
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 9, 2016**

FLAMEL TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

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**

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))
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Item 2.02 Results of Operations and Financial Condition.

On May 9, 2016, Flamel Technologies S.A. issued a press release announcing its earnings for the quarter ended March 31, 2016. That press release is attached as Exhibit 99.1 and is incorporated herein 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.

Item 9.01 Financial Statements and Exhibits.

- (a) Not applicable
- (b) Not applicable
- (c) Not applicable
- (d) Exhibits

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

99.1	Press release dated May 9, 2016, issued by Flamel Technologies S.A.
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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: May 9, 2016

Exhibit Index

99.1

Press release dated May 9, 2016, issued by Flamel Technologies S.A.



Flamel Technologies Reports First Quarter 2016 Results

Total revenues of \$36.2 million
Adjusted net income of \$1.6 million and adjusted diluted EPS of \$0.04
Adjusted EBITDA of \$11.8 million
Cash flow from operations of \$22.5 million

Lyon, France – May 9, 2016 - Flamel Technologies (NASDAQ: FLML) today announced its financial results for the first quarter of 2016.

First Quarter Highlights Include:

- Total revenue for first quarter 2016 was \$36.2 million, compared to \$32.7 million during the same period last year.
 - GAAP net loss for the first quarter was (\$6.4) million, or (\$0.15) per diluted share, compared to GAAP net income of \$11.6 million, or \$0.27 per diluted share during the same period last year.
 - Adjusted EBITDA was \$11.8 million, compared to \$12.9 million in the prior year.*
 - Adjusted net income for the first quarter was \$1.6 million, or \$0.04 per diluted share, compared to an adjusted net income of \$4.7 million, or \$0.11 per diluted share, during the same period last year. *
 - Cash and marketable securities at March 31, 2016 were \$160.0 million, compared to \$144.8 million at December 31, 2015 and \$113.2 million at March 31, 2015.
 - Special Protocol Assessment (SPA) submitted to the U.S. Food and Drug Administration (FDA) for the once nightly version of Micropump® sodium oxybate.
- * *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 were pleased with our strong revenues of \$36.2 million during the first quarter. The entrance of a third competitor to the neostigmine market in December 2015 was less impactful to pricing and share for Bloxiverz® during the first quarter than initially anticipated; however, we still expect a decline in market share throughout the year to approximately 30% to 35%. As expected on April 29th, we received FDA approval for our third unapproved marketed drug, Akovaz™, which is our formulation of ephedrine sulfate injection. Following launch in the third quarter of this year, Akovaz will provide yet another stream of cash flow to help us continue executing against our strategic plan of advancing our pipeline products and growth through acquisitions, the first of which we made early in the first quarter. We continue to focus on integrating the FSC business and revenues are meeting our expectations. We are particularly excited by physicians' reception of Karbinal™ ER, which accounted for the majority of revenues from the FSC product portfolio."



Mr. Anderson continued, “At the end of the first quarter, we submitted our SPA to the FDA for our pivotal trial of Micropump® sodium oxybate, which will provide the FDA an opportunity to review our trial protocol and provide feedback. We expect to begin patient registration for our pivotal trial in mid-year 2016. We view sodium oxybate as our most valuable pipeline asset, and will continue to take the necessary steps to ensure the Company returns maximum value to our shareholders.”

First Quarter 2016 Results

The Company achieved revenues during the first quarter of 2016 of \$36.2 million, compared to \$32.7 million during the same period last year. On a GAAP basis, Flamel recorded a net loss of (\$6.4) million during the first quarter, or (\$0.15) per diluted share, compared to a net income of \$11.6 million, or \$0.27 per diluted share, for the same period last year. Adjusted net income for the first quarter was \$1.6 million, or \$0.04 per diluted share, compared to an adjusted net income of \$4.7 million, or \$0.11 per diluted share, during the same period last year. The decline in adjusted diluted EPS from the previous year was primarily due to higher SG&A resulting from investments made in infrastructure and people in order to execute the Company’s strategic plan. Included in GAAP net loss in the first quarter of 2016 was a \$7.9 million charge to its contingent consideration liability resulting from the Company’s reassessment of its long term Éclat revenue forecast. In addition, the Company incurred a foreign currency exchange loss of (\$2.9) million, compared to a foreign currency exchange gain of \$11.5 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.

Cash flow from operations was \$22.5 million, compared to \$25.3 million in the same period last year. Cash and marketable securities at March 31, 2016 were \$160.0 million, compared to \$144.8 million at December 31, 2015, an increase of \$15.2 million.

2016 Revenue and R&D Spending Guidance

The Company is maintaining its full year 2016 revenue guidance of \$110 - \$130 million and expects the recently acquired FSC products, AcipHex® Sprinkle™, Karbinal™ ER, Cefaclor for Oral Suspension and Flexichamber™, to contribute revenues in the range of \$10 - \$15 million. As a result of the multiple clinical trials expected to run throughout 2016, the Company expects research & development expenses to be in the range of \$35 - \$50 million, up from \$25.6 million in 2015.



Conference Call

A conference call to discuss these results and other updates is scheduled for 10:00 a.m. ET on Monday, May 9, 2016. A question and answer period will follow management's prepared remarks. To participate in the conference call, investors are invited to dial 800-753-0420 (U.S. and Canada) or 913-312-0645 (international). The conference ID number is 3821495. 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 received approval for its third, Akovaz™ 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 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®, 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.
Consolidated Statements of Income (Loss) - (Unaudited)
(In Thousands, Except Per Share Data)

	Three Months Ended	
	March 31,	
	2016	2015
Revenues:		
Product sales and services	\$ 35,353	\$ 32,726
License and research revenue	863	-
Total	36,216	32,726
Operating expenses:		
Cost of products and services sold	4,395	3,630
Research and development expenses	5,388	6,022
Selling, general and administrative expenses	9,461	4,463
Intangible asset amortization	3,514	3,143
Changes in fair value of related party acquisition-related contingent consideration	7,916	5,254
Total	30,674	22,512
Operating income	5,542	10,214
Investment Income	200	664
Interest Expense	(175)	-
Interest Expense - changes in fair value of related party financing-related contingent consideration	(1,861)	(259)
Foreign exchange gain (loss)	(2,941)	11,501
Income before income taxes	765	22,120
Income tax provision	7,141	10,473
Net income (loss)	\$ (6,376)	\$ 11,647
Net income (loss) per share - Basic	\$ (0.15)	\$ 0.29
Net income (loss) per share - Diluted	\$ (0.15)	\$ 0.27
Weighted average number of shares outstanding - Basic	41,241	40,207
Weighted average number of shares outstanding - Diluted	41,241	42,879

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

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,870	\$ 65,064
Marketable securities	122,084	79,738
Accounts receivable (net of allowance of \$35 at both March 31, 2016 and December 31, 2015)	4,865	6,978
Inventories	5,312	4,155
Research and development tax credit receivable - current portion	368	2,382
Prepaid expenses and other current assets	9,975	7,989
Total current assets	180,474	166,306
Property and equipment, net	3,100	2,616
Goodwill	24,055	18,491
Intangible assets, net	32,911	15,825
Research and Development tax credit receivable less current portion	2,490	-
Income tax deferred charge	11,964	11,581
Other	16	158
Total assets	\$ 255,010	\$ 214,977
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 454	\$ 434
Current portion of long-term related party contingent consideration payable	28,403	28,614
Accounts payable	17,674	10,565
Deferred revenue	4,611	5,121
Accrued expenses	3,346	3,598
Income taxes	5,844	323
Other	611	133
Total current liabilities	60,943	48,788
Long-term debt, less current portion	710	684
Long-term related party contingent consideration payable, less current portion	102,656	94,079
Long-term related party payable	15,000	-
Deferred taxes	3,507	1,351
Other	2,495	2,210
Total liabilities	185,311	147,112
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,178 shares authorized; 41,241 issued and outstanding at March 31, 2016 and December 31, 2015, respectively	6,331	6,331
Additional paid-in capital	366,459	363,984
Accumulated deficit	(286,169)	(279,793)
Accumulated other comprehensive loss	(16,922)	(22,657)
Total shareholders' equity	69,699	67,865
Total liabilities and shareholders' equity	\$ 255,010	\$ 214,977

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

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$ (6,376)	\$ 11,647
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,754	3,260
Loss on disposal of property and equipment	102	-
Loss (gain) on sale of marketable securities	285	(489)
Unrealized exchange loss (gain)	2,941	(11,296)
Remeasurement of related party acquisition-related contingent consideration	7,916	5,254
Remeasurement of related party financing-related contingent consideration	1,861	259
Change in deferred tax and income tax deferred charge	(1,682)	5,864
Stock-based compensation expense	2,475	1,593
Increase (decrease) in cash from:		
Accounts receivable	2,120	1,376
Inventories	1,212	1,207
Prepaid expenses and other current assets	(206)	(368)
Research and development tax credit receivable	(363)	(127)
Accounts payable & other current liabilities	4,029	2,295
Deferred revenue	(758)	2,177
Accrued expenses	(809)	(858)
Accrued income taxes	5,520	3,283
Other long-term assets and liabilities	477	198
Net cash provided by operating activities	<u>22,498</u>	<u>25,275</u>
Cash flows from investing activities:		
Purchases of property and equipment	(460)	(234)
Proceeds from disposal of property and equipment	161	-
Proceeds from sales of marketable securities	9,766	2,817
Purchase of marketable securities	(50,454)	(26,012)
Net cash used in investing activities	<u>(40,987)</u>	<u>(23,429)</u>
Cash flows from financing activities:		
Earn-out payments for related party acquisition-related contingent consideration	(8,014)	(325)
Royalty payments for related party financing-related contingent consideration	(1,092)	-
Cash proceeds from issuance of ordinary shares and warrants	-	246
Net cash used in financing activities	<u>(9,106)</u>	<u>(79)</u>
Effect of exchange rate changes on cash and cash equivalents	401	(2,992)
Net decrease in cash and cash equivalents	(27,194)	(1,225)
Cash and cash equivalents at January 1	65,064	39,760
Cash and cash equivalents at March 31	\$ <u>37,870</u>	\$ <u>38,535</u>
Free Cash Flow	12,932	24,716

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

	Three Months Ended March 31,	
	2016	2015
Revenue by product:		
Bloxiverz	\$ 24,747	\$ 28,642
Vazculep	9,406	3,524
Other	1,200	560
Total product sales and services	35,353	32,726
License and research revenue	863	-
Total revenues	\$ 36,216	\$ 32,726

Reconciliation of Reported to Adjusted Financial Statement Line Items:

Operating Income and EBITDA:		
Reported Operating Income	\$ 5,542	\$ 10,214
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)	7,916	5,254
Intangible asset amortization	3,514	3,143
Purchase accounting adjustments - FSC	763	-
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(6,217)	(5,796)
Total adjustments	5,976	2,601
Adjusted Operating Income	\$ 11,518	\$ 12,815
<i>Exclude:</i> Depreciation Expense	240	117
Adjusted EBITDA	\$ 11,758	\$ 12,932

Net income (loss)		
Reported	\$ (6,376)	\$ 11,647
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)	7,916	5,254
Contingent consideration - Financing-related fair value remeasurements - Inc./Dec.)	1,861	259
Intangible asset amortization	3,514	3,143
Purchase accounting adjustments - FSC	763	-
Foreign exchange (gain)/loss	2,941	(11,501)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(6,217)	(5,796)
Contingent consideration - Financing-related paid/accrued	(1,023)	(845)
Income tax expense (benefit) related to all above adjustments	(1,829)	2,555
Total adjustments	7,926	(6,931)
Adjusted	\$ 1,550	\$ 4,716

Net income (loss) per share - Diluted		
Reported	\$ (0.15)	\$ 0.27
<i>Exclude:</i> Contingent consideration - Acquisition-related fair value remeasurements - Inc./Dec.)	0.17	0.13
Contingent consideration - Financing-related fair value remeasurements - Inc./Dec.)	0.05	0.01
Intangible asset amortization	0.09	0.07
Purchase accounting adjustments - FSC	0.02	-
Foreign exchange (gain)/loss	0.07	(0.27)
<i>Include:</i> Contingent consideration - Acquisition-related paid/accrued	(0.15)	(0.14)
Contingent consideration - Financing-related paid/accrued	(0.02)	(0.02)
Income tax expense (benefit) related to all above adjustments	(0.04)	0.06

Total adjustments	<u>0.19</u>	<u>(0.16)</u>
Adjusted	<u>\$ 0.04</u>	<u>\$ 0.11</u>
Free Cash Flow		
Net cash provided by operating activities	\$ 22,498	\$ 25,275
Less: Purchases of property and equipment	(460)	(234)
Contingent consideration - Acquisition-related payments	(8,014)	(325)
Contingent consideration - Financing-related payments	(1,092)	-
Free Cash Flow	<u>\$ 12,932</u>	<u>\$ 24,716</u>
