

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K/A**

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**Amendment No. 1**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)**

**of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **November 7, 2016**

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**FLAMEL TECHNOLOGIES S.A.**

(Exact name of registrant as specified in its charter)

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**Republic of France**  
(State or Other Jurisdiction  
of Incorporation)

**000-28508**  
(Commission File Number)

**98-0639540**  
(I.R.S. Employer  
Identification No.)

**Parc Club du Moulin à Vent**  
**33, avenue du Docteur Georges Levy**  
**69200 Vénissieux France**  
(Address of Principal Executive Offices)

**Not Applicable**  
(Zip Code)

Registrant's telephone number, including area code: **011 +33 472 78 34 34**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## **Explanatory Note**

On November 7, 2016, Flamel Technologies S.A. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2016 and filed a Current Report on Form 8-K (the "Press Release") in connection therewith.

Subsequent to issuing the Press Release, the Company discovered that there were clerical errors on page 1 of Exhibit 99.1 under the section "Third Quarter Highlights". Specifically, adjusted net loss per share for the third quarter should have been \$(0.08), and the adjusted net loss for the third quarter 2015 should have been adjusted net income of \$13.1 million.

Therefore, the Company is filing this Current Report on Form 8-K/A to correct these clerical errors in the press release furnished by the Company as Exhibit 99.1 with its Current Report on Form 8-K filed with the Securities and Exchange Commission on November 7, 2016.

## **Item 2.02. Results of Operations and Financial Condition.**

On November 7, 2016, Flamel Technologies S.A. (the "Company") issued a press release announcing its earnings for the quarter ended September 30, 2016. That press release, as corrected, is attached as Exhibit 99.1 and is incorporated herein by reference.

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### ***Limitation of Incorporation by Reference***

The information in this current report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall such information be incorporated by reference into any registration statement or other filing pursuant to the Securities Act of 1933, except as may be expressly set forth by specific reference in such filing.

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## **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following exhibits relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press release dated November 7, 2016, issued by Flamel Technologies S.A.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### **FLAMEL TECHNOLOGIES S.A.**

By: /s/ Phillandas T. Thompson

Phillandas T. Thompson

Senior Vice President, General Counsel and Corporate Secretary

Date: November 7, 2016

### Exhibit Index

99.1 Press release dated November 7, 2016, issued by Flamel Technologies S.A.

## Flamel Technologies Reports Third Quarter 2016 Results

*Total Revenues Were \$32.1 Million*

*2016 Revenue Guidance Increased to \$133 to \$143 Million*

*REST-ON Phase III Trial of Micropump Sodium Oxybate Initiated*

**Lyon, France – November 7, 2016** - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the third quarter 2016.

### **Third Quarter Highlights Include:**

- Total revenues for third quarter 2016 were \$32.1 million, compared to \$47.3 million during the same period last year.
- GAAP net loss for the third quarter was \$22.3 million, or \$(0.54) per diluted share, compared to GAAP net loss of \$28.1 million, or \$(0.69) per diluted share, during the same period last year.
- Adjusted operating income was \$2.5 million, compared to \$24.4 million in the prior year.\*
- Adjusted net loss was \$3.5 million, or \$(0.08) per diluted share, compared to an adjusted net income of \$13.1 million, or \$0.32 per diluted share, during the same period last year. \*
- Cash and marketable securities at September 30, 2016 were \$149.7 million, compared to \$154.9 million at June 30, 2016 and \$144.8 million at December 31, 2015.
- Protocol for REST-ON Phase III trial of once-nightly Micropump sodium oxybate approved by the U.S. Food & Drug Administration (FDA) through a Special Protocol Assessment (SPA) and trial initiated in Europe and Canada.

Michael Anderson, Flamel's Chief Executive Officer, commented, "Our base business, consisting of Bloxiverz® (neostigmine methylsulfate), Vazculep® (phenylephrine hydrochloride) and Akovaz™ (ephedrine sulfate), remained strong during the third quarter with revenues coming in just above top line consensus. Although we were able to maintain strong share in the neostigmine market at about forty percent (40%) during the third quarter, the overall market volume slightly declined. This, in addition to a small loss in price, resulted in lower quarter over quarter sales of Bloxiverz, at \$15.6 million for the quarter. The phenylephrine business remained stable with third quarter 2016 sales of \$9.3 million, relatively in line with the previous quarter

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\* *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.*

after adjusting for our change in revenue recognition. As expected in the third quarter, we launched Akovaz, the first FDA-approved ephedrine sulfate injection. Akovaz added \$5.6 million in revenues, partially offsetting some weakness in the neostigmine market which, as we outlined at the beginning of the year, was expected with increased competition. I am very pleased with the on-time and successful launch of Akovaz as it once again demonstrates our ability to identify, develop and launch commercially viable pharmaceutical products. Given that we launched later in the quarter, we are off to a good start.”

Mr. Anderson continued, “In addition to our solid base business, we were pleased to host our first investor and analyst day in September, at which we announced the initiation of our Phase III trial of once nightly sodium oxybate in Canada. We have since initiated sites in Europe and received SPA approval from the FDA, which has given us further confidence as we proceed with our trial. We look forward to providing more updates on trial progress as we begin to dose patients.”

### **Third Quarter 2016 Results**

The Company generated revenues during the third quarter 2016 of \$32.1 million, compared to \$47.3 million during the same period last year. On a GAAP basis, the Company recorded a net loss of \$22.3 million during the third quarter 2016, or \$(0.54) per diluted share, compared to a net loss of \$28.1 million, or \$(0.69) per diluted share, for the same period last year. Included in the net loss for the third quarter 2016 were \$22.7 million of charges related to changes in the fair value of related party contingent consideration and related party payables. The Company recognized a foreign currency exchange loss of \$1.1 million in the third quarter 2016, compared to a foreign currency exchange gain of \$0.2 million the prior year quarter. Adjusted net loss for the third quarter was \$3.5 million, or \$(0.08) per diluted share, compared to an adjusted net income of \$13.1 million, or \$0.32 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 for neostigmine and higher SG&A from increased headcount. Please see the Supplemental Information section within this document for a reconciliation of adjusted net income and adjusted diluted EPS to the respective GAAP amounts.

For the nine months ended September 30, 2016, cash flow from operations was \$11.2 million, compared to \$58.0 million in the same period last year. Cash and marketable securities at September 30, 2016 were \$149.7 million, compared to \$154.9 million at June 30, 2016.

### **2016 Guidance**

As a result of the stable market to date for both Bloxiverz and Vazculep, in addition to a strong market for Akovaz, the Company is increasing its full year 2016 revenue guidance to the range of \$133 to \$143 million from its previous guidance range of \$125 to \$140 million. The Company expects to allocate a substantial amount of its R&D expenses to its REST-ON trial and is reiterating its full year 2016 guidance in the range of \$30 to \$40 million.

## Conference Call

A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Monday, November 7, 2016. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 800-765-0709 (U.S. and Canada) or 913-312-0726 (international). The conference ID number is 9865797. A live audio webcast and accompanying slides can be accessed by visiting the Events & Presentations page of the Company's Investor website at <http://www.flamel.com/investors>. A replay of the webcast will be archived on Flamel's website for 90 days following the event.

## 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 three branded, sterile injectable products in the United States, Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection), and Akovaz™ (ephedrine sulfate injection). 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. Applications of Flamel's drug delivery products include sodium oxybate (Micropump®), currently being studied in a Phase III trial to assess the safety and efficacy of a once nightly dose for treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy, and extended-release of liquid medicines (LiquiTime®) through a license arrangement with Elan Pharma International Limited for the U.S. Over-the-Counter market. Additionally, the Company's Trigger Lock™ technology is currently being studied with hydromorphone, and several proof of concept studies of exenatide utilizing the Medusa™ technology were completed in 2016. In February 2016, Flamel acquired FSC Pediatrics, a company that markets three pediatric pharmaceutical products - Cefaclor for oral suspension, Karbinal™ ER, and AcipHex® Sprinkle™ (rabeprazole sodium). FSC also received 510(k) clearance from the FDA in October 2014 for Flexichamber™, a collapsible holding chamber 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](http://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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**FLAMEL TECHNOLOGIES S.A.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS**  
*(In thousands, except per share data)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Product sales and services	\$ 31,340	\$ 47,313	\$ 104,858	\$ 128,441
License and research revenue	747	—	2,303	—
<b>Total</b>	<b>32,087</b>	<b>47,313</b>	<b>107,161</b>	<b>128,441</b>
<b>Operating expenses:</b>				
Cost of products and services sold	2,844	2,087	10,657	8,473
Research and development expenses	8,143	7,221	21,135	20,447
Selling, general and administrative expenses	12,740	4,568	33,491	14,904
Intangible asset amortization	3,702	3,141	10,918	9,423
Changes in fair value of related party contingent consideration	20,848	44,782	52,989	82,036
<b>Total</b>	<b>48,277</b>	<b>61,799</b>	<b>129,190</b>	<b>135,283</b>
Operating loss	(16,190)	(14,486)	(22,029)	(6,842)
Investment income, net	490	197	1,080	1,171
Interest expense, net	(264)	—	(702)	—
Other expense - changes in fair value of related party payable	(1,828)	(6,644)	(6,135)	(9,629)
Foreign exchange gain (loss)	(1,054)	160	(2,315)	8,096
Loss before income taxes	(18,846)	(20,773)	(30,101)	(7,204)
Income tax provision	3,451	7,302	18,212	24,516
<b>Net loss</b>	<b>\$ (22,297)</b>	<b>\$ (28,075)</b>	<b>\$ (48,313)</b>	<b>\$ (31,720)</b>
<b>Net loss per share - basic</b>	<b>\$ (0.54)</b>	<b>\$ (0.69)</b>	<b>\$ (1.17)</b>	<b>\$ (0.79)</b>
<b>Net loss per share - diluted</b>	<b>\$ (0.54)</b>	<b>\$ (0.69)</b>	<b>\$ (1.17)</b>	<b>\$ (0.79)</b>
<b>Weighted average number of shares outstanding - basic</b>	<b>41,241</b>	<b>40,625</b>	<b>41,241</b>	<b>40,397</b>
<b>Weighted average number of shares outstanding - diluted</b>	<b>41,241</b>	<b>40,625</b>	<b>41,241</b>	<b>40,397</b>

**FLAMEL TECHNOLOGIES S.A.**  
**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(In thousands, except per share data)*

	September 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,780	\$ 65,064
Marketable securities	130,887	79,738
Accounts receivable	15,395	7,487
Inventories	3,909	3,666
Research and development tax credit receivable	—	2,382
Prepaid expenses and other current assets	8,883	8,064
<b>Total current assets</b>	<b>177,854</b>	<b>166,401</b>
Property and equipment, net	3,186	2,616
Goodwill	19,134	18,491
Intangible assets, net	25,508	15,825
Research and development tax credit receivable	4,240	—
Income tax deferred charge	11,243	11,581
Other	6,820	167
<b>Total assets</b>	<b>\$ 247,985</b>	<b>\$ 215,081</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 286	\$ 434
Current portion of long-term related party payable	33,359	25,204
Accounts payable	8,966	5,048
Deferred revenue	3,115	5,121
Accrued expenses	13,032	9,308
Other	427	133
<b>Total current liabilities</b>	<b>59,185</b>	<b>45,248</b>
Long-term debt, less current portion	734	684
Long-term related party payable, less current portion	146,926	97,489
Other	4,307	2,526
<b>Total liabilities</b>	<b>211,152</b>	<b>145,947</b>
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,178 shares authorized; 41,241 issued and outstanding at September 30, 2016 and December 31, 2015	6,331	6,331
Additional paid-in capital	374,724	363,984
Accumulated deficit	(326,837)	(278,524)
Accumulated other comprehensive loss	(17,385)	(22,657)
<b>Total shareholders' equity</b>	<b>36,833</b>	<b>69,134</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 247,985</b>	<b>\$ 215,081</b>

**FLAMEL TECHNOLOGIES S.A.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(In thousands)*

	Nine Months Ended September 30,	
	2016	2015
<b>Cash flows from operating activities:</b>		
Net loss	\$ (48,313)	\$ (31,718)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	11,555	9,800
Loss on disposal of property and equipment	110	—
Loss on sale of marketable securities	666	635
Unrealized exchange loss (gain)	2,315	(7,248)
Grants recognized in research and development expenses	(70)	(1,086)
Remeasurement of related party acquisition-related contingent consideration	52,989	82,036
Remeasurement of related party financing-related contingent consideration	6,135	9,628
Change in deferred tax and income tax deferred charge	(5,680)	(714)
Stock-based compensation expense	10,541	5,485
Increase (decrease) in cash from:		
Accounts receivable	(7,594)	(1,553)
Inventories	2,080	1,543
Prepaid expenses and other current assets	671	(4,293)
Research and development tax credit receivable	(1,794)	2,481
Accounts payable & other current liabilities	1,291	(4,231)
Deferred revenue	(2,198)	(1,317)
Accrued expenses	2,700	(1,094)
Accrued income taxes	—	(490)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(14,488)	—
Royalty payments for related party payable in excess of original fair value	(1,790)	—
Other long-term assets and liabilities	2,033	131
Net cash provided by operating activities	11,159	57,995
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,000)	(1,065)
Acquisitions of businesses	628	—
Proceeds from sales of marketable securities	46,483	23,995
Purchase of marketable securities	(96,199)	(36,210)
Net cash used in investing activities	(50,088)	(13,280)
<b>Cash flows from financing activities:</b>		
Earn-out payments for related party contingent consideration	(6,834)	(15,497)
Royalty payments for related party payable	(1,117)	(2,099)
Repayment of debt	—	(4,965)
Reimbursement of conditional grants	(61)	(681)
Cash proceeds from issuance of ordinary shares and warrants	—	6,990
Net cash used in financing activities	(8,012)	(16,252)
Effect of exchange rate changes on cash and cash equivalents	657	(2,358)

Net increase (decrease) in cash and cash equivalents	(46,284)	26,105
Cash and cash equivalents at January 1	65,064	39,760
Cash and cash equivalents at September 30	<u>\$ 18,780</u>	<u>\$ 65,865</u>

**FLAMEL TECHNOLOGIES S.A.**  
**UNAUDITED SUPPLEMENTAL INFORMATION**  
*(In thousands, except per share data)*

<b>Revenues</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Bloxiverz	\$ 15,591	\$ 41,243	\$ 65,958	\$ 114,074
Vazculep	9,340	5,605	29,167	12,757
Akovaz	5,568	—	5,568	—
Other	841	465	4,165	1,610
Total product sales and services	31,340	47,313	104,858	128,441
License and research revenue	747	—	2,303	—
<b>Total revenues</b>	<b>\$ 32,087</b>	<b>\$ 47,313</b>	<b>\$ 107,161</b>	<b>\$ 128,441</b>









