

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: **March 31, 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)

**43-1050617**  
(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 Office and Zip Code)

**+33 472 78 34 34**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller Reporting Company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:  
41,241,254 shares of Common Stock outstanding as of March 31, 2016.

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## Forward-Looking Statements

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. In particular, information appearing under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” includes forward-looking statements.

Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from our expectations.

More information on factors that could cause actual results or events to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (SEC), including our annual report on Form 10-K for the year ended December 31, 2015, in particular under the captions “Forward-Looking Statements” and “Risk Factors.”

All forward-looking statements speak only as of the date of this report and are expressly qualified in their entirety by the cautionary statements included or referenced in or incorporated by reference into this report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this report.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended March 31,	
	2016	2015
<b>Revenues:</b>		
Product sales and services	\$ 35,353	\$ 32,726
License and research revenue	863	-
<b>Total</b>	<b>36,216</b>	<b>32,726</b>
<b>Operating expenses:</b>		
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
<b>Total</b>	<b>30,674</b>	<b>22,512</b>
<b>Operating income</b>	<b>5,542</b>	<b>10,214</b>
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
<b>Income before income taxes</b>	<b>765</b>	<b>22,120</b>
Income tax provision	7,141	10,473
<b>Net income (loss)</b>	<b>\$ (6,376)</b>	<b>\$ 11,647</b>
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

See accompanying notes to consolidated financial statements.

**Flamel Technologies S.A.**  
**Consolidated Statements of Comprehensive Loss**  
*(In Thousands)*  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2016</u>	<u>2015</u>
<b>Net income/(loss)</b>	<b>\$ (6,376)</b>	<b>\$ 11,647</b>
Other comprehensive income/(loss), net of tax:		
Foreign currency translation gain/(loss), net	4,817	(16,649)
Unrealized gains on marketable securities	918	356
<b>Total other comprehensive income/(loss), net of tax</b>	<b>5,735</b>	<b>(16,293)</b>
<b>Total comprehensive loss</b>	<b>\$ (641)</b>	<b>\$ (4,646)</b>

See accompanying notes to consolidated financial statements.

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

	March 31, 2016	December 31, 2015
<b>ASSETS</b>		
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
<b>Total current assets</b>	<b>180,474</b>	<b>166,306</b>
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
<b>Total assets</b>	<b>\$ 255,010</b>	<b>\$ 214,977</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
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
<b>Total current liabilities</b>	<b>60,943</b>	<b>48,788</b>
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
<b>Total liabilities</b>	<b>185,311</b>	<b>147,112</b>
<b>Shareholders' equity:</b>		
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)
<b>Total shareholders' equity</b>	<b>69,699</b>	<b>67,865</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 255,010</b>	<b>\$ 214,977</b>

See accompanying notes to consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
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>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(460)	(234)
Acquisitions of businesses	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>
<b>Cash flows from financing activities:</b>		
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>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>401</b>	<b>(2,992)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(27,194)</b>	<b>(1,225)</b>
<b>Cash and cash equivalents at January 1</b>	<b>65,064</b>	<b>39,760</b>
<b>Cash and cash equivalents at March 31</b>	<b>\$ <u>37,870</u></b>	<b>\$ <u>38,535</u></b>

See accompanying notes to consolidated financial statements.

**Flamel Technologies S.A.**  
**Notes to Consolidated Financial Statements**  
*(In Thousands, Except Per Share Data)*  
(Unaudited)

**NOTE 1 : Summary of Significant Accounting Policies**

**Nature of Operations.** Flamel Technologies S.A. (“Flamel,” the “Company,” “we” or “us”) is organized as a Société Anonyme, a form of corporation under the laws of The Republic of France. The Company was founded in 1990. Flamel is a specialty pharmaceutical company utilizing core competencies in drug delivery and formulation development to create safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. The Company has a balanced business model consisting of:

- (i) an Unapproved Marketed Drugs (“UMDs”) business with two approved products in the USA, Bloxiverz<sup>®</sup> (neostigmine methylsulfate injection) and Vazculep<sup>®</sup> (phenylephrine hydrochloride injection) that are currently marketed, a third product, Akovaz<sup>®</sup> (ephedrine sulphate injection) for which we obtained FDA approval on April 29, 2016 and which we intend to begin marketing in the third quarter of 2016, and a fourth product currently being studied by us for possible submission for review by the FDA, all obtained through the acquisition of Éclat Pharmaceuticals, LLC’s (or “Éclat”) portfolio on March 13, 2012,
- (ii) a branded pediatric specialty pharmaceutical business, acquired through the acquisition of FSC Laboratories and FSC Pediatrics (“FSC”) on February 5, 2016; and
- (iii) a branded business, focusing on the development of products utilizing Flamel’s proprietary drug delivery platforms. The branded products that are based on Flamel’s proprietary drug delivery platforms target high-value solid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits.

Flamel is headquartered in Lyon, France and has operations in St. Louis, Missouri and Charlotte, NC, USA, and Dublin, Ireland.

**Basis of Presentation.** The consolidated balance sheet as of December 31, 2015, which is derived from the prior year 2015 audited consolidated financial statements, and the interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP), the requirements of Form 10-Q and Article 10 of Regulation S-X and, consequently, do not include all information or footnotes required by U.S. GAAP for complete financial statements or all the disclosures normally made in an annual report on Form 10-K. Accordingly, the unaudited consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2016.

The unaudited consolidated financial statements include the accounts of the Company and all majority-owned subsidiaries, and reflect all adjustments (consisting only of normal recurring adjustments) that are, in the opinion of management, necessary for a fair presentation of the Company’s financial position, results of operations and cash flows for the dates and periods presented. All significant intercompany accounts and transactions have been eliminated. Results for interim periods are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

**Foreign Currency Translation.** The reporting currency of the Company and its wholly-owned subsidiaries is the U.S. dollar. Each of the Company’s non-U.S. subsidiaries and the parent entity uses local currency as its functional currency. Subsidiaries and entities that do not use the U.S. Dollar as their functional currency translate 1) profit and loss accounts at the weighted average exchange rates during the reporting period, 2) assets and liabilities at period end exchange rates and 3) shareholders’ equity accounts at historical rates. Resulting translation gains and losses are included as a separate component of stockholders’ equity in Accumulated Other Comprehensive Income. Assets and liabilities denominated in a currency other than the subsidiary’s functional currency are translated to the subsidiary’s functional currency at period end exchange rates. Resulting gains and losses are recognized in the consolidated statements of income.

**Reclassifications.** The accompanying consolidated financial statements for prior years contain certain reclassifications to conform to the presentation used in 2016.

**Revenue.** Revenue includes sales of pharmaceutical products, upfront licensing fees, milestone payments for R&D achievements, and compensation for the execution of R&D activities.

*Product Sales and Services*

Revenue is generally realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller’s price to the buyer is fixed or determinable, and collectability is reasonably assured. The Company records revenue from product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company’s gross product sales are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of its products, an estimate of provision for sales return and allowances is recorded which reduces product sales. These adjustments include estimates for product returns, chargebacks, payment discounts and other sales allowances and rebates. The estimate for chargebacks is determined when product is shipped from the wholesalers to their customers. The return allowance, when estimable, is based on an analysis of the historical returns of the product or similar products.



For generic products and branded products sold in mature and stable markets where changes in selling price are rare, the Company recognizes revenues upon shipment. For products where market conditions remain volatile and selling price is subject to changes, the Company delays revenue recognition until the wholesaler sells the product through to its customers. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent wholesaler inventory tracking service. Net sales of wholesalers to their customers are calculated by deducting estimates for returns for wholesaler customers, chargebacks, payment discounts and other sales or discounts offered from the applicable gross sales value. Estimates for product returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors.

#### *License and Research Revenue*

Where agreements have more than one deliverable, a determination is made as to whether the license and R&D elements should be recognized separately or combined into a single unit of account in accordance with ASU 2009-13, Revenue with Multiple Deliverables.

The Company uses a Multiple Attribution Model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e., can be used by the partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Revenue associated with signed feasibility study agreements is recognized over the term of the agreement as services are performed.

#### **NOTE 2 : Newly Issued Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 "*Revenue from Contracts with Customers*" which supersedes the most current revenue recognition requirements. This ASU requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. In March and April 2016, the FASB issued ASU 2016-08 "*Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*" related to principal versus agent considerations and ASU 2016-10 "*Identifying Performance Obligations and Licensing*" related to identifying performance obligations and licensing, which provide supplemental adoption guidance and clarification to ASU 2014-09, respectively. These ASUs will be effective for annual and interim periods beginning after December 15, 2017 with early adoption for annual and interim periods beginning after December 15, 2016 permitted and should be applied retrospectively to each prior reporting period presented or as a cumulative effect adjustment as of the date of adoption. The Company is currently evaluating this pronouncement to determine the impact of its adoption on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09 "*Improvements to Employee Share-Based Payment Accounting*" which amends ASC Topic 718 "*Compensation – Stock Compensation*". This update simplifies several aspects of accounting for share-based payment awards to employees, including the accounting for income taxes, classification of awards as either equity or liabilities and classification in the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the effect of this update on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 "*Leases*" which supersedes ASC 840 "*Leases*" and creates a new topic, ASC 842 "*Leases*." This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the effect of this update on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17 "*Balance Sheet Classification of Deferred Taxes*" which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for the Company in its first quarter of fiscal 2017, with early application permitted and, upon adoption, may be applied either prospectively or retrospectively. The Company early adopted the provisions of ASU 2015-17 for the year ended December 31, 2015 on a prospective basis.

In July 2015, the FASB issued ASU 2015-11 “*Simplifying the Measurement of Inventory*”, which requires an entity to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The effective date for the standard is for fiscal years beginning after December 15, 2016, which for the Company is January 1, 2017. Early adoption is permitted. The new standard is to be applied prospectively. The Company does not expect ASU 2015-11 to have a material impact on its consolidated financial statements.

### NOTE 3 : Marketable Securities

The Company has investments in available-for-sale marketable equity securities which are recorded at fair market value and measured using quoted prices in their respective active market, thus representing a level 1 fair value measurement as defined in ASC 820. Unrealized gains and losses are recorded as other comprehensive income (loss) in shareholders’ equity, net of income tax effects.

The value at cost, gross unrealized holding gains or losses, and fair value of the Company’s available-for-sale marketable securities are summarized below as of:

	March 31, 2016	December 31, 2015
Value at cost	\$ 122,823	\$ 81,395
Gross unrealized holding gains	614	15
Gross unrealized holding losses	(1,353)	(1,672)
<b>Fair value</b>	<b>\$ 122,084</b>	<b>\$ 79,738</b>

### NOTE 4 : Inventories

The principal categories of inventories at December 31, 2015 and 2014 are as follows:

	March 31, 2016	December 31, 2015
Finished Goods	\$ 5,046	\$ 2,545
Raw Materials	266	1,610
<b>Total</b>	<b>\$ 5,312</b>	<b>\$ 4,155</b>

### NOTE 5 : Acquisitions

On February 5, 2016, the Company completed its acquisition of FSC Holdings, LLC (“FSC”), a Charlotte, NC-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a related party.

This acquisition has been accounted for using the acquisition method of accounting and, accordingly, its results are included in the Company’s consolidated financial statements from the date of acquisition. Total consideration to acquire FSC was \$22,695 and was funded with a combination of the following:

- \$15,000 long-term liability to Deerfield. Under the terms of the acquisition agreement, the Company will pay \$1,050 annually for five years with a final payment in January 2021 of \$15,000. The present value of these discounted future cash flows is reported in Long-term related party payable within the Company’s Consolidated Balance Sheets.
- \$7,695 contingent consideration to Deerfield. Under the terms of the acquisition agreement, the Company shall pay quarterly a 15% royalty on the net sales of certain FSC products, up to \$12,500 for a period not exceeding ten years. The present value of these estimated discounted future cash flows is reported in Long-term contingent consideration payable within the Company’s Consolidated Balance Sheets, and is further disclosed at Note 7 – Long-term Contingent Consideration Payable.

During the first quarter of 2016, the Company determined its preliminary accounting for the FSC acquisition. As the Company completes its final accounting for the acquisition, future adjustments related to working capital, amortizable intangible assets, goodwill and deferred taxes could occur. The preliminary fair values assigned to the acquired assets and liabilities have been recognized as follows:

<b>Assigned Fair Value:</b>	
Inventories	\$ 2,360
Prepaid expenses and other current assets	1,711
Goodwill	5,564
Intangible assets:	
Acquired product marketing rights	16,200
Acquired developed technology	4,400
Other assets	278
Accounts payable and other current liabilities	(3,868)
Deferred tax liabilities	(3,950)
<b>Total</b>	<b>\$ 22,695</b>

Goodwill resulting from the acquisition is largely attributable to the existing workforce of FSC, and is not expected to be deductible for tax purposes. Transaction expenses for legal and professional fees associated with the acquisition of FSC amounted to \$76 during the first quarter of 2016 and are reported within the Selling, general and administrative expenses line in the consolidated statements of income.

FSC contributed \$876 and (\$1,393) to the Company's first quarter 2016 net revenues and net loss, respectively, after its acquisition on February 5, 2016. Had the FSC acquisition been completed as of the beginning of 2015, the Company's unaudited pro forma net sales for the three months ended March 31, 2016 and 2015 would have been \$36,694 and \$33,226, respectively, and the Company's unaudited pro forma net income (loss) for the same periods would have been (\$7,390) and \$8,480, respectively.

#### NOTE 6 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at March 31, 2016 and December 31, 2015 are as follows:

	March 31, 2016			December 31, 2015		
	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets:						
Acquired IPR&D - Bloxiverz	\$ 35,248	\$ (26,435)	\$ 8,813	\$ 35,248	\$ (23,498)	\$ 11,750
Acquired IPR&D - Vazculep	12,061	(8,190)	3,871	12,061	(7,986)	4,075
Acquired product marketing rights	16,200	(300)	15,900	-	-	-
Acquired developed technology	4,400	(73)	4,327	-	-	-
<b>Total amortizable intangible assets</b>	<b>\$ 67,909</b>	<b>\$ (34,998)</b>	<b>\$ 32,911</b>	<b>\$ 47,309</b>	<b>\$ (31,484)</b>	<b>\$ 15,825</b>
Unamortizable intangible assets:						
Goodwill	24,599	(544)	24,055	19,035	(544)	18,491
<b>Total unamortizable intangible assets</b>	<b>\$ 24,599</b>	<b>\$ (544)</b>	<b>\$ 24,055</b>	<b>\$ 19,035</b>	<b>\$ (544)</b>	<b>\$ 18,491</b>

The Company recorded amortization expense related to amortizable intangible assets of \$3,514 and \$3,143 for the three months ended March 31, 2016 and 2015, respectively.

Amortizable intangible assets are amortized over their estimated useful lives, which range from three to ten years. Estimated amortization of intangible assets for the next five years is as follows:

Years ending December 31,	Estimated Amortization Expense
2016	\$ 14,616
2017	3,056
2018	3,056
2019	3,056
2020	3,056
<b>Total</b>	<b>\$ 26,840</b>

The change in net goodwill during the three months ended March 31, 2016 is as follows:

Balance - December 31, 2015	\$ 18,491
Impact of FSC Acquisition	5,564
<b>Balance - March 31, 2016</b>	<b>\$ 24,055</b>

#### NOTE 7 : Long-Term Contingent Consideration Payable

Long-term contingent consideration payable and related activity are reported at fair value and consist of the following at March 31, 2016 and December 31, 2015:

	Balance, December 31, 2015	Activity During Quarter Ended March 31, 2016				Balance, March 31, 2016
		Additions	Payments to Related Parties	Changes in Fair Value of Contingent Consideration		
				Operating Expense; Acquisition- Related	Interest Expense; Financing- Related	
Acquisition-related:						
Warrants - Éclat Pharmaceuticals (a)	\$ 20,617	\$ -	\$ -	\$ (3,535)	\$ -	\$ 17,082
Earn-out payments - Éclat Pharmaceuticals (b)	90,468	-	(8,014)	11,451	-	93,905
Financing-related:						
Royalty agreement - Deerfield (c)	7,862	-	(739)	-	1,038	8,161
Royalty agreement - Broadfin (d)	3,746	-	(353)	-	496	3,889
Royalty agreement - FSC (e)	-	7,695	-	-	327	8,022
<b>Total contingent consideration</b>	<b>\$ 122,693</b>	<b>\$ 7,695</b>	<b>\$ (9,106)</b>	<b>\$ 7,916</b>	<b>\$ 1,861</b>	<b>\$ 131,059</b>
Less: Current portion	(28,614)					(28,403)
<b>Total long-term contingent consideration payable</b>	<b>\$ 94,079</b>					<b>\$ 102,656</b>

- (a) As part of the consideration for the Company's acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012, the Company issued two warrants with a six-year term which allow for the purchase of a combined total of 3,300 ordinary shares of Flamel. One warrant is exercisable for 2,200 shares at an exercise price of \$7.44 per share, and the other warrant is exercisable for 1,100 shares at an exercise price of \$11.00 per share.

The fair value of the warrants is estimated on a quarterly basis using a Black-Scholes option pricing model with the following assumptions as of March 31,:

	2016	2015
Weighted average exercise price per share	\$ 8.63	\$ 8.63
Expected term (years)	2.00	3.00
Expected volatility	70.50%	61.80%
Risk-free interest rate	0.73%	0.89%
Expected dividend yield	-	-

These Black-Scholes fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. The fair value of the warrant consideration is most sensitive to movement in the Company's share price and expected volatility at the balance sheet date.

*Expected term:* The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

*Expected volatility:* The expected volatility is calculated based on an average of the historical volatility of the Company's stock price for a period approximating the expected term.

*Risk-free interest rate:* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant and a maturity that approximates the expected term.

*Expected dividend yield:* The Company has not distributed any dividends since its inception, and has no plan to distribute dividends in the foreseeable future.

At the closing date of the 2012 Éclat acquisition and at March 31, 2016, it was uncertain as to whether the Company would ultimately fulfill its obligation under these warrants using Company shares or cash. Accordingly, pursuant to the guidance of ASC 480, the Company determined that these warrants should be classified as a long-term liability. This classification as a long-term liability was further supported by the Company's determination, pursuant to the guidance of ASC 815-40-15-7(i), that these warrants could also not be considered as being indexed to the Company's own stock, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Company at the closing date of the Éclat acquisition was the Euro.

- (b) As part of the consideration for the Company's acquisition of Éclat Pharmaceuticals, LLC in March 2012, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat Pharmaceuticals products. These payments will continue in perpetuity, to the extent revenues of the related product also continue in perpetuity.
- (c) As part of a February 2013 debt financing transaction conducted with Deerfield Management, a related party and current shareholder, the Company received cash of \$2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat Pharmaceuticals products until December 31, 2024.
- (d) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Company received cash of \$2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat Pharmaceuticals products until December 31, 2024.
- (e) As part of the consideration for the Company's acquisition of FSC Holdings, LLC in February 2016, the Company entered into a royalty agreement whereby the Company shall pay quarterly a 15% royalty on the net sales of certain FSC products, up to \$12,500 for a period not exceeding ten years.

At March 31, 2016, the fair value of each contingent consideration item in (b) through (e) above was estimated using a discounted cash flow model based on probability-adjusted annual net revenues or gross profit, as appropriate, of each of the specified Éclat Pharmaceuticals and FSC products at an appropriate discount rate. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related and financing-related contingent consideration payable, resulting primarily from management's revision of key assumptions, will be recorded in the changes in fair value of related party acquisition-related contingent consideration and interest expense – changes in fair value of related party financing-related contingent consideration lines, respectively, within the Company's Consolidated Statements of Income.

#### NOTE 8 : Income Taxes

The components of income (loss) before income taxes are as follows:

	Three Months Ended	
	March 31,	
	2016	2015
United States	\$ 13,416	\$ 18,020
France	(6,801)	7,880
Ireland	(5,850)	(3,780)
<b>Total income before income taxes</b>	<b>\$ 765</b>	<b>\$ 22,120</b>

The items accounting for the difference between the income tax provision computed at the French statutory rate and the Company's effective tax rate are as follows:

	Three Months Ended March 31,	
	2016	2015
<b>Statutory tax rate</b>	33.3%	33.3%
International tax rates differential	190.8%	4.9%
Valuation allowance on net operating losses	317.4%	(4.5)%
Nondeductible contingent consideration	362.2%	9.7%
Nondeductible stock-based compensation	28.5%	1.3%
Deferred charge from IP transfer	64.6%	1.2%
State and local income taxes	15.8%	0.5%
Other	(79.2)%	0.9%
<b>Effective income tax rate</b>	<b>933.5%</b>	<b>47.3%</b>
<b>Income tax provision - at Statutory tax rate</b>	<b>\$ 255</b>	<b>\$ 7,366</b>
International tax rates differential	1,460	1,093
Valuation allowance on net operating losses	2,428	(1,006)
Nondeductible contingent consideration	2,771	2,146
Nondeductible stock-based compensation	218	285
Deferred charge from IP transfer	494	264
State and local income taxes	121	119
Other	(606)	206
<b>Income tax provision - at Effective income tax rate</b>	<b>\$ 7,141</b>	<b>\$ 10,473</b>

The effective tax rate for the first quarter 2016 and 2015 was 933.5% and 47.3%, respectively. The higher income tax rate in 2016 is primarily the result of recording valuation allowances against the tax benefits from book losses in France and Ireland. An increase in the amount of nondeductible contingent consideration and the effect of lower income levels in low-tax jurisdictions also contributed to the increased income tax rate.

#### NOTE 9 : Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

	March 31, 2016	December 31, 2015
<b>Prepaid expenses and other current assets</b>		
Valued-added tax recoverable	\$ 1,182	\$ 1,099
Prepaid expenses	6,011	2,846
Advance to suppliers and other current assets	2,782	518
Income tax receivable	-	3,526
<b>Total</b>	<b>\$ 9,975</b>	<b>\$ 7,989</b>
	March 31, 2016	December 31, 2015
<b>Accrued expenses</b>		
Accrued compensation	\$ 1,898	\$ 1,888
Accrued social charges	1,285	1,710
Other	163	-
<b>Total</b>	<b>\$ 3,346</b>	<b>\$ 3,598</b>

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
<b>Other current liabilities</b>		
Valued-added tax payable	\$ 134	\$ -
Other	477	133
<b>Total</b>	<u>\$ 611</u>	<u>\$ 133</u>
	<u>March 31, 2016</u>	<u>December 31, 2015</u>
<b>Other non-current liabilities</b>		
Provision for retirement indemnity	2,297	2,170
Other	198	40
<b>Total</b>	<u>\$ 2,495</u>	<u>\$ 2,210</u>

**NOTE 10 : Net Income (Loss) Per Share**

Basic net income (loss) per share is calculated using the weighted average number of shares outstanding during each period. The diluted net income (loss) per share calculation includes the impact of dilutive equity compensation awards and contingent consideration warrants.

A reconciliation of basic and diluted net income (loss) per share, together with the related shares outstanding in thousands is as follows:

	<b>Three Months Ended March 31,</b>	
	<u>2016</u>	<u>2015</u>
<b>Net income (loss)</b>	\$ (6,376)	\$ 11,647
<b>Weighted average shares:</b>		
Basic shares	41,241	40,207
Effect of dilutive securities—options and warrants outstanding	-	2,672
Diluted shares	<u>41,241</u>	<u>42,879</u>
<b>Net income (loss) per share - Basic</b>	\$ (0.15)	\$ 0.29
<b>Net income (loss) per share - Diluted</b>	\$ (0.15)	\$ 0.27

Potential common shares of 6,597 and 72 were excluded from the calculation of weighted average shares for the three months ended March 31, 2016 and 2015, because their effect was considered to be anti-dilutive. For the quarter ended March 31, 2016, the effects of dilutive securities were entirely excluded from the calculation of net income (loss) per share as a net loss was reported in this period.

**NOTE 11 : Comprehensive Income (Loss)**

The following table shows the components of accumulated other comprehensive income (loss) for the three months ended March 31, 2016 and 2015 net of tax effects:

	<b>Foreign Currency Translation Adjustment Income (Loss), Net</b>	<b>Unrealized Gain (Loss) on Marketable Securities, Net</b>	<b>Total</b>
<b>Balance - December 31, 2015</b>	\$ (22,312)	\$ (345)	\$ (22,657)
Other comprehensive income	4,817	918	5,735
<b>Balance - March 31, 2016</b>	<u>\$ (17,495)</u>	<u>\$ 573</u>	<u>\$ (16,922)</u>
<b>Balance - December 31, 2014</b>	\$ (7,225)	\$ (198)	\$ (7,423)
Other comprehensive income (loss)	(16,649)	356	(16,293)
<b>Balance - March 31, 2015</b>	<u>\$ (23,874)</u>	<u>\$ 158</u>	<u>\$ (23,716)</u>

The effect on the Company's consolidated financial statements of amounts reclassified out of Accumulated other comprehensive income was immaterial for all years presented.

**NOTE 12 : Shareholders' Equity**

The following table presents a reconciliation of the Company's beginning and ending balances in shareholders' equity for the three months ended March 31,:

	<u>2016</u>	<u>2015</u>
<b>Shareholders' Equity - January 1</b>	\$ 67,865	\$ 24,895
Net income (loss)	(6,376)	11,647
Other comprehensive income	5,735	(16,293)
Exercise of stock options or warrants	-	246
Stock-based compensation expense	2,475	1,751
<b>Shareholders' Equity - March 31</b>	<u>\$ 69,699</u>	<u>\$ 22,246</u>

**NOTE 13 : Company Operations by Product, Customer and Geographic Area**

The Company has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology. The Company's Chief Operating Decision Maker is the CEO. The CEO and the Board review profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products are included in one segment because the majority of our products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

The following table presents a summary of total revenues by these products:

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



The following table presents a summary of total revenues by significant wholesaler customer:

	Three Months Ended March 31,	
	2016	2015
Customer A	\$ 13,026	\$ 6,867
Customer B	10,677	13,771
Customer C	7,398	9,749
Other	4,252	2,339
<b>Total product sales and services</b>	<b>35,353</b>	<b>32,726</b>
<b>License and research revenue</b>	<b>863</b>	<b>-</b>
<b>Total revenues</b>	<b>\$ 36,216</b>	<b>\$ 32,726</b>

The following table summarizes revenues and non-monetary long-lived assets by geographic region. Non-monetary long-lived assets primarily consist of property and equipment, goodwill and intangible assets:

	2016	2015
<b>Revenues, for the three months ended March 31,</b>		
United States	\$ 35,478	\$ 32,711
France	-	-
Ireland	738	15
<b>Total</b>	<b>\$ 36,216</b>	<b>\$ 32,726</b>
<b>Long-lived assets, as of March 31, 2016 and December 31, 2015</b>		
United States	\$ 57,459	\$ 34,515
France	2,367	2,317
Ireland	256	258
<b>Total</b>	<b>\$ 60,082</b>	<b>\$ 37,090</b>

#### NOTE 14 : Related Party Transactions

In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. (“Breaking Stick”, formerly Éclat Holdings), an affiliate of Deerfield Capital L.P (“Deerfield”), a significant shareholder of the Company. As of March 31, 2016, the remaining consideration obligations for this transaction consisted of two warrants to purchase a total of 3,300 shares of Flamel and commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the “Products”). Breaking Stick is majority owned by Deerfield, with a minority interest owned by Mr. Michael Anderson, the Company’s CEO, and certain other current and former employees. The original consideration for the acquisition of Éclat also included a \$12 million senior note payable to the majority owners of Breaking Stick, which was fully repaid in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

As part of a February 2013 debt financing transaction conducted with Deerfield Management, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, “Deerfield PDF/Horizon”). The Royalty Agreement provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales of the Products sold by the Company and any of its affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Company has also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the intellectual property and regulatory rights related to the Products to secure the obligations of Éclat and Flamel US, including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement. This original Deerfield debt financing transaction also included a \$15 million facility agreement which was repaid in full in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund (“Broadfin”), the Company entered into a Royalty Agreement with Broadfin, a significant shareholder of the Company, dated as of December 3, 2013 (the “Broadfin Royalty Agreement”). Pursuant to the Broadfin Royalty Agreement, the Company is required to pay a royalty of 0.834% on the net sales of certain products sold by the Company and any of its affiliates until December 31, 2024. This original Broadfin debt financing transaction also included a \$5 million facility agreement which was repaid in full in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

In February 2016, the Company acquired all of the membership interests of FSC Holdings, LLC (“FSC”) from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a significant shareholder of the Company. The consideration obligations for this transaction consisted of payments \$1,050 annually for five years with a final payment in January 2021 of \$15,000, and commitments to pay quarterly a 15% royalty on the net sales of certain FSC products, up to \$12,500 for a period not exceeding ten years.

**NOTE 15 : Contingent Liabilities and Commitments**

***Litigation***

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At March 31, 2016 and December 31, 2015, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company’s consolidated financial position, results of operations, cash flows or liquidity.

***Material Commitments***

Other than commitments to Recipharm and for operating leases as disclosed in Note 12 - Contingent Liabilities and Commitments to the Company's consolidated financial statements included in Part II, Item 8 of the Company’s 2015 Annual Report, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, and post-retirement benefit plan obligations which are disclosed in Note 7 - Long-Term Debt and Note 10 – Post-Retirement Benefit Plans, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Company’s 2015 Annual Report and long-term contingent consideration payable as disclosed in Note 7 – Long-term Contingent Consideration Payable, to the Company's consolidated financial statements included in Part I, Item 1 of this report.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Management's Discussion And Analysis

(In Thousands, Except Per Share Data)

(Unaudited)

*You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 2 together with our consolidated financial statements and the related notes appearing elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Disclosure Regarding Forward-Looking Statements" set forth immediately following the Table of Content of the Company's 2015 Annual report on Form 10-K filed with the SEC on March 15, 2016 (the "2015 Annual Report") for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section in Part I Item 1A of the 2015 Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Report.*

#### Overview

We are a specialty pharmaceutical company utilizing core competencies in drug delivery and formulation to develop safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. Flamel has a balanced business model consisting of:

- a successful previously Unapproved Marketed Drugs ("UMDs") business with three marketed products in the USA, Bloxiverz, Vazculep and Akovaz,
- a branded pediatric specialty pharmaceutical business, acquired through the acquisition of FSC Laboratories and FSC Pediatrics ("FSC") on February 5, 2016, and
- a branded development business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. The branded products are based on proprietary drug delivery platforms and target high-value solid oral and alternative dosage forms using 505(b)(2) and biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits.

Flamel's business model allows the Company to select, develop, seek approval for, and commercialize niche branded and generic products, initially targeted for the U.S. market. The Company is able to self-fund the development of most product development opportunities. On May 2, 2016, the company announced that the U.S. Food and Drug Administration (FDA) has approved the Company's New Drug Application (NDA) for Akovaz™ (ephedrine sulfate), a drug administered parenterally as a pressor agent to address clinically important hypotension in surgical settings. The NDA, which is the first to receive approval from the FDA for ephedrine sulfate, was approved as scheduled on April 29, 2016. Flamel expects to launch Akovaz during the third quarter 2016 in a strength of 50mg/mL.

#### Strategy

The Company's business strategy is designed to drive overall sales and earnings growth while maintaining a return on invested capital at an appropriate premium above the Company's cost of capital. Our key areas of focus address the most significant opportunities and challenges facing the Company, including:

- **Unapproved Marketed Drug Development:** The Company now derives cash flow and profitability from the sales of two of its UMD products. During the three months ended March 31, 2016 the Company generated \$34,153 of sales from the UMD products compared to \$32,166 in the same period of 2015.
  - o The first UMD product, Bloxiverz, which had sales of \$24,747 in the first quarter of 2016 was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S.
  - o The second UMD product, Vazculep, which had sales of \$9,406 in the first quarter of 2016, was approved by the FDA on June 27, 2014 and launched in October 2014 in the USA.
  - o A third UMD product, Akovaz, the brand name for the Company's ephedrine sulfate injection, obtained NDA approval on April 29, 2016.

Each of the above products are currently or will be commercialized in the USA by Flamel's subsidiary Éclat. These sales were derived from the acquisition of Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) regulatory pathway. Through our acquisition of Éclat we obtained marketing and licensing knowledge of the commercial and regulatory process in the U.S. and EU. We believe this knowledge has enhanced our ability to identify product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and license and market products in the U.S and EU. The revenues from these UMD products are now generating cash flow which we can use to fund our second strategy, the development and commercialization of our drug delivery products.

- **Development and Commercialization of the Company's Drug Delivery Pipeline Products:** In addition to the UMD strategy, the Company is continuing to advance the commercialization of its innovative drug delivery platforms. We have now enhanced our ability to identify new product candidates and to pursue commercial opportunities associated with our drug delivery platforms. The Company's drug delivery platforms allow the creation of competitive and differentiated drug product profiles (e.g., with improved pharmacokinetics, efficacy and/or safety). Flamel owns and develops drug delivery platforms that address key formulation challenges, leading to the development of differentiated drug products for administration in various forms (e.g., capsules, tablets, sachets or liquid suspensions for oral use; or injectables for subcutaneous administration) and can be applied to a broad range of drugs (novel, already-marketed, or off-patent). These product development opportunities allow us to protect our products through patent protection and product differentiation. As a result of developing its own drug delivery platforms the Company's business is now less dependent on the development activities performed by partners, and relies more on the development of its own, self-funded, products. Our proprietary drug delivery platforms include:



- o **Micropump**<sup>®</sup> is a microparticulate system that allows the development and marketing of modified and/or controlled release of solid, oral dosage formulations of drugs (Micropump<sup>®</sup>-carvedilol and Micropump<sup>®</sup>-aspirin formulations have been approved in the U.S. and in the E.U., respectively).
- o **LiquiTime**<sup>®</sup> allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or for patients having issues swallowing tablets or capsules.
- o **Trigger Lock**<sup>™</sup> allows development of abuse-resistant modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse.
- o **Medusa**<sup>™</sup> allows the development of extended/modified release of injectable dosage formulations of drugs (*e.g.*, peptides, polypeptides, proteins, and small molecules).

Several products formulated using our proprietary drug delivery platforms are currently under various stages of development for possible marketing either by the Company and/or by partners via licensing/distribution agreements:

The key elements of our pipeline strategy include:

- o Continuing to build commercially successful products utilizing Micropump;
- o Identifying and optimizing time-to-market for our (not yet approved) drug delivery platforms, i.e., LiquiTime, Trigger Lock and Medusa;
- o Maximizing the technical potential of our existing drug delivery platforms for developing new and proprietary products; and
- o Developing and validating additional drug delivery platforms utilizing our current drug delivery platforms

· **Inorganic growth through Acquisitions and/or Partnerships:** The Company maintains a strong balance sheet with substantial liquidity and little long term debt. As part of its overall enterprise strategy, the company expects to explore and pursue appropriate inorganic growth opportunities that complement its drug delivery platforms or acquire proprietary products that enhance profitability and cash flow. This was evidenced in early 2016 with the acquisition of FSC Holdings, LLC, a Charlotte, NC-based specialty pharmaceutical company, dedicated to providing innovative solutions to unmet medical needs for pediatric patients. Additionally, the Company will leverage the capabilities of its existing and future proprietary products and/or drug delivery platforms with pharmaceutical and biotechnology partnerships or licensing transactions. In 2015, the Company completed a licensing transaction for its LiquiTime technology based-OTC products which was licensed to Elan Pharma International Limited.

### **Key Business Trends and Highlights**

In operating our business and monitoring our performance, we consider a number of performance measures, as well as trends affecting our industry as a whole, which include the following:

- **Healthcare and Regulatory reform:** Various health care reform laws in the United States may impact our ability to successfully commercialize our products and technologies. The success of our commercialization efforts may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of healthcare products and services.
- **Pricing Environment for Pharmaceuticals:** The pricing environment continues to be in the spotlight of many regulators. As a result the need to obtain and maintain appropriate pricing and reimbursement for our products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.
- **Generics playing a larger role in healthcare:** Generic pharmaceutical products will continue to play a large role in the US healthcare system. Specifically the Company has seen additional generic competition to its products and continues to expect generic competition in the future.
- **Access to and Cost of Capital:** The recent tightening of credit in the US may create challenges for the Company if it were to have the need to raise capital. Currently the Company has no needs to raise capital.

Highlights of our consolidated results for the three months ended March 31, 2016 are as follows:

- Revenue was \$36,216 for the three months ended March 31, 2016 compared to \$32,726 in the same period last year. This increase was primarily the result of increases in volume and pricing of Vazculep sales, partially offset by a decrease in Bloxiverz sales volume as a result of additional competition.
- Operating income was \$5,542 compared to \$10,214 during the same period in 2015.
- Net loss was (\$6,376) compared to a net income of \$11,647 in the first quarter of 2015, largely driven by a less favorable income tax rate.
- Diluted net loss per share was (\$0.15), compared to diluted net income of \$0.27 in the same period of 2015.
- Cash and marketable securities increased \$15,152 to \$159,954 from \$144,802 at December 31, 2015.

### **Critical Accounting Estimates**

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. To prepare these financial statements, management must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as the disclosures of contingent assets and liabilities. Actual results could be significantly different from these estimates.

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our 2015 Form 10-K. The SEC suggests companies provide additional disclosure on those accounting policies considered most critical. The SEC considers an accounting policy to be critical if it is important to our financial condition and results of operations and requires significant judgments and estimates on the part of management in its application. Our estimates are often based on complex judgments, probabilities and assumptions that management believes to be reasonable, but that are inherently uncertain and unpredictable. It is also possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For a complete discussion of our critical accounting policies, see the "Critical Accounting Policies" section of the MD&A in our 2015 Form 10-K. There were no significant changes to our critical accounting policies during the three months ended March 31, 2016.

## Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts):

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Product sales and services	\$ 35,353	\$ 32,726	\$ 2,627	8.0%
License and research revenue	863	-	863	n/a
<b>Total revenues</b>	<b>36,216</b>	<b>32,726</b>	<b>3,490</b>	<b>10.7%</b>
Cost of products and services sold	4,395	3,630	765	21.1%
Research and development expenses	5,388	6,022	(634)	(10.5)%
Selling, general and administrative expenses	9,461	4,463	4,998	112.0%
Intangible asset amortization	3,514	3,143	371	11.8%
Changes in fair value of acquisition-related contingent consideration	7,916	5,254	2,662	50.7%
<b>Total operating expenses</b>	<b>30,674</b>	<b>22,512</b>	<b>8,162</b>	<b>36.3%</b>
Operating income (loss)	5,542	10,214	(4,672)	(45.7)%
Investment Income	200	664	(464)	(69.9)%
Interest Expense	(175)	-	(175)	n/a
Interest Expense - changes in fair value of financing-related contingent consideration	(1,861)	(259)	(1,602)	(618.5)%
Foreign exchange gain (loss)	(2,941)	11,501	(14,442)	(125.6)%
Income (loss) before income taxes	765	22,120	(21,355)	(96.5)%
Income tax provision (benefit)	7,141	10,473	(3,332)	(31.8)%
Net income (loss)	(6,376)	11,647	(18,023)	(154.7)%
Earnings (loss) per share - Diluted	\$ (0.15)	\$ 0.27	\$ (0.43)	(156.9)%

## Revenues

The revenues for each of the Company's significant products were as follows:

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Bloxiverz	\$ 24,747	\$ 28,642	\$ (3,895)	(13.6)%
Vazculep	9,406	3,524	5,882	166.9%
Other	1,200	560	640	114.3%
<b>Total product sales and services</b>	<b>35,353</b>	<b>32,726</b>	<b>2,627</b>	<b>8.0%</b>
<b>License and research revenue</b>	<b>863</b>	<b>-</b>	<b>863</b>	<b>n/a</b>
<b>Total revenues</b>	<b>\$ 36,216</b>	<b>\$ 32,726</b>	<b>\$ 3,490</b>	<b>10.7%</b>

Product sales and services revenues were \$35,353 for the quarter ended March 31, 2016, compared to \$32,726 for the same prior year period, resulting in a \$2,627 or 8.0% increase. The primary driver of growth was higher sales of Vazculep<sup>®</sup> as both volume and pricing continued to increase following the product's launch late in 2014. Bloxiverz<sup>®</sup> sales decreased (\$3,895), driven largely by declines in volume as two new competitors have entered the market subsequent to the first quarter of 2015. The decrease in Bloxiverz<sup>®</sup> volume was partially offset by increases in pricing which were mainly introduced throughout the first quarter of 2015. The acquisition of FSC in February 2016 contributed \$826, or 1.9%, to the product sales increase in the first quarter of 2016.

License and research revenues increased \$863 during the quarter ended March 31, 2016 compared to the same prior year period, driven primarily by the Company's entrance into an exclusive licensing agreement of our LiquiTime drug delivery platform for the U.S. (OTC) drug market during the third quarter of 2015.

### Cost of Products and Services Sold

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Cost of products and services sold	\$ 4,395	\$ 3,630	\$ 765	21.1%
Percentage of sales	12.1%	11.1%		

Cost of products and services sold increased \$765 during the quarter ended March 31, 2016 compared to the same prior year period primarily due to increases in respective product sales and services. As a percentage of sales, cost of products sold was slightly higher than the previous year due to product mix, largely related to FSC.

### Research and Development Expenses

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Research and development expenses	\$ 5,388	\$ 6,022	\$ (634)	(10.5)%
Percentage of sales	14.9%	18.4%		

The following table provides a breakout of our research and development expenses by major categories of expense:

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Salaries and employee benefits	\$ 2,277	\$ 2,469	\$ (192)	(7.8)%
Clinical studies and outside services	2,764	4,158	(1,394)	(33.5)%
Other	974	55	919	1,670.9%
Government grants and R&D tax credit	(627)	(660)	33	5.0%
<b>Total research and development expenses</b>	<b>\$ 5,388</b>	<b>\$ 6,022</b>	<b>\$ (634)</b>	<b>(10.5)%</b>

Research and development expenses decreased (\$634) or (10.5%) during the three months ended March 31, 2016 as compared to the same period in 2015 primarily due to the timing of clinical studies and outside services costs, reductions in headcount and changes in foreign currency exchange rates.

### Selling, General and Administrative Expenses

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Selling, general and administrative expenses	\$ 9,461	\$ 4,463	\$ 4,998	112.0%
Percentage of sales	26.1%	13.6%		

Selling, general and administrative expenses increased \$4,998 or 112.0% during the three months ended March 31, 2016 as compared to the same period in 2015 primarily due to a \$1,600 increase attributable to ongoing payroll-related and other operating costs of the acquired FSC business, higher payroll costs of \$1,200 and stock-based compensation expenses of \$900 relative to increases in headcount to reinforce the Company's management team, and additional professional audit and tax consulting fees.

### Intangible Asset Amortization

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Intangible asset amortization	\$ 3,514	\$ 3,143	\$ 371	11.8%
Percentage of sales	9.7%	9.6%		

Intangible asset amortization expense increased \$371 or 11.8% during the three months ended March 31, 2016 as compared to the same period in 2015 due to the commencement of amortization related to the acquired intangible assets of FSC.



**Changes in Fair Value of Related Party Acquisition-Related Contingent Consideration**

	<b>Three Months Ended</b>		<b>Increase / (Decrease)</b>	
	<b>March 31,</b>		<b>2016 vs. 2015</b>	
	<b>2016</b>	<b>2015</b>	<b>\$</b>	<b>%</b>
Changes in fair value of related party acquisition-related contingent consideration	\$ 7,916	\$ 5,254	\$ 2,662	50.7%
Percentage of sales	21.9%	16.1%		

Changes in fair value of related party acquisition-related contingent consideration increased \$2,662 or 50.7% during the three months ended March 31, 2016 as compared to the same period in 2015 primarily due to increased profits generated by the Éclat products and changes in the respective long-term product sales forecasts.

**Income Taxes**

	<b>Three Months Ended</b>		<b>Increase / (Decrease)</b>	
	<b>March 31,</b>		<b>2016 vs. 2015</b>	
	<b>2016</b>	<b>2015</b>	<b>\$</b>	<b>%</b>
Income tax provision (benefit)	\$ 7,141	\$ 10,473	\$ (3,332)	(31.8)%
Percentage of income (loss) before income taxes	933.5%	47.3%		

The items accounting for the difference between the income tax provision computed at the French statutory rates and the Company's effective tax rate are as follows:

	<b>Three Months Ended</b>	
	<b>2016</b>	<b>2015</b>
<b>Statutory tax rate</b>	<b>33.3%</b>	<b>33.3%</b>
International tax rates differential	190.8%	4.9%
Valuation allowance on net operating losses	317.4%	(4.5)%
Nondeductible contingent consideration	362.2%	9.7%
Nondeductible stock-based compensation	28.5%	1.3%
Deferred charge from IP transfer	64.6%	1.2%
State and local income taxes	15.8%	0.5%
Other	(79.2)%	0.9%
<b>Effective income tax rate</b>	<b>933.5%</b>	<b>47.3%</b>
<b>Income tax provision - at Statutory tax rate</b>	<b>\$ 255</b>	<b>\$ 7,366</b>
International tax rates differential	1,460	1,093
Valuation allowance on net operating losses	2,428	(1,006)
Nondeductible contingent consideration	2,771	2,146
Nondeductible stock-based compensation	218	285
Deferred charge from IP transfer	494	264
State and local income taxes	121	119
Other	(606)	206
<b>Income tax provision - at Effective income tax rate</b>	<b>\$ 7,141</b>	<b>\$ 10,473</b>

The effective tax rate for the first quarter 2015 and 2016 was 933.5% and 47.3%, respectively. The higher income tax rate in 2016 is primarily the result of recording valuation allowances against the tax benefits from book losses in France and Ireland. An increase in the amount of nondeductible contingent consideration and the effect of lower income levels in low-tax jurisdictions also contributed to the increased income tax rate.

## Liquidity and Capital Resources

The Company's cash flows from operating, investing and financing activities, as reflected in the Consolidated Statements of Cash Flows, are summarized in the following table:

	Three Months Ended		Increase / (Decrease)	
	March 31,		2016 vs. 2015	
	2016	2015	\$	%
Net cash provided by (used in):				
Operating activities	\$ 22,498	\$ 25,275	\$ (2,777)	(11.0)%
Investing activities	(40,987)	(23,429)	(17,558)	(74.9)%
Financing activities	(9,106)	(79)	(9,027)	(11,426.6)%

### Operating Activities

Net cash provided by operating activities of \$22,498 for the three months ended March 31, 2016 decreased \$2,777 from the same prior year period, driven primarily by a \$2,360 decrease in pre-tax income after adjusting for non-cash changes in fair value of contingent consideration, unrealized foreign exchange gains and losses, and depreciation and amortization expenses.

### Investing Activities

Cash used in investing activities of \$40,987 for the three months ended March 31, 2016 increased \$17,558 compared to the same prior year period. This increase was primarily driven by higher use of cash for net purchases of marketable securities of \$17,493.

### Financing Activities

Cash used in financing activities of \$9,106 for the three months ended March 31, 2016 increased \$9,027 compared to \$79 of cash used in financing activities in the same period of 2015. The increase in cash used in financing activities during 2016 was driven primarily by the timing of earn-out and royalty payments paid to Deerfield and Broadfin, as such payments are due quarterly in arrears and substantially lower revenue and gross profit was earned on sales of the related Éclat products during the fourth quarter of 2014 compared to the same period in 2015.

## Liquidity and Risk Management

We believe that our existing cash and marketable securities balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product revenues and expenses, as well as the other factors set forth in "Risk Factors" within Part I Item 1A of the Company's 2015 Annual Report. To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product development and clinical trials of product candidates. In this regard, we have evaluated and expect to continue to evaluate a variety of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

## **Other Matters**

### ***Litigation***

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At March 31, 2016 and December 31, 2015, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

### ***Material Commitments***

Other than commitments to Recipharm and for operating leases as disclosed in Note 12 - Contingent Liabilities and Commitments to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2015 Annual Report, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, and post-retirement benefit plan obligations which are disclosed in Note 7 - Long-Term Debt and Note 10 - Post-Retirement Benefit Plans, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Annual Report and long-term contingent consideration payable as disclosed in Note 7 - Long-term Contingent Consideration Payable, to the Company's consolidated financial statements included in Part I, Item 1 of this report.

### ***Contractual Obligations***

Disclosures regarding contractual obligations are included in Part II, Item 7 of the Company's 2015 Annual Report and updated in Note 7 - Long-term Contingent Consideration Payable to the Company's consolidated financial statements included in Part I, Item 1 of this Report.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

#### **Interest Rate Risk**

The Company is subject to interest rate risk as a result of its portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and common stocks.

#### **Foreign Exchange Risk**

We have significant operations in Europe as well as in the U.S. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in Euro.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign currency gain (loss) in the consolidated statements of income. As of March 31, 2016, our primary exposure to transaction risk related to U.S. dollar net monetary assets and liabilities held by subsidiaries with a Euro functional currency. Realized and unrealized foreign exchange losses resulting from transactional exposure were (\$2,941) for the three months ended March 31, 2016.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### **Disclosure Controls and Procedures**

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of March 31, 2016, the end of the period covered by this quarterly report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were not effective because of the material weaknesses in our internal control over financial reporting described in our Form 10-K as of December 31, 2015.

## **Remediation Plan and Status**

Management believes that the rapid growth of the size and complexity of the Company's business during 2015, without a commensurate growth in the size and expertise of our finance and accounting organizations contributed to the weaknesses described above.

We have commenced and continue to identify and implement actions to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. These plans include but are not limited to, adding to our finance staff and enhancing our training with respect to financial reporting and disclosure responsibilities. Recently, we hired a Chief Financial Officer, Chief Accounting officer and a Senior Tax Director, all of whom have the appropriate experience, certification, education, and training in financial reporting and accounting. Additionally, to assist in mitigating some of the segregation of duties weaknesses, we expect to complete the implementation of a new information technology system in 2016 that will employ a more robust and effective set of general computer and access controls. We will review our remediation plans with our audit committee during 2016 and periodically update them with our progress. Leading this remediation process is our Senior Vice President and Chief Financial Officer, who was hired in November 2015, with the assistance of our Chief Accounting Officer, who was hired in December 2015. Further, our Board of Directors recognizes the critical importance of a sound internal control structure and has directed senior management to ensure that a proper, consistent tone is communicated throughout the organization, which emphasizes the expectation that these deficiencies will be rectified through implementation of more effective processes and controls. To assist management in this regard, the Company has engaged a nationally recognized consulting firm to enhance existing documentation and implement improvements or changes to the existing internal control structure.

While our remediation actions described above represent significant progress to enhance our internal control over financial reporting relating to the identified material weaknesses, we continue to implement and test the effectiveness of these actions and procedures and additional time is required to complete implementation and to assess and ensure the sustainability of the resulting enhancements. We believe the above actions, together with any modifications thereto which we may determine to be appropriate and such further additional remedial steps we may identify during 2016, will ultimately be effective in remediating the material weaknesses described above, and we will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial enhancements operate for a sufficient period of time and management has concluded, through testing, that our internal controls are operating effectively.

## **Changes in Internal Control Over Financial Reporting**

There were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

The information contained in Note 15 – Contingent Liabilities and Commitments to the Company's consolidated financial statements included in Part I, Item 1 of this Report is incorporated by reference herein.

### ITEM 1A. RISK FACTORS.

There have been no material changes in our risk factors from those previously disclosed in the Company's 2015 Annual Report.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

### ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

### ITEM 5. OTHER INFORMATION.

None.

**ITEM 6. EXHIBITS.**

<b>Exhibit No.</b>	<b>Description</b>
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act.
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith.

**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 thereunto duly authorized.

**FLAMEL TECHNOLOGIES S.A.**  
(Registrant)

May 10, 2016

By: /s/ Michael F. Kanan  
Michael F. Kanan  
*Senior Vice President and Chief Financial Officer*  
*(Duly Authorized Officer and Principal Financial Officer)*



**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael S. Anderson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Flamel Technologies S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Michael S. Anderson

Michael S. Anderson

Chief Executive Officer

(Principal Executive Officer)

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**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael F. Kanan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Flamel Technologies S.A.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Michael F. Kanan

Michael F. Kanan

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Flamel Technologies S.A. (the "Company") for the period ended March 31, 2016 (the "Report"), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

/s/ Michael S. Anderson

Michael S. Anderson

Chief Executive Officer

(Principal Executive Officer)

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Flamel Technologies S.A. (the "Company") for the period ended March 31, 2016 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

/s/ Michael F. Kanan

Michael F. Kanan

Senior Vice President and Chief Financial Officer

(Principal Financial Officer)

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