemental Information" section within this document under the caption "Reconciliations of Non-GAAP Financial Measures."*

Michael Anderson, Flamel's Chief Executive Officer, commented, "2015 was an exciting and productive year for the Company during which we set and then achieved a number of important goals: We began the year by setting revenue guidance of \$170 - \$185 million and achieved our goal by generating \$173.2 million in revenues, principally from our marketed products, Bloxiverz® and Vazculep®. Following our global reorganization at the end of 2014, we made key senior level hires during 2015 to support our rapid growth, including a Chief Financial Officer, a SVP of Quality



and Regulatory Affairs, a VP of Strategic Marketing and a VP of Business and Corporate Development.”

“In addition to meeting full year guidance, Flamel outlined a number of expected clinical milestones at the beginning of 2015 and subsequently reported positive data on each, including Trigger Lock™ hydromorphone, Medusa™ exenatide and LiquiTime® guaifenesin. We executed our strategy to license the LiquiTime® technology to a major OTC marketer, Perrigo, through its subsidiary Elan Pharma International Limited, a deal from which we expect to see at least \$50 million in milestone payments in addition to mid-single digit royalties on a minimum of seven products. This license is a tremendous validation of our product-delivery technology and going forward we expect to apply that technology to a number of prescription products where we believe it can fulfill a number of unmet medical needs. During the third quarter of 2015, we received FDA acceptance of our third NDA for Éclat #3, and have an expected PDUFA date of April 30th.”

Mr. Anderson concluded, “We are very pleased with the excellent progress we made during 2015, and are even more excited about 2016, during which we will be running several pivotal trials, the most important of which is Micropump® sodium oxybate, as well as launching Éclat #3 and unveiling several new prescription product candidates for use with LiquiTime®. Our acquisition of FSC Pediatrics in early February provides Flamel with four new commercial stage products, three of which are IP protected, and an established commercial infrastructure. We plan to leverage this infrastructure as the Company continues to expand and become a more diversified specialty pharmaceutical company with world-class drug delivery technologies that address unmet medical needs and underserved patient populations.”

Fourth Quarter 2015 Results

The Company achieved revenues during the fourth quarter of 2015 of \$43.4 million, compared to \$3.0 million during the same period last year. On a GAAP basis, Flamel had net income of \$76.1 million during the fourth quarter, or \$1.75 per diluted share, compared to a net loss of (\$27.1) million, or (\$0.69) per diluted share, in the prior year period. Adjusted net income was \$13.9 million, or \$0.32 per diluted share, compared to an adjusted net loss of (\$9.7) million, or (\$0.25) per diluted share, during the same period last year. Adjusted net income increased over the prior year principally as a result of substantially higher revenues from Bloxiverz® and Vazculep® in 2015 compared to 2014. Included in GAAP net income in the fourth quarter 2015 was a \$51.1 million gain resulting from the reduction of the Company’s contingent consideration liability. The Company reassessed its long term sales forecast and reduced its contingent consideration liability



primarily due to the December 28, 2015 FDA announcement of a generic version of neostigmine, creating a market of three approved providers, exclusive of Merck's sugammadex approval. Please see the appendix to this earnings release for a reconciliation of adjusted net income and diluted EPS to GAAP net income and diluted EPS.

Full Year 2015 Results

Flamel met its full year 2015 revenue guidance by generating \$173.2 million in revenues, compared to \$14.8 million in 2014. GAAP net income for 2015 was \$40.7 million, or \$0.93 per diluted share, compared to a net loss of (\$84.9) million, or (\$2.34) per diluted share, in 2014. Adjusted net income was \$43.1 million, or \$0.99 per diluted share, compared to an adjusted net loss of (\$24.6) million, or (\$0.68) per diluted share, in 2014. Adjusted net income increased over the prior year principally as a result of substantially higher revenues from Bloxiverz® and Vazculep® in 2015 compared to 2014. Cash flow from operations was \$84.3 million compared to cash used in operations of \$(10.6) million in the same period last year. Cash and marketable securities at December 31, 2015 were \$144.8 million, compared to \$128.4 million on September 30, 2015 and \$92.8 million at December 31, 2014.

2016 Revenue and R&D Spending Guidance

Following the Company's acquisition of FSC Pediatrics (FSC) on February 8, 2016, Flamel updated its 2016 full year revenue guidance from \$100 - \$120 million to \$110 - \$130 million. The Company expects newly acquired FSC products, AcipHex® Sprinkle™, Karbinal™ ER, Cefaclor for Oral Suspension and Flexichamber™, to generate revenues in the range of \$10 - \$15 million in 2016. As a result of the multiple clinical trials expected to run throughout 2016, the Company expects Research & Development costs to be in the range of \$35 - \$50 million, up from \$25.6 million in 2015.

A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Thursday, March 10, 2016. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 888-215-7015 (U.S. and Canada) or 913-312-0687 (international). The conference ID number is 9724678. 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 markets two previously Unapproved Marketed Drugs (“UMDs”) in the United States, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride injection), and in September 2015 announced that the NDA for its third UMD filing was accepted by the FDA and assigned a PDUFA date of April 30, 2016. The Company also develops products utilizing its proprietary drug delivery platforms, Micropump® (oral sustained release microparticles platform), along with its tangent technologies, LiquiTime® (a Micropump-derivative platform for liquid oral products) and Trigger Lock™ (a Micropump-derivative platform for abuse-resistant opioids). Additionally, the Company has developed a long acting injectable platform, Medusa™, a hydrogel depot technology, particularly suited to the development of subcutaneously administered formulations. Current applications of Flamel’s drug delivery products include sodium oxybate (Micropump®), extended-release of liquid medicines such as ibuprofen and guaifenesin (LiquiTime®, through a license arrangement with Elan Pharma International Limited for the U.S. Over-the-Counter market) and a current study of the delivery of exenatide utilizing the Medusa™ technology. In February 2016, Flamel acquired FSC Pediatrics, a Charlotte, North Carolina-based company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, indicated for infection, Karbinal™ ER, indicated for allergic rhinitis and AcipHex® Sprinkle™ (rabeprazole sodium) indicated for the treatment of gastroesophageal disease (GERD). FSC also received 510(k) clearance from the FDA in October 2014 for Flexichamber™, a collapsible holding chamber for used in the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. The Company is headquartered in Lyon, France and has operations in Dublin, Ireland and in the USA in both St. Louis, Missouri and Charlotte, North Carolina. 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.

Non GAAP Disclosures and Adjustments

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, if any, fair value remeasurements of its contingent consideration, impairment of intangible assets, amortization of intangible assets, effects of accelerated reimbursement of certain debt instruments, unrealized foreign exchange gains and losses on assets and liabilities denominated in foreign currency, the net income (loss) from discontinued operations and related tax effects, but includes the operating cash flows plus any unpaid accrued amounts associated with the contingent consideration, 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 table provided within the following “Supplemental Information” section reconciles GAAP net income and loss and diluted earnings or loss per share to the corresponding adjusted amounts.

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Flamel Technologies S.A.
Consolidated Statements of Income (Loss) - (Unaudited)
(In Thousands, Except Per Share Data)

	Three months ended		Years ended	
	December 31,		December 31,	
	2015	2014	2015	2014
Revenues:				
Product sales and services	\$ 42,647	\$ 2,936	\$ 172,488	\$ 11,993
License and research revenue	721	30	721	2,782
Total	43,368	2,966	173,209	14,775
Operating expenses:				
Cost of products and services sold	2,448	1,396	10,921	3,383
Research and development expenses	5,161	5,636	25,608	17,298
Selling, general and administrative expenses	6,808	4,092	21,712	15,698
Intangible asset amortization	3,141	2,937	12,564	11,749
Changes in fair value of related party acquisition-related contingent consideration	(51,079)	22,393	30,957	57,491
Loss on early repayment of related party acquisition-related note	-	-	-	3,013
Total	(33,521)	36,454	101,762	108,632
Operating income (loss)	76,889	(33,488)	71,447	(93,857)
Investment Income	934	738	2,651	963
Interest Expense	(837)	(195)	(1,415)	(5,747)
Interest Expense - changes in fair value of related party financing-related contingent consideration	4,746	(804)	(4,883)	(3,525)
Foreign exchange gain (loss)	2,498	3,326	10,594	11,871
Other income (expense)	(32)	(188)	-	(36)
Income (loss) before income taxes	84,198	(30,611)	78,394	(90,331)
Income tax provision (benefit)	8,101	1,272	37,735	(1,407)
Net income (loss) from continuing operations	76,097	(31,883)	40,659	(88,924)
Net income from discontinued operations	-	4,734	-	4,018
Net income (loss)	\$ 76,097	\$ (27,149)	\$ 40,659	\$ (84,906)
Earnings (loss) per share - Basic:				
Continuing operations	\$ 1.85	\$ (0.81)	\$ 1.00	\$ (2.45)
Discontinued operations	-	0.12	-	0.11
Net income (loss)	\$ 1.85	\$ (0.69)	\$ 1.00	\$ (2.34)
Earnings (loss) per share - Diluted:				
Continuing operations	\$ 1.75	\$ (0.81)	\$ 0.93	\$ (2.45)
Discontinued operations	-	0.12	-	0.11
Net income (loss)	\$ 1.75	\$ (0.69)	\$ 0.93	\$ (2.34)
Weighted average number of shares outstanding - Basic	41,125	39,208	40,580	36,214
Weighted average number of shares outstanding - Diluted	43,430	39,208	43,619	36,214



Flamel Technologies S.A.
Consolidated Balance Sheets - (Unaudited)
(In Thousands, Except Per Share Data)

	December 31,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 65,064	\$ 39,760
Marketable securities	79,738	53,074
Accounts receivable (net of allowance of \$35 and \$127 at December 31, 2015 and 2014 respectively)	6,978	1,679
Inventories	4,155	6,729
Research and development tax credit receivable - current portion	2,382	5,932
Prepaid expenses and other current assets	7,989	4,418
Current assets held for sale	-	730
Total current assets	166,306	112,322
Property and equipment, net	2,616	1,776
Goodwill	18,491	18,491
Intangible assets, net	15,825	28,389
Income tax deferred charge	11,581	13,102
Other	158	125
Total assets	\$ 214,977	\$ 174,205
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 434	\$ 2,440
Current portion of long-term related party contingent consideration payable	28,614	39,892
Accounts payable	10,565	8,024
Deferred revenue	5,121	1,336
Accrued expenses	3,598	5,667
Income taxes	323	7,643
Other	133	5,672
Current liabilities held for sale	-	168
Total current liabilities	48,788	70,842
Long-term debt, less current portion	684	1,277
Long-term related party contingent consideration payable, less current portion	94,079	74,858
Deferred taxes	1,351	-
Other	2,210	2,333
Total liabilities	147,112	149,310
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,198 shares authorized; 41,241 and 40,191 issued and outstanding at December 31, 2015 and 2014, respectively	6,331	6,188
Additional paid-in capital	363,984	346,582
Accumulated deficit	(279,793)	(320,452)
Accumulated other comprehensive loss	(22,657)	(7,423)
Total shareholders' equity	67,865	24,895
Total liabilities and shareholders' equity	\$ 214,977	\$ 174,205



Flamel Technologies S.A.
Consolidated Statements of Cash Flows - (Unaudited)
(In Thousands)

	Years ended December 31,	
	2015	2014
Cash flows from operating activities:		
Net income (loss)	\$ 40,659	\$ (84,906)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	13,132	14,141
Loss (gain) on disposal of property and equipment	-	(4,952)
Loss (gain) on sale of marketable securities	779	-
Unrealized exchange gain	(8,969)	(6,252)
Grants recognized in research and development expenses and operating income	(1,498)	(589)
Remeasurement of related party acquisition-related contingent consideration	30,957	60,503
Remeasurement of related party financing-related contingent consideration	4,883	3,319
Change in deferred tax and income tax deferred charge	1,420	(2,806)
Stock-based compensation expense	7,741	2,690
Increase (decrease) in cash from:		
Accounts receivable	(8,108)	3,426
Inventory	2,547	(3,112)
Prepaid expenses and other current assets	(610)	(2,330)
Research and development tax credit receivable	2,975	13,210
Accounts payable & other current liabilities	(3,887)	8,090
Deferred revenue	3,815	(55)
Accrued expenses	(1,617)	(265)
Other long-term assets and liabilities	74	(10,730)
Net cash provided by (used in) operating activities	84,293	(10,618)
Cash flows from investing activities:		
Purchases of property and equipment	(1,629)	(1,728)
Proceeds from disposal of property and equipment	-	13,242
Proceeds from sales of marketable securities	20,490	13,678
Purchase of marketable securities	(50,591)	(68,275)
Net cash provided by (used in) investing activities	(31,730)	(43,083)
Cash flows from financing activities:		
Reimbursement of loans	(4,911)	(34,186)
Reimbursement of conditional grants	(747)	(355)
Principal payments on capital lease obligations	-	(161)
Earn-out payments for related party acquisition-related contingent consideration	(24,526)	(1,357)
Royalty payments for related party financing-related contingent consideration	(3,371)	(206)
Excess tax benefit from stock-based compensation	2,814	-
Cash proceeds from issuance of ordinary shares and warrants	6,990	132,260
Net cash provided by financing activities	(23,751)	95,995
Effect of exchange rate changes on cash and cash equivalents	(3,508)	(9,170)
Net increase in cash and cash equivalents	25,304	33,124
Cash and cash equivalents at January 1	39,760	6,636
Cash and cash equivalents at December 31	\$ 65,064	\$ 39,760



Flamel Technologies S.A.
Supplemental Information - (Unaudited)
(In Thousands, Except Per Share Data)

	Three months ended December 31,		Years ended December 31,	
	2015	2014	2015	2014
Revenue by product:				
Bloxiverz	\$ 34,860	\$ 2,230	\$ 150,283	\$ 10,211
Vazculup	7,394	-	20,151	-
Dextroamphetamine	336	677	1,946	1,643
Other	57	29	108	139
Total product sales and services	42,647	2,936	172,488	11,993
License and research revenue	721	30	721	2,782
Total revenues	\$ 43,368	\$ 2,966	\$ 173,209	\$ 14,775

Reconciliation of Non-GAAP Financial Measures:

Net income (loss)

Reported	\$ 76,097	\$ (27,149)	\$ 40,659	\$ (84,906)
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./(Dec.)	(51,079)	22,393	30,957	57,491
Contingent consideration - Financing-related fair value remeasurements - Inc./(Dec.)	(4,746)	804	4,883	3,525
Intangible asset amortization	3,141	2,937	12,564	11,749
Unrealized foreign exchange (gain)/loss	(1,942)	(3,330)	(6,757)	(11,667)
Loss on early repayment of related party acquisition-related note	-	-	-	3,013
Loss on early repayment of related party facility agreement notes	-	-	-	4,741
Net income from discontinued operations	-	(4,734)	-	(4,018)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(8,016)	(323)	(32,219)	(1,678)
Contingent consideration - Financing-related paid/accrued	(1,092)	(58)	(4,418)	(262)
Income tax expense (benefit) related to all above adjustments	1,512	(222)	(2,568)	(2,560)
Total adjustments	(62,222)	17,467	2,442	60,334
Adjusted	\$ 13,875	\$ (9,682)	\$ 43,101	\$ (24,572)

Net income (loss) per share - Diluted:

Reported	\$ 1.75	\$ (0.69)	\$ 0.93	\$ (2.34)
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./(Dec.)	(1.17)	0.57	0.71	1.59
Contingent consideration - Financing-related fair value remeasurements - Inc./(Dec.)	(0.11)	0.02	0.11	0.10
Intangible asset amortization	0.07	0.07	0.29	0.32
Unrealized foreign exchange (gain)/loss	(0.04)	(0.08)	(0.15)	(0.32)
Loss on early repayment of related party acquisition-related note	-	-	-	0.08
Loss on early repayment of related party facility agreement notes	-	-	-	0.13
Net income from discontinued operations	-	(0.12)	-	(0.11)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(0.18)	(0.01)	(0.74)	(0.05)
Contingent consideration - Financing-related paid/accrued	(0.03)	-	(0.10)	(0.01)
Income tax expense (benefit) related to all above adjustments	0.03	(0.01)	(0.06)	(0.07)
Total adjustments	(1.43)	0.44	0.06	1.66
Adjusted	\$ 0.32	\$ (0.25)	\$ 0.99	\$ (0.68)