
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): **August 8, 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))

Item 2.02. Results of Operations and Financial Condition.

On August 8, 2016, Flamel Technologies S.A. (the “Company”) issued a press release announcing its earnings for the quarter ended June 30, 2016. That press release is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On August 8, 2016, the Company posted to its website a set of presentation materials that it will use during its earnings call and webcast to assist participants with understanding the Company’s financial results for the quarter ended June 30, 2016. A copy of this presentation is attached hereto as Exhibit 99.2.

Limitation of Incorporation by Reference

The information in this current report on Form 8-K (including Exhibit 99.1 and Exhibit 99.2) 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 exhibits relating to Item 2.02 and Item 7.01 shall be deemed to be furnished, and not filed:

- 99.1 Press release dated August 8, 2016, issued by Flamel Technologies S.A.
- 99.2 Presentation materials

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: August 8, 2016

Exhibit Index

- 99.1 Press release dated August 8, 2016, issued by Flamel Technologies S.A.
- 99.2 Presentation materials



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

	Three Months Ended		Six Months Ended	
	June 30,		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 acquisition-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	<u>15,921</u>	<u>39,301</u>
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	<u>(50,114)</u>	<u>(10,556)</u>
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	<u>(7,388)</u>	<u>(10,872)</u>
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	<u>\$ 23,899</u>	<u>\$ 55,236</u>

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

	Three Months Ended		Six Months Ended	
	June 30,		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



Second Quarter 2016 Earnings
Conference Call



August 8, 2016



Forward Looking Statements

This presentation 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 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.



FT228 - Medusa™ Exenatide Phase 1b

FT228: Once-weekly subcutaneous injection formulation of exenatide using its proprietary Medusa™ technology for treatment of type 2 diabetes

Purpose: Assess safety & steady-state pharmacokinetic (PK) & pharmacodynamic (PD) profile of 1 dose FT228 (140mcg) per week for 4 weeks in 12 type 2 diabetes mellitus patients

PK data showed continuous release of exenatide over period of up to 14 days & RBA > 94%

PD Performance comparable to current marketed products Bydureon® & Victoza®

Biomarkers / Surrogate Endpoints:

- Glycated Hemoglobin (HbA1c)
- Fasted Plasma Glucose (FPG)
- Weight Loss

Favorable Safety Profile:

- Low incidence prolonged gastrointestinal side effects
- Low incidence mild injection site reactions

FT227 – Trigger Lock™ Hydromorphone

FT227: Abuse-deterrent, extended-release, oral hydromorphone using Trigger Lock™ technology for treatment of pain

FDA Guidance

- Feedback from FDA regarding clinical development pathway: In vivo alcohol interaction study to be conducted during 3Q 2016
- **Goal:** Provide further confirmation of abuse-deterrent capabilities

Progress To Date

- Completed two pharmacokinetic (PK) studies in 30 healthy volunteers
- Independent in vitro study confirming superior resistance to extraction/recovery in various media under several different conditions compared to Exalgo® and Oxycontin®



Perrigo Partnership (OTC)

- Ibuprofen likely to be lengthy and expensive approval process – evaluating potential replacement product
- Guaifenesin slated to begin pivotal trial in 1H 2017

Prescription Products

- Feasibility studies underway
- Product selection late 2016 / early 2017



FT218 – Micropump® Sodium Oxybate

FT218: Once nightly version oral formulation of sodium oxybate utilizing Micropump® technology for the treatment of narcolepsy

Special Protocol Assessment (SPA) Filed with FDA end of Q1 2016

Dialogue with FDA

- No substantive issues
- Expect finalization near-term
- Overall trial timeline intact – NDA filing end 2017 / early 2018

Ongoing Activities

- Registration of clinical sites

Competitive Landscape

- 6 of 7 Risk Evaluation & Mitigation (REMS) patents held by JAZZ invalidated on July 26, 2016
- Flamel continues to develop its own REMS strategy

Bloxiverz[®], Vazculep[®] & Akovaz[™]



Bloxiverz held between 40% - 45% of neostigmine market during 2Q 2016

Vazculep increased market share in 2Q 2016

- 32% 1mL market volume
- 100% 5mL market volume
- 100% 10mL market volume



Akovaz to launch in August 2016

- Market value ~ 200 million

Combined Sales of Bloxiverz & Vazculep
totaled \$36 Million in 2Q 2016

Karbinal^{ER}
(carbinoxamine maleate) extended-release
oral suspension | 4mg/5mL

flexichamber[®]
Anti-static Valved Collapsible Holding Chamber *Rx Only*

CEFACTOR
For Oral Suspension, USP
125 mg/5 mL • 250 mg/5 mL • 375 mg/5 mL


AcipHex[®]
Sprinkle[™]
(rabeprazole sodium)
Delayed-Release
Capsules

- Sales below expectations, but up ~ \$1 million Q/Q
- Growth across all products
- Flexichamber launched planned for early Q4
- Continue to optimize sales territories, product distribution & 3rd party payer access
- Charlotte office closed end of July 2016

GAAP Financial Results

(in 000s)

	Q2 2016	Q1 2016	Q2 2015
Revenue	\$ 38,858	\$ 36,216	\$ 48,602
Cost of products and services sold	3,907	3,906	2,756
Research and development expenses	7,604	5,388	7,204
Selling, general and admin expenses	11,290	9,461	5,873
Intangible asset amortization	3,702	3,514	3,139
Fair value adjustments of contingent consideration	23,898	8,243	32,000
Operating Expenses	50,401	30,512	50,972
Operating income (loss)	(11,543)	5,704	(2,370)
Interest & Other Expense (net)	(966)	(4,450)	(5,981)
Income (loss) before income taxes	(12,509)	1,254	(8,351)
Income tax provision	7,449	7,312	8,507
Net loss	\$ (19,958)	\$ (6,058)	\$ (16,858)
Diluted loss per share	\$ (0.48)	\$ (0.15)	\$ (0.42)

Difference - Inc./[Dec.]

Q2 2016 vs. Q1 2016	Q2 2016 vs. Q2 2015
\$ 2,642	\$ (9,744)
1	1,151
2,216	400
1,829	5,417
188	563
15,655	(8,102)
19,889	(571)
(17,247)	(9,173)
3,484	5,015
(13,763)	(4,158)
137	(1,058)
\$ (13,900)	\$ (3,100)
\$ (0.34)	\$ (0.07)

Included in Q2 2016 is \$5,900 of Additional Revenue Due to the Change in Revenue Model

Non-GAAP Financial Results

*Reconciliations from GAAP to Non-GAAP can be found in the appendix

(in 000s)

	Q2 2016	Q1 2016	Q2 2015
Revenue	\$ 38,858	\$ 36,216	\$ 48,602
Cost of products and services sold	3,145	3,143	2,756
Research and development expenses	7,604	5,388	7,204
Selling, general and admin expenses	11,290	9,461	5,873
Intangible asset amortization	-	-	-
Fair value adjustments of contingent consideration	6,992	6,445	9,140
Operating Expenses	29,031	24,437	24,973
Operating income (loss)	9,827	11,779	23,629
Interest & Other Expense (net)	(814)	(867)	(930)
Income (loss) before income taxes	9,013	10,912	22,699
Income tax provision	9,998	9,071	11,195
Net loss	\$ (985)	\$ 1,841	\$ 11,504
Diluted loss per share	\$ (0.02)	\$ 0.04	\$ 0.29

Difference - Inc./Dec.

Q2 2016 vs. Q1 2016	Q2 2016 vs. Q2 2015
\$ 2,642	\$ (9,744)
2	389
2,216	400
1,829	5,417
-	-
547	(2,148)
4,594	4,058
(1,952)	(13,802)
53	116
(1,899)	(13,686)
927	(1,197)
\$ (2,826)	\$ (12,489)
\$ (0.07)	\$ (0.31)

Increase in SG&A Primarily Driven from Investments in Infrastructure, People and One-Time Cross Border Merger Expenses

Product Sales

(in 000s)

	<u>Q2 2016</u>	<u>Q1 2016</u>	<u>Q2 2015</u>
Bloxiverz	\$ 25,620	\$ 24,747	\$ 44,283
Vazculep	10,421	9,406	3,627
Other	<u>2,124</u>	<u>1,200</u>	<u>692</u>
Total product sales and services	\$ 38,165	\$ 35,353	\$ 48,602
License and research revenue	<u>\$ 693</u>	<u>\$ 863</u>	<u>\$ -</u>
Total revenues	\$ 38,858	\$ 36,216	\$ 48,602

<u>Difference - Inc./ (Dec.)</u>	
<u>Q2 2016 vs. Q1 2016</u>	<u>Q2 2016 vs. Q2 2015</u>
\$ 873	\$ (18,663)
1,015	6,794
<u>924</u>	<u>1,432</u>
\$ 2,812	\$ (10,437)
<u>\$ (170)</u>	<u>\$ 693</u>
\$ 2,642	\$ (9,744)

Bloxiverz Market Share Averaged Just North of 40% in the Second Quarter
Total Product Sales Declined Year-over-Year Due to Increased Competition for
Bloxiverz

Cash Flow Summary

(in 000s)	Six Months Ended June 30,	
	2016	2015
<u>TOTAL Cash and Marketable Securities</u>		
Beginning Balance	\$ 144,802	\$ 92,834
Operating Cash Flows (excluding tax and earnout/royalty payments)	36,816	60,176
Tax Payments	(13,100)	(20,875)
Earnout/Royalty Payments	(16,316)	(7,006)
Repayment of Debt	-	(5,518)
Capital Spending	(760)	(659)
Other	1,736	1,565
FX	1,685	(4,397)
<i>Change in Total</i>	<u>10,061</u>	<u>23,286</u>
Ending Balance	<u>\$ 154,863</u>	<u>\$ 116,120</u>

Balance Sheet Remains Strong with No Bank Debt and \$154.9 Million in Cash and Marketable Securities

Full-Year 2016 Guidance



Revenue

<u>UPDATED</u>	<u>PREVIOUS</u>
\$125M - \$140M	\$110M - \$130M



Research & Development Expenses

\$30M - \$40M	\$35M - \$50M
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Question & Answer

Appendix

GAAP to Non-GAAP Reconciliations

Three Months Ended June 30, 2016:
(in thousands - US\$)

	GAAP	Adjustments						Total Adjustments	NON-GAAP
		Exclude			Include				
		Intangible asset amortization	Foreign exchange (gain)/loss	Purchase accounting adjustments - FSC	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Income tax expense (benefit) related to adjustments		
Product sales and services	\$ 38,165	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 38,165
License and research revenue	693	-	-	-	-	-	-	-	693
Total revenue	38,858	-	-	-	-	-	-	-	38,858
Cost of products and services sold	3,907	-	-	(762)	-	-	-	(762)	3,145
Research and development expenses	7,604	-	-	-	-	-	-	-	7,604
Selling, general and administrative expenses	11,290	-	-	-	-	-	-	-	11,290
Intangible asset amortization	3,702	(3,702)	-	-	-	-	-	(3,702)	-
Changes in fair value of related party contingent consideration	23,898	-	-	-	(23,898)	6,992	-	(16,906)	6,992
Total operating expenses	50,401	(3,702)	-	(762)	(23,898)	6,992	-	(21,370)	29,031
Operating income (loss)	(11,543)	3,702	-	762	23,898	(6,992)	-	21,370	9,827
Investment income	390	-	-	-	-	-	-	-	390
Interest Expense	(263)	-	-	-	-	-	-	-	(263)
Other Expense - changes in fair value of related party payable	(2,773)	-	-	-	2,773	(941)	-	1,832	(941)
Foreign exchange gain (loss)	1,680	-	(1,680)	-	-	-	-	(1,680)	-
Income (loss) before income taxes	(12,509)	3,702	(1,680)	762	26,671	(7,933)	-	21,522	9,013
Income tax provision	7,449	-	-	-	-	-	2,549	2,549	9,998
Income Tax Rate	(60%)	-	-	-	-	-	-	12%	111%
Net Loss	\$ (19,958)	\$ 3,702	\$ (1,680)	\$ 762	\$ 26,671	\$ (7,933)	\$ (2,549)	\$ 18,973	\$ (985)
Net loss per share - Diluted	\$ (0.48)	\$ 0.09	\$ (0.04)	\$ 0.02	\$ 0.64	\$ (0.19)	\$ (0.06)	\$ 0.46	\$ (0.02)
Weighted average number of shares outstanding - Diluted	41,241	41,241	41,241	41,241	41,241	41,241	41,241	41,241	41,241

GAAP to Non-GAAP Reconciliations

Three Months Ended March 31, 2016:
(in thousands - USD\$)

	GAAP	Adjustments					Income tax expense (benefit) related to adjustments	Total Adjustments	NON-GAAP
		Exclude		Include					
		Intangible asset amortization	Foreign exchange (gain)/loss	Purchase accounting adjustments - FSC	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued			
Product sales and services	\$ 35,353	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 35,353
License and research revenue	863	-	-	-	-	-	-	-	863
Total revenue	36,216	-	-	-	-	-	-	-	36,216
Cost of products and services sold	3,906	-	-	(763)	-	-	-	(763)	3,143
Research and development expenses	5,388	-	-	-	-	-	-	-	5,388
Selling, general and administrative expenses	9,461	-	-	-	-	-	-	-	9,461
Intangible asset amortization	3,514	(3,514)	-	-	-	-	-	(3,514)	-
Changes in fair value of related party contingent consideration	8,243	-	-	-	(8,243)	6,445	-	(1,798)	6,445
Total operating expenses	30,512	(3,514)	-	(763)	(8,243)	6,445	-	(6,075)	24,437
Operating income	5,704	3,514	-	763	8,243	(6,445)	-	6,075	11,779
Investment income	200	-	-	-	-	-	-	-	200
Interest Expense	(175)	-	-	-	-	-	-	-	(175)
Other Expense - changes in fair value of related party payable	(1,534)	-	-	-	1,534	(892)	-	642	(892)
Foreign exchange gain (loss)	(2,941)	-	2,941	-	-	-	-	2,941	-
Income before income taxes	1,254	3,514	2,941	763	9,777	(7,337)	-	9,658	10,912
Income tax provision	7,312	-	-	-	-	-	1,759	1,759	9,071
<i>Income Tax Rate</i>	<i>583%</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>18%</i>	<i>83%</i>
	\$ (6,058)	\$ 3,514	\$ 2,941	\$ 763	\$ 9,777	\$ (7,337)	\$ (1,759)	\$ 7,899	\$ 1,841
Net loss per share - Diluted	\$ (0.15)	\$ 0.09	\$ 0.07	\$ 0.02	\$ 0.23	\$ (0.18)	\$ (0.04)	\$ 0.19	\$ 0.04
<i>Weighted average number of shares outstanding - Diluted</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>	<i>41,241</i>

GAAP to Non-GAAP Reconciliations

Three Months Ended June 30, 2015:
(in thousands - USD\$)

	GAAP	Adjustments					Total Adjustments	NON-GAAP
		Exclude		Include		Income tax expense (benefit) related to adjustments		
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued			
Product sales and services	\$ 48,602	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 48,602	
License and research revenue	-	-	-	-	-	-	-	
Total revenue	48,602	-	-	-	-	-	48,602	
Cost of products and services sold	2,756	-	-	-	-	-	2,756	
Research and development expenses	7,204	-	-	-	-	-	7,204	
Selling, general and administrative expenses	5,873	-	-	-	-	-	5,873	
Intangible asset amortization	3,139	(3,139)	-	-	-	-	-	
Changes in fair value of related party contingent consideration	32,000	-	-	(32,000)	9,140	-	9,140	
Total operating expenses	50,972	(3,139)	-	(32,000)	9,140	-	24,973	
Operating income (loss)	(2,370)	3,139	-	32,000	(9,140)	-	23,629	
Investment income	310	-	-	-	-	-	310	
Interest Expense	-	-	-	-	-	-	-	
Other Expense - changes in fair value of related party payable	(2,726)	-	-	2,726	(1,240)	-	(1,240)	
Foreign exchange gain (loss)	(3,565)	-	3,565	-	-	-	-	
Income (loss) before income taxes	(8,351)	3,139	3,565	34,726	(10,380)	-	22,699	
Income tax provision	8,507	-	-	-	-	2,688	11,195	
<i>Income Tax Rate</i>	<i>(102%)</i>	-	-	-	-	9%	49%	
Net Income (Loss)	\$ (16,858)	\$ 3,139	\$ 3,565	\$ 34,726	\$ (10,380)	\$ (2,688)	\$ 11,504	
Net loss per share - Diluted	\$ (0.42)	\$ 0.08	\$ 0.09	\$ 0.87	\$ (0.26)	\$ (0.07)	\$ 0.29	
<i>Weighted average number of shares outstanding - Diluted</i>	<i>40,353</i>	<i>40,353</i>	<i>40,353</i>	<i>40,353</i>	<i>40,353</i>	<i>40,353</i>	<i>40,353</i>	

