Flamel Technologies Reports Second Quarter 2016 Results

Total Revenues of $38.9 Million
2016 Revenue Guidance Increased to $125 to $140 Million
Akovaz™ to Launch in August 2016

Lyon, France – August 8, 2016 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the second quarter 2016.

Second Quarter Highlights Include:

- Total revenue for second quarter 2016 was $38.9 million, compared to $48.6 million during the same period last year.
- GAAP net loss for the second quarter was ($20.0) million, or ($0.48) per diluted share, compared to GAAP net loss of ($16.9) million, or ($0.42) per diluted share, during the same period last year.
- Adjusted EBITDA was $10.1 million, compared to $23.8 million in the prior year.*****
- Adjusted net loss for the second quarter was ($985,000), or ($0.02) per diluted share, compared to an adjusted net income of $11.5 million, or $0.29 per diluted share, during the same period last year. *****
- Cash and marketable securities at June 30, 2016 were $154.9 million, compared to $160.0 million at March 31, 2016 and $144.8 million at December 31, 2015.
- Akovaz received FDA approval on April 29, 2016 and is scheduled to launch in August 2016.

* *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.*

Michael Anderson, Flamel's Chief Executive Officer, commented, "We are particularly pleased with our second quarter results. Bloxiverz® averaged over 40% share of the neostigmine market during the quarter, and Vazculep® continued to build share to 32% of the 1mL market volume, while holding all of the 5mL and 10mL markets. We generated revenue of $38.9 million for the quarter and we look forward to launching our third sterile injectable product, Akovaz™, this month. We believe the market potential for Akovaz is the largest yet from our portfolio of previously unapproved marketed drugs, or UMDs."

Mr. Anderson continued, "In addition to our strong UMD business, we continue to advance our pipeline of proprietary products forward. We received positive data from our Phase 1b trial with

Medusa™ exenatide and, following guidance from FDA, we will be conducting an alcohol interaction study in the second half of 2016 with our Trigger Lock™ hydromorphone product to further test its abuse-deterrent capabilities."

"In regards to our most important project, Micropump® sodium oxybate, we have been in dialogue with FDA and look forward to finalizing the Special Protocol Assessment for our Phase III trial in the very near term. We continue to make all the necessary preparations associated with running the trial, including registering clinical sites and preparing clinical supplies, in order to hit the ground running once we begin patient enrollment. Our once nightly version of sodium oxybate is a very exciting opportunity for us, and we are on track to complete our study in approximately one year, with the goal of filing a New Drug Application by the end of 2017 or early 2018," concluded Mr. Anderson.

Second Quarter 2016 Results

The Company achieved revenues during the second quarter 2016 of $38.9 million, compared to $48.6 million during the same period last year. In the second quarter 2016, the Company determined that it is now able to estimate the ultimate net selling price of its products at the time of shipment from its warehouse. Previously, the Company was unable to completely estimate certain gross to net deductions that occur throughout the selling channel due to a lack of historical data. . This sales through accounting method resulted in an approximate one month lag between the time product was shipped from the Company's warehouse until it reached the final customer. As a result of this change, the Company recorded approximately $5.9 million of additional revenue in the second quarter 2016.

On a GAAP basis, the Company recorded a net loss of ($20.0) million during the second quarter 2016, or ($0.48) per diluted share, compared to a net loss of ($16.9) million, or ($0.42) per diluted share, for the same period last year. Included in the net loss for the second quarter 2016 was $23.9 million of charges related to the change in the fair value of related party contingent consideration. Adjusted net loss for the second quarter was ($985,000), or ($0.02) per diluted share, compared to an adjusted net income of $11.5 million, or $0.29 per diluted share, during the same period last year. The decline in adjusted net income and adjusted diluted EPS from the previous year was due to lower product sales resulting from increased competition and higher SG&A from investments in infrastructure, people, and expenses related to the Company's planned cross-border merger to Ireland from France. The Company recognized a foreign currency exchange gain of $1.7 million in the second quarter 2016, compared to a foreign currency exchange loss of ($3.6) million in the prior year quarter. Please see the Supplemental

Information section within this document for a reconciliation of adjusted EBITDA, adjusted net income and adjusted diluted EPS to the respective GAAP amounts.

Sales for the FSC product line were below the Company's expectations for the second quarter 2016 as the Company continues to work on improving product distribution, increasing third party payer access, and refining territories to maximize representative effectiveness. The Company expects to continue making progress throughout the remainder of the year in this business segment. It recently closed the Charlotte office facility and has strengthened the sales management team.

For the six months ended June 30, 2016 cash flow from operations was $15.9 million, compared to $40.3 million in the same period last year. Cash and marketable securities at June 30, 2016 were $154.9 million, compared to $160.0 million at March 31, 2016.

2016 Revenue and R&D Spending Guidance

As a result of the stronger than expected market share for Bloxiverz, slightly better expected market conditions for Akovaz and the change in the Company's ability to better estimate net selling price upon shipment of product from its warehouse, the Company is increasing its full year 2016 revenue guidance to the range of $125 to $140 million from its previous guidance range of $110 to $130 million. The Company expects to allocate a substantial amount of its R&D expenses on its sodium oxybate trial; however, timing of the spend will be slightly shifted to 2017 and, as a result, has lowered its 2016 R&D spending guidance to the range or $30 to $40 million from the range of $35 to $50 million.

Clinical Pipeline Updates

Flamel received positive results from a Phase 1b clinical trial of FT228, a once-weekly subcutaneous injection formulation of exenatide using its proprietary Medusa™ technology. The study achieved all pharmacokinetic (PK) and pharmacodynamic (PD) objectives throughout four weekly administrations of Medusa™ exenatide (FT228), and assessed the safety, steady-state PK profile and the product's potential effect on biomarkers and surrogate endpoints upon repeated administrations. Exenatide is a GLP1 analog used to treat patients suffering from Type 2 Diabetes Mellitus. Medusa™ is a hydrogel depot technology that enables the modified/controlled delivery of drugs, and is ideally suited to the development of subcutaneously administered formulations.

One dose per week of FT228 at 140mcg was administered to twelve Type 2 Diabetes Mellitus patients over a four week period. Following each administration, a continuous release of exenatide was observed over a period of up to 14 days and a relative bioavailability exceeding 94% was demonstrated. The PD performance of FT228 was comparable to current marketed products, Victoza® (liraglutide IR) and Bydureon® (exenatide SR).

In addition, Flamel received feedback from the U.S. Food and Drug Administration (FDA) regarding the clinical development pathway for FT227, an abuse-deterrent, extended-release, oral hydromorphone product using the Company's proprietary Trigger Lock™ drug delivery platform.

To date, the Company has completed two pharmacokinetic (PK) studies of FT227 in 30 healthy volunteers, in addition to an independent in vitro study confirming FT227's superior resistance to extraction/recovery in various media under several different conditions compared to both Exalgo® and Oxycontin®. Following guidance from the FDA, Flamel will be conducting during the third quarter of 2016 an in vivo alcohol interaction study, which the Company believes will provide further confirmation of the robust abuse-deterrent capabilities of Trigger Lock.

Conference Call

A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Monday, August 8, 2016. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 800-930-7616 (U.S. and Canada) or 913-312-1375 (international). The conference ID number is 9799429. Interested parties may access a live audio webcast and accompanying slides via the events and presentations section of the Company's investor website, www.flamel.com/investors. 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 received approval for its third, Akovaz™ (ephedrine sulfate) on April 29, 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 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 St. Louis, Missouri. 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®,Vazculep® and Akovaz™ 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 pipeline product 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 product and apply for FDA approval of such product 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 10-K for the year ended December 31, 2015, 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 and earnings before interest, taxes, depreciation and amortization (EBITDA) 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, 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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Contacts: **Michael F. Kanan**
Chief Financial Officer

Phone: (636) 449-1844
Email : kanan@flamel.com

Lauren Stival
Sr. Director, Investor Relations & Corporate Communications
Phone: (636) 449-5866
Email: stival@flamel.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Product sales and services	**$ 38,165**	$ 48,602	**$ 73,518**	$ 81,128
License and research revenue	**693**	-	**1,556**	-
Total	**38,858**	48,602	**75,074**	81,128
Operating expenses:				
Cost of products and services sold	**3,907**	2,756	**7,813**	6,386
Research and development expenses	**7,604**	7,204	**12,992**	13,226
Selling, general and administrative expenses	**11,290**	5,873	**20,751**	10,336
Intangible asset amortization	**3,702**	3,139	**7,216**	6,282
Changes in fair value of related party contingent consideration	**23,898**	32,000	**32,141**	37,254
Total	**50,401**	50,972	**80,913**	73,484
Operating income (loss)	**(11,543)**	(2,370)	**(5,839)**	7,644
Investment Income	**390**	310	**590**	974
Interest Expense	**(263)**	-	**(438)**	-
Other Expense - changes in fair value of related party payable	**(2,773)**	(2,726)	**(4,307)**	(2,985)
Foreign exchange gain (loss)	**1,680**	(3,565)	**(1,261)**	7,936
Income (loss) before income taxes	**(12,509)**	(8,351)	**(11,255)**	13,569
Income tax provision	**7,449**	8,507	**14,761**	17,214
Net loss	**$ (19,958)**	$ (16,858)	**$ (26,016)**	$ (3,645)
Net loss per share - Basic	**$ (0.48)**	$ (0.42)	**$ (0.63)**	$ (0.09)
Net loss per share - Diluted	$ (0.48)	$ (0.42)	$ (0.63)	$ (0.09)
Weighted average number of shares outstanding - Basic	41,241	40,353	41,241	40,281
Weighted average number of shares outstanding - Diluted	41,241	40,353	41,241	40,281

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

	June 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 23,899**	$ 65,064
Marketable securities	**130,964**	79,738
Accounts receivable (net of allowance of $35 at both June 30, 2016 and December 31, 2015)	**9,488**	7,487
Inventories	**3,640**	3,666
Research and development tax credit receivable - current portion	**-**	2,382
Prepaid expenses and other current assets	**9,657**	8,064
Total current assets	**177,648**	166,401
Property and equipment, net	**3,104**	2,616
Goodwill	**18,669**	18,491
Intangible assets, net	**29,209**	15,825
Research and Development tax credit receivable less current portion	**4,034**	-
Income tax deferred charge	**11,381**	11,581
Other	**4,968**	158
Total assets	**$ 249,013**	$ 215,072
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	**$ 283**	$ 434
Current portion of long-term related party payable	**29,500**	25,204
Accounts payable	**7,043**	5,048
Deferred revenue	**3,820**	5,121
Accrued expenses	**10,592**	9,308
Income taxes	**6,286**	-
Other	**664**	133
Total current liabilities	**58,188**	45,248
Long-term debt, less current portion	**788**	684
Long-term related party payable, less current portion	**136,021**	97,489
Deferred taxes	**-**	684
Other	**2,871**	2,526
Total liabilities	**197,868**	146,631
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,178 shares authorized; 41,241 issued and outstanding at June 30, 2016 and December 31, 2015, respectively	**6,331**	6,331
Additional paid-in capital	**368,897**	363,984
Accumulated deficit	**(305,233)**	(279,217)
Accumulated other comprehensive loss	**(18,850)**	(22,657)
Total shareholders' equity	**51,145**	68,441
Total liabilities and shareholders' equity	**$ 249,013**	$ 215,072

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

	Six Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	**$ (26,016)**	$ (3,645)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	**7,681**	6,531
Loss on disposal of property and equipment	**110**	-
Loss on sale of marketable securities	**455**	225
Unrealized exchange loss (gain)	**1,261**	(7,315)
Grants recognized in research and development expenses	**(70)**	(1,086)
Remeasurement of related party acquisition-related contingent consideration	**32,141**	37,254
Remeasurement of related party financing-related contingent consideration	**4,307**	2,985
Change in deferred tax and income tax deferred charge	**(5,028)**	3,442
Stock-based compensation expense	**4,914**	4,152
Increase (decrease) in cash from:		
Accounts receivable	**(1,689)**	467
Inventories	**2,345**	1,175
Prepaid expenses and other current assets	**546**	(1,876)
Research and development tax credit receivable	**(1,630)**	3,807
Accounts payable & other current liabilities	**(348)**	2,194
Deferred revenue	**(1,461)**	(1,314)
Accrued expenses	**777**	(614)
Accrued income taxes	**6,285**	(7,636)
Earn-out payments for related party contingent consideration in excess of acquisiton-date fair value	**(7,769)**	-
Royalty payments for related party payable in excess of original fair value	**(1,159)**	-
Other long-term assets and liabilities	**269**	555
Net cash provided by operating activities	**15,921**	39,301
Cash flows from investing activities:		
Purchases of property and equipment	**(760)**	(659)
Acquisitions of businesses	**161**	-
Proceeds from sales of marketable securities	**26,013**	21,196
Purchase of marketable securities	**(75,528)**	(31,093)
Net cash used in investing activities	**(50,114)**	(10,556)
Cash flows from financing activities:		
Earn-out payments for related party contingent consideration	**(6,572)**	(6,118)
Royalty payments for related party payable	**(816)**	(888)
Repayment of long-term debt	**-**	(4,903)
Reimbursement of conditional R&D grants	**-**	(615)
Cash proceeds from issuance of ordinary shares and warrants	**-**	1,652
Net cash used in financing activities	**(7,388)**	(10,872)
Effect of exchange rate changes on cash and cash equivalents	**416**	(2,397)
Net increase (decrease) in cash and cash equivalents	**(41,165)**	15,476
Cash and cash equivalents at January 1	**65,064**	39,760
Cash and cash equivalents at June 30	**$ 23,899**	$ 55,236

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenue by product:				
Bloxiverz	**$ 25,620**	$ 44,283	**$ 50,367**	$ 72,726
Vazculep	**10,421**	3,627	**19,827**	7,151
Other	**2,124**	692	**3,324**	1,251
Total product sales and services	**38,165**	48,602	**73,518**	81,128
License and research revenue	**693**	-	**1,556**	-
Total revenues	**$ 38,858**	$ 48,602	**$ 75,074**	$ 81,128
Reconciliation of Reported to Adjusted Financial Statement Line Items:				
Operating income and EBITDA:				
Reported Operating income (loss)	**$ (11,543)**	$ (2,370)	**$ (5,839)**	$ 7,644
Exclude: Contingent related party payable fair value remeasurements - Acquisition-related - Inc./(Dec.)	**23,898**	32,000	**32,141**	37,254
Intangible asset amortization	**3,702**	3,139	**7,216**	6,282
Purchase accounting adjustments - FSC	**762**	-	**1,525**	-
Include: Contingent related party payable paid/accrued - Acquisition-related	**(6,992)**	(9,140)	**(13,437)**	(14,896)
Total adjustments	**21,370**	25,999	**27,445**	28,640
Adjusted Operating income	**$ 9,827**	$ 23,629	**$ 21,606**	$ 36,284
Exclude: Depreciation Expense	**225**	132	**465**	249
Adjusted EBITDA	**$ 10,052**	$ 23,761	**$ 22,071**	$ 36,533
Net income (loss)				
Reported	**$ (19,958)**	(16,858)	**$ (26,016)**	$ (3,645)
Exclude: Contingent related party payable fair value remeasurements - Acquisition-related - Inc./(Dec.)	**23,898**	32,000	**32,141**	37,254
Contingent related party payable fair value remeasurements - Financing-related - Inc./(Dec.)	**2,773**	2,726	**4,307**	2,985
Intangible asset amortization	**3,702**	3,139	**7,216**	6,282
Purchase accounting adjustments - FSC	**762**	-	**1,525**	-
Foreign exchange (gain)/loss	**(1,680)**	3,565	**1,261**	(7,936)
Include: Contingent related party payable paid/accrued - Acquisition-related	**(6,992)**	(9,140)	**(13,437)**	(14,896)
Contingent related party payable paid/accrued - Financing-related	**(941)**	(1,240)	**(1,833)**	(2,080)
Income tax expense (benefit) related to all above adjustments	**(2,549)**	(2,688)	**(4,308)**	(135)
Total adjustments	**18,973**	28,362	**26,872**	21,474
Adjusted	**$ (985)**	11,504	**$ 856**	$ 17,829
Net income (loss) per share - Diluted				
Reported	**$ (0.48)**	$ (0.42)	**$ (0.63)**	$ (0.09)
Exclude: Contingent related party payable fair value remeasurements - Acquisition-related - Inc./(Dec.)	**0.57**	0.80	**0.76**	0.92
Contingent related party payable fair value remeasurements - Financing-related - Inc./(Dec.)	**0.07**	0.07	**0.11**	0.07
Intangible asset amortization	**0.09**	0.08	**0.18**	0.16
Purchase accounting adjustments - FSC	**0.02**	-	**0.04**	-
Foreign exchange (gain)/loss	**(0.04)**	0.09	**0.03**	(0.20)
Include: Contingent related party payable paid/accrued - Acquisition-related	**(0.17)**	(0.23)	**(0.33)**	(0.37)
Contingent related party payable paid/accrued - Financing-related	**(0.02)**	(0.03)	**(0.04)**	(0.05)
Income tax expense (benefit) related to all above adjustments	**(0.06)**	(0.07)	**(0.10)**	-
Total adjustments	**0.46**	0.71	**0.65**	0.53
Adjusted	**$ (0.02)**	$ 0.29	**$ 0.02**	$ 0.44