

**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): **November 7, 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 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 is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 7, 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 September 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.

(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 November 7, 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: November 7, 2016

Exhibit Index

- 99.1 Press release dated November 7, 2016, issued by Flamel Technologies S.A.
- 99.2 Presentation materials

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 for the third quarter was \$3.5 million, or \$(0.11) per diluted share, compared to an adjusted net loss 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 _____

* *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.

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
Revenues:				
Product sales and services	\$ 31,340	\$ 47,313	\$ 104,858	\$ 128,441
License and research revenue	747	—	2,303	—
Total	32,087	47,313	107,161	128,441
Operating expenses:				
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
Total	48,277	61,799	129,190	135,283
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
Net loss	\$ (22,297)	\$ (28,075)	\$ (48,313)	\$ (31,720)
Net loss per share - basic	\$ (0.54)	\$ (0.69)	\$ (1.17)	\$ (0.79)
Net loss per share - diluted	\$ (0.54)	\$ (0.69)	\$ (1.17)	\$ (0.79)
Weighted average number of shares outstanding - basic	41,241	40,625	41,241	40,397
Weighted average number of shares outstanding - diluted	41,241	40,625	41,241	40,397

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

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
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
Total current assets	177,854	166,401
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
Total assets	\$ 247,985	\$ 215,081
LIABILITIES AND SHAREHOLDERS' EQUITY		
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
Total current liabilities	59,185	45,248
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
Total liabilities	211,152	145,947
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)
Total shareholders' equity	36,833	69,134
Total liabilities and shareholders' equity	\$ 247,985	\$ 215,081

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
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
Cash flows from investing activities:		
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)
Cash flows from financing activities:		
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)

Revenues	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
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	—
Total revenues	\$ 32,087	\$ 47,313	\$ 107,161	\$ 128,441



Third Quarter 2016 Earnings
Conference Call

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.



Call Outline

- *Phase III Trial Initiation – REST-ON*
- *Sodium Oxybate Patent Landscape*
- *Base Business Overview*
 - Akovaz™
 - Bloxiverz®
 - Vazculep®
- Business Development Status
- Cross-Border Merger & Name Change
- Overview of Income Statement
 - Revenue
 - Expenses
 - Tax
 - Non-GAAP Results
- Revenue by Business Segment
- Guidance

REST-ON Phase III Trial



- ✓ Initiation of Phase III Pivotal Trial (REST-ON) announced (Sept 26th)
- ✓ Special Protocol Assessment process completed (Oct 6th)
- ✓ Sites in Canada and Germany have started screening and enrollment

- Expect to dose first patient before year end
- First U.S. site expected to initiate patient enrollment January 2017
- Goal to complete patient enrollment by 4Q 2017

Sodium Oxybate IP Landscape

- JAZZ – 6 of 7 REMS patents overturned by PTAB
- Settled with Wockhardt & Ranbaxy for 2026 generic entry
- Yet to settle with other filers – including first to file, Roxane (Hikma)
- '306 patent for concomitant dosing of sodium oxybate and valproate / divalproex sodium still in place (exp. 2033)
- '306 patent to be evaluated again during trial with Roxane
- Label requirements for NDA filers are not the same as for ANDAs, even through 505(b)(2)

Flamel will have unique REMS & strong patent strategy for '306

Base Business

Akovaz™



- Akovaz launched Aug 2016
- \$5.6 million in revenues 3Q 2016
- On target to exit 2016 with 20-30% market share

Bloxiverz®



- Averaged 40% neostigmine market during 3Q 2016
- \$15.6 million in revenues 3Q 2016
- Smaller overall market volume and increased competition resulted in lower revenues – anticipate stable market Q4

Vazculep®



- Share remained stable in 3Q 2016
- \$9.3 million in revenues 3Q 2016
- Expect market to remain stable going forward

Business Development

- **4th Unapproved Marketed Drug identified – awaiting feedback from FDA on potential clinical work**
- **Looking to grow inorganically – searching for accretive commercial stage products to fold into FSC**
- **Actively seeking licensing deal for Trigger Lock™**
- **Actively seeking licensing or sale of Medusa™**

Coming soon...

- *Avadel Pharmaceuticals plc* (NASDAQ: AVDL)
- “**AdVA**nced **DEL**ivery”
- Cross-border merger from France to Ireland effective January 1, 2017
- No changes to capital structure or share count

COMPANY WILL CONTINUE TO OPERATE AS FLAMEL TECHNOLOGIES SA
UNTIL JANUARY 1, 2017

GAAP Financial Results

(in \$000s)

	Q3 2016	Q2 2016	Q3 2015
Revenue	\$ 32,087	\$ 38,858	\$ 47,313
Cost of products and services sold	2,844	3,907	2,087
Research and development expenses	8,143	7,604	7,221
Selling, general and admin expenses	12,740	11,290	4,568
Intangible asset amortization	3,702	3,702	3,141
Fair value adjustments of contingent consideration	20,848	23,898	44,782
Operating Expenses	48,277	50,401	61,799
Operating income (loss)	(16,190)	(11,543)	(14,486)
Interest & Other Expense (net)	(2,656)	(966)	(6,287)
Income (loss) before income taxes	(18,846)	(12,509)	(20,773)
Income tax provision	3,451	7,449	7,302
Net loss	\$ (22,297)	\$ (19,958)	\$ (28,075)
Diluted loss per share	\$ (0.54)	\$ (0.48)	\$ (0.69)

Difference - Inc./Dec.	
Q3 2016	Q3 2016
vs.	vs.
Q2 2016	Q3 2015
\$ (6,771)	\$ (15,226)
(1,063)	757
539	922
1,450	8,172
-	561
(3,050)	(23,934)
(2,124)	(13,522)
(4,647)	(1,704)
(1,690)	3,631
(6,337)	1,927
(3,998)	(3,851)
\$ (2,339)	\$ 5,778
\$ (0.06)	\$ 0.15

Non-GAAP Financial Results

(in \$000s)

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

	Q3 2016	Q2 2016	Q3 2015
Revenue	\$ 32,087	\$ 38,858	\$ 47,313
Cost of products and services sold	2,844	3,145	2,087
Research and development expenses	8,143	7,604	7,221
Selling, general and admin expenses	12,740	11,290	4,568
Intangible asset amortization	-	-	-
Fair value adjustments of contingent consideration	5,884	6,992	9,027
Operating Expenses	29,611	29,031	22,903
Operating income (loss)	2,476	9,827	24,410
Interest & Other Expense (net)	(559)	(814)	(1,014)
Income (loss) before income taxes	1,917	9,013	23,397
Income tax provision	5,416	9,998	10,255
Net loss	\$ (3,499)	\$ (985)	\$ 13,142
Diluted loss per share	\$ (0.08)	\$ (0.02)	\$ 0.32

Difference - Inc./Dec.	
Q3 2016	Q3 2016
vs.	vs.
Q2 2016	Q3 2015
\$ (6,771)	\$ (15,226)
(301)	757
539	922
1,450	8,172
-	-
(1,108)	(3,143)
580	6,708
(7,351)	(21,934)
255	455
(7,096)	(21,480)
(4,581)	(4,839)
\$ (2,515)	\$ (16,641)
\$ (0.06)	\$ (0.40)

Product Sales

(in \$000s)

	Q3 2016	Q2 2016	Q3 2015
Bloxiverz	\$ 15,591	\$ 25,620	\$ 41,243
Vazculep	9,340	10,421	5,605
Akovaz	5,568	-	-
Other	841	2,124	465
Total product sales and services	\$ 31,340	\$ 38,165	\$ 47,313
License and research revenue	\$ 747	\$ 693	\$ -
Total revenues	\$ 32,087	\$ 38,858	\$ 47,313

Difference - Inc./ (Dec.)	
Q3 2016 vs. Q2 2016	Q3 2016 vs. Q3 2015
\$ (10,029)	\$ (25,652)
(1,081)	3,735
5,568	5,568
(1,283)	376
\$ (6,825)	\$ (15,973)
\$ 54	\$ 747
\$ (6,771)	\$ (15,226)

Cash Flow Summary

(in \$000s)

	Nine Months Ended September 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)	47,154	92,377
Tax Payments	(22,200)	(34,382)
Earnout/Royalty Payments	(24,229)	(17,596)
Repayment of Debt	-	(4,965)
Issuance of Ordinary Shares and Warrants	-	6,990
Other	915	(4,528)
FX	3,225	(2,358)
<i>Change in Total</i>	4,865	35,538
Ending Balance	\$ 149,667	\$ 128,372

Full-Year 2016 Guidance



Revenue

<u>Current</u>	<u>PREVIOUS</u>
\$133M - \$143M	\$125M - \$140M



Research & Development Expenses

\$30M - \$40M

\$30M - \$40M



Question & Answer

Appendix

GAAP to Non-GAAP Reconciliations

Three Months Ended September 30, 2016:

(in thousands - US\$)

	GAAP	Adjustments				Total Adjustments	NON-GAAP
		Exclude		Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 31,340	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 31,340
License and research revenue	747	-	-	-	-	-	747
Total revenue	32,087	-	-	-	-	-	32,087
Cost of products and services sold	2,844	-	-	-	-	-	2,844
Research and development expenses	8,143	-	-	-	-	-	8,143
Selling, general and administrative expenses	12,740	-	-	-	-	-	12,740
Intangible asset amortization	3,702	(3,702)	-	-	-	(3,702)	-
Changes in fair value of related party contingent consideration	20,848	-	-	(20,848)	5,884	(14,964)	5,884
Total operating expenses	48,277	(3,702)	-	(20,848)	5,884	(18,666)	29,611
Operating income (loss)	(16,190)	3,702	-	20,848	(5,884)	18,666	2,476
Investment Income	490	-	-	-	-	-	490
Interest Expense	(264)	-	-	-	-	-	(264)
Other Expense - changes in fair value of related party payable	(1,828)	-	-	1,828	(785)	1,043	(785)
Foreign exchange gain (loss)	(1,054)	-	1,054	-	-	1,054	-
Income (loss) before income taxes	(18,846)	3,702	1,054	22,676	(6,669)	20,763	1,917
Income tax provision	3,451	1,329	-	1,021	(385)	1,965	5,416
<i>Income Tax Rate</i>	<i>(18%)</i>	<i>36%</i>	<i>-</i>	<i>5%</i>	<i>6%</i>	<i>9%</i>	<i>283%</i>
Net Loss	\$ (22,297)	\$ 2,373	\$ 1,054	\$ 21,655	\$ (6,284)	\$ 18,798	\$ (3,499)
Net loss per share - Diluted	\$ (0.54)	\$ 0.06	\$ 0.03	\$ 0.52	\$ (0.15)	\$ 0.46	\$ (0.08)
<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>

GAAP to Non-GAAP Reconciliations

Three Months Ended June 30, 2016:

(in thousands - USD\$)

	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		
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	1,329	-	266	1,414	(460)	2,549	9,998
Income Tax Rate	(60%)	36%	-	35%	5%	6%	12%	111%
Net Loss	\$ (19,958)	\$ 2,373	\$ (1,680)	\$ 496	\$ 25,257	\$ (7,473)	\$ 18,973	\$ (985)
Net loss per share - Diluted	\$ (0.48)	\$ 0.06	\$ (0.04)	\$ 0.01	\$ 0.61	\$ (0.18)	\$ 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

GAAP to Non-GAAP Reconciliations

Three Months Ended September 30, 2015:

(in thousands - US\$)

	GAAP	Adjustments				Total Adjustments	NON-GAAP
		Exclude		Include			
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Product sales and services	\$ 47,313	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 47,313
License and research revenue	-	-	-	-	-	-	-
Total revenue	47,313	-	-	-	-	-	47,313
Cost of products and services sold	2,087	-	-	-	-	-	2,087
Research and development expenses	7,221	-	-	-	-	-	7,221
Selling, general and administrative expenses	4,568	-	-	-	-	-	4,568
Intangible asset amortization	3,141	(3,141)	-	-	-	(3,141)	-
Changes in fair value of related party contingent consideration	44,782	-	-	(44,782)	9,027	(35,755)	9,027
Total operating expenses	61,799	(3,141)	-	(44,782)	9,027	(38,896)	22,903
Operating income (loss)	(14,486)	3,141	-	44,782	(9,027)	38,896	24,410
Investment income	197	-	-	-	-	-	197
Interest Expense	-	-	-	-	-	-	-
Other Expense - changes in fair value of related party payable	(6,644)	-	-	6,644	(1,211)	5,433	(1,211)
Foreign exchange gain (loss)	160	-	(160)	-	-	(160)	-
Income (loss) before income taxes	(20,773)	3,141	(160)	51,426	(10,237)	44,170	23,397
Income tax provision	7,302	1,099	(48)	2,325	(424)	2,953	10,255
<i>Income Tax Rate</i>	<i>(35%)</i>	<i>35%</i>	<i>30%</i>	<i>5%</i>	<i>4%</i>	<i>7%</i>	<i>44%</i>
Net Loss	\$ (28,075)	\$ 2,042	\$ (112)	\$ 49,101	\$ (9,814)	\$ 41,217	\$ 13,142
Net loss per share - Diluted	\$ (0.69)	\$ 0.05	\$ -	\$ 1.20	\$ (0.24)	\$ 1.01	\$ 0.32
<i>Weighted average number of shares outstanding - Diluted</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>	<i>40,625</i>

