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: September 30, 2016

FLAMEL TECHNOLOGIES S.A.
(Exact name of registrant as specified in its charter)

Republic of France	**000-28508**	**98-0639540**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

The number of shares of the registrant's common stock outstanding at November 7, 2016 was 41,241,254.

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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.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales and services	$ 31,340	$ 47,313	$ 104,858	$ 128,441
License and research revenue	747	—	2,303	—
Total	32,087	47,313	107,161	128,441
Operating expenses:				
Cost of products and services sold	2,844	2,087	10,657	8,473
Research and development expenses	8,143	7,221	21,135	20,447
Selling, general and administrative expenses	12,740	4,568	33,491	14,904
Intangible asset amortization	3,702	3,141	10,918	9,423
Changes in fair value of related party contingent consideration	20,848	44,782	52,989	82,036
Total	48,277	61,799	129,190	135,283
Operating loss	(16,190)	(14,486)	(22,029)	(6,842)
Investment income, net	490	197	1,080	1,171
Interest expense, net	(264)	—	(702)	—
Other expense - changes in fair value of related party payable	(1,828)	(6,644)	(6,135)	(9,629)
Foreign exchange gain (loss)	1,249	160	(12)	8,096
Loss before income taxes	(16,543)	(20,773)	(27,798)	(7,204)
Income tax provision	3,451	7,302	18,212	24,516
Net loss	$ (19,994)	$ (28,075)	$ (46,010)	$ (31,720)
Net loss per share - basic	$ (0.48)	$ (0.69)	$ (1.12)	$ (0.79)
Net loss per share - diluted	$ (0.48)	$ (0.69)	$ (1.12)	$ (0.79)
Weighted average number of shares outstanding - basic	41,241	40,625	41,241	40,397
Weighted average number of shares outstanding - diluted	41,241	40,625	41,241	40,397

See accompanying notes to condensed consolidated financial statements.

FLAMEL TECHNOLOGIES S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$ (19,994)	$ (28,075)	$ (46,010)	$ (31,720)
Other comprehensive income (loss), net of tax:				
Foreign currency translation gain (loss)	1,567	102	3,927	(11,285)
Net other comprehensive (loss) income, net of $152, ($9), ($49), ($9) tax, respectively	(2,405)	(365)	(958)	(365)
Total other comprehensive income (loss), net of tax	(838)	(263)	2,969	(11,650)
Total comprehensive loss	$ (20,832)	$ (28,338)	$ (43,041)	$ (43,370)

See accompanying notes to condensed consolidated financial statements.

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

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,780	$ 65,064
Marketable securities	130,887	79,738
Accounts receivable	15,395	7,487
Inventories	3,909	3,666
Research and development tax credit receivable	—	2,382
Prepaid expenses and other current assets	8,883	8,064
Total current assets	177,854	166,401
Property and equipment, net	3,186	2,616
Goodwill	19,134	18,491
Intangible assets, net	25,508	15,825
Research and development tax credit receivable	4,240	—
Income tax deferred charge	11,243	11,581
Other	6,820	167
Total assets	$ 247,985	$ 215,081
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 286	$ 434
Current portion of long-term related party payable	33,359	25,204
Accounts payable	8,966	5,048
Deferred revenue	3,115	5,121
Accrued expenses	13,032	9,308
Other	427	133
Total current liabilities	59,185	45,248
Long-term debt, less current portion	734	684
Long-term related party payable, less current portion	146,926	97,489
Other	4,307	2,526
Total liabilities	211,152	145,947
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,178 shares authorized; 41,241 issued and outstanding at September 30, 2016 and December 31, 2015	6,331	6,331
Additional paid-in capital	374,724	363,984
Accumulated deficit	(324,534)	(278,524)
Accumulated other comprehensive loss	(19,688)	(22,657)
Total shareholders' equity	36,833	69,134
Total liabilities and shareholders' equity	$ 247,985	$ 215,081

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (46,010)	$ (31,720)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	11,555	9,800
Loss on disposal of property and equipment	110	—
Loss on sale of marketable securities	666	443
Foreign exchange loss (gain)	12	(7,475)
Grants recognized in research and development expenses	(70)	(1,086)
Remeasurement of related party acquisition-related contingent consideration	52,989	82,036
Remeasurement of related party financing-related contingent consideration	6,135	9,629
Change in deferred tax and income tax deferred charge	(5,680)	(745)
Stock-based compensation expense	10,541	5,574
Increase (decrease) in cash from:		
Accounts receivable	(7,594)	(1,363)
Inventories	2,080	1,757
Prepaid expenses and other current assets	671	(4,005)
Research and development tax credit receivable	(1,794)	2,469
Accounts payable & other current liabilities	1,291	2,387
Deferred revenue	(2,198)	(1,318)
Accrued expenses	2,700	(1,048)
Accrued income taxes	—	(7,584)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(14,486)	—
Royalty payments for related party payable in excess of original fair value	(1,790)	—
Other long-term assets and liabilities	2,032	144
Net cash provided by operating activities	11,160	57,895
Cash flows from investing activities:		
Purchases of property and equipment	(1,000)	(1,077)
Acquisitions of businesses	628	—
Proceeds from sales of marketable securities	46,483	37,007
Purchase of marketable securities	(96,199)	(59,058)
Net cash used in investing activities	(50,088)	(23,128)
Cash flows from financing activities:		
Earn-out payments for related party contingent consideration	(6,834)	(15,497)
Royalty payments for related party payable	(1,117)	(2,158)
Repayment of debt	—	(4,904)
Reimbursement of conditional grants	(61)	(681)
Cash proceeds from issuance of ordinary shares and warrants	—	6,990
Net cash used in financing activities	(8,012)	(16,250)
Effect of exchange rate changes on cash and cash equivalents	656	(2,236)
Net increase (decrease) in cash and cash equivalents	(46,284)	16,281
Cash and cash equivalents at January 1	65,064	39,760
Cash and cash equivalents at September 30	$ 18,780	$ 56,041

See accompanying notes to condensed consolidated financial statements.

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 business model consisting of:

- an Unapproved Marketed Drugs ("UMDs") business with three approved products in the United States: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulphate injection). On May 2, 2016, the company announced that the U.S. Food and Drug Administration (FDA) had 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 on April 29, 2016. We began marketing Akovaz in a strength of 50mg/mL in the third quarter of 2016. We are also currently studying a fourth unapproved drug for possible submission for review by the FDA in early 2017. The UMD business was obtained through the acquisition of Éclat Pharmaceuticals, LLC ("Éclat"), on March 13, 2012;
- a branded pediatric specialty pharmaceutical business with three FDA approved products and one FDA approved medical device, acquired through the acquisition of FSC Holdings, LLC ("FSC") on February 5, 2016; and
- a technology business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. The products that are based on Flamel's proprietary drug delivery platforms target high-value solid and liquid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company is able to develop strong intellectual property positions and deliver meaningful patient benefits.

Flamel is headquartered in Lyon, France and has operations in St. Louis, Missouri, United States, and Dublin, Ireland.

Proposed Reincorporation as an Irish Public Limited Company (plc). At our shareholders meeting on August 10, 2016, our shareholders approved resolutions to change our jurisdiction of incorporation from France to Ireland. Based on such approval, we intend to give effect to this reincorporation on December 31, 2016 by merging with and into our wholly owned Irish corporate subsidiary, Avadel Pharmaceuticals Limited (the "Merger"). Prior to completing the Merger, Avadel Pharmaceuticals Limited will re-register as an Irish public limited company, or plc, and at the time of the Merger and thereafter our shareholders (and holders of our American Depositary Shares (ADSs)) will own shares (or ADSs, as applicable) in a company known as Avadel Pharmaceuticals plc. Our definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016 contains additional information about the proposed reincorporation.

Basis of Presentation. The Condensed Consolidated Balance Sheet as of December 31, 2015, which is primarily derived from the prior year 2015 audited consolidated financial statements, and the interim condensed 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 condensed 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 condensed consolidated financial statements include the accounts of the Company and its 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 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 their 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 shareholders' equity in Accumulated Other Comprehensive Loss. Assets and liabilities, excluding available-for-sale marketable securities, denominated in a currency other than the subsidiary's functional currency are translated to the subsidiary's functional currency at period end exchange rates with resulting gains and losses recognized in the condensed consolidated statements of loss. Available-for-sale marketable securities denominated in a currency other than the subsidiary's functional currency are translated to the subsidiary's functional currency at period end exchange rates with resulting gains and losses recognized in the condensed consolidated statements of other comprehensive loss.

Reclassifications and Immaterial Corrections of Prior Period Amounts. The accompanying condensed consolidated financial statements for prior periods contain certain reclassifications to conform to the presentation used in 2016. Additionally, the Company has identified certain immaterial errors related to prior reporting periods. The Company has assessed the impact of the errors on its prior period financial statements included in our December 31, 2015 Annual Report on Form 10-K and concluded that the errors were not material to those financial statements. Although the effect of the errors was not material to any previously issued financial statements, the cumulative effect of correcting the errors would have been material for the period ended September 30, 2016. Consequently, the Company has presented the effects of these errors and reclassifications on its prior period financial statements in the tables below. In future filings the financial statements for comparative periods affected by these errors and reclassifications will be revised.

The impact of the above errors and reclassifications on previously presented line items for each comparative period presented is as follows:

	Three Months Ended September 30, 2015					
		Correction of Immaterial Errors				
Consolidated Statement of Loss:	**As filed**	**(a)**	**(b)**	**(d)**	**(i)**	**As revised**
Product sales and services	$ 47,320	$ —	$ —	$ (1,200)	$ 1,193	$ 47,313
Total revenue	47,320	—	—	(1,200)	1,193	47,313
Operating income (loss)	(14,479)	—	—	(1,200)	1,193	(14,486)
Income (loss) before income taxes	(20,766)	—	—	(1,200)	1,193	(20,773)
Income tax provision	8,919	(863)	(751)	(420)	417	7,302
Net loss	(29,685)	863	751	(780)	776	(28,075)
Net loss per share - basic	$ (0.73)	$ 0.02	$ 0.02	$ (0.02)	$ 0.02	$ (0.69)
Net loss per share - diluted	$ (0.73)	$ 0.02	$ 0.02	$ (0.02)	$ 0.02	$ (0.69)

	Nine Months Ended September 30, 2015					
		Correction of Immaterial Errors				
Consolidated Statement of Loss:	**As filed**	**(a)**	**(b)**	**(c)**	**(d)**	**As revised**
Product sales and services	$ 129,841	$ —	$ —	$ (200)	$ (1,200)	$ 128,441
Total revenue	129,841	—	—	(200)	(1,200)	128,441
Operating income (loss)	(5,442)	—	—	(200)	(1,200)	(6,842)
Income (loss) before income taxes	(5,804)	—	—	(200)	(1,200)	(7,204)
Income tax provision	29,634	(2,021)	(2,607)	(70)	(420)	24,516
Net loss	(35,438)	2,021	2,607	(130)	(780)	(31,720)
Net loss per share - basic	$ (0.88)	$ 0.05	$ 0.06	$ —	$ (0.02)	$ (0.79)
Net loss per share - diluted	$ (0.88)	$ 0.05	$ 0.06	$ —	$ (0.02)	$ (0.79)

Consolidated Balance Sheet:	As filed	Correction of Immaterial Errors (a)	Correction of Immaterial Errors (e)	Correction of Immaterial Errors (f)	Reclassifications (g)	Reclassifications (h)	As revised
	December 31, 2015						
Accounts receivable	$ 6,978	$ —	$ —	$ —	$ 509	$ —	$ 7,487
Inventories	4,155	—	(489)	—	—	—	3,666
Prepaid expenses and other current assets	7,989	—	—	—	—	75	8,064
Total current assets	166,306	—	(489)	—	509	75	166,401
Other	158	—	—	—	—	9	167
Total assets	214,977	—	(489)	—	509	84	215,081
Current portion of long-term related party payable	28,614	—	—	(3,410)	—	—	25,204
Accounts payable	10,565	—	—	—	(5,517)	—	5,048
Accrued expenses	3,598	—	—	—	5,710	—	9,308
Income taxes	323	(227)	(171)	—	—	75	—
Total current liabilities	48,788	(227)	(171)	(3,410)	193	75	45,248
Long-term related party payable, less current portion	94,079	—	—	3,410	—	—	97,489
Deferred taxes	1,351	(1,360)	—	—	—	9	—
Other	2,210	—	—	—	316	—	2,526
Total liabilities	147,112	(1,587)	(171)	—	509	84	145,947
Accumulated deficit	(279,793)	1,587	(318)	—	—	—	(278,524)
Total shareholders' equity	67,865	1,587	(318)	—	—	—	69,134
Total liabilities and shareholders' equity	214,977	—	(489)	—	509	84	215,081

(a) Reflects the cumulative 2015 correction of $1,587 of income tax benefits related to the deductibility of the U.S. Internal Revenue Code Section 483 imputed interest on contingent consideration liabilities which should have been recorded in prior periods ($866, $292, $863 and ($434) in the first, second, third and fourth quarters of 2015, respectively).

(b) Reflects the correction of $2,607 of income tax benefits from stock-based compensation and certain other items which were originally recorded in the fourth quarter of 2015 but should have been recorded in prior periods ($360 in 2012, $333 in 2013, $(693) in 2014, and $830, $1,026 and $751 in the first, second and third quarters of 2015, respectively). As these items were originally corrected in the fourth quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

(c) Reflects the correction of a $200 overstatement of revenue in the first quarter of 2015 resulting from errors in certain estimates of ending inventory amounts at our wholesalers which were originally corrected in the first quarter of 2015 but should have been recorded in the fourth quarter of 2014. As this item was originally corrected in the first quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

(d) Reflects the correction of a $1,200 understatement in the third quarter of 2015 of the gross to net revenue reserves with respect to the Company’s customer rebate calculations. As this item was originally corrected in the fourth quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

(e) Reflects the correction of a $489 error in the Company’s inventory obsolescence reserve accrual and expense which was originally recorded in the first quarter of 2016 but should have been recorded in the fourth quarter of 2015.

(f) Reflects the correction of a balance sheet classification error which overstated the current portion of the long-term related party payable by $3,410.

(g) Reflects revisions to the presentation of certain gross to net revenue reserves which were previously included in accounts payable and are now included in accrued expenses.

(h) Reflects balance sheet reclassifications required to properly net the accrued income tax and deferred income tax amounts within the balance sheet as a result of the adjustments made in items (a) through (g) above.

(i) Reflects the correction of a $1,193 understatement in the second quarter of 2015 of the gross to net revenue reserves with respect to estimates for product returns as a result of improper reconciliation to revenue data communicated by service providers. As this item was originally corrected in the third quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

In addition to the specific amounts identified within the tables above, the Company also changed the names of the previously-reported "Interest expense – changes in fair value of related party financing related contingent consideration" line on the condensed consolidated statement of income (loss) to "Other expense – changes in fair value of related party payable", and the previously-reported "Long-term related party contingent consideration payable" line on the condensed consolidated balance sheet to "Long-term related party payable" to better reflect the underlying nature of certain royalty agreements in prior periods.

While the balance sheet revisions and reclassifications noted in the tables above impact their corresponding captions within the cash flows provided by (used in) operating activities section of the Company's consolidated statements of cash flows in each period of 2015, there was no impact to the total net cash provided by (used in) operating activities in any of these periods.

Revenue. Revenue includes sales of pharmaceutical products, amortization of licensing fees, and if any, milestone payments for R&D achievements.

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. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

For generic products and branded products sold in mature markets where the ultimate net selling price to customer is estimable, the Company recognizes revenues upon shipment to the wholesaler. 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. As part of the third quarter 2016 launch of Akovaz, the Company determined that sufficient data was available to determine the ultimate net selling price to the customer and therefore recognized revenue upon shipment to its wholesaler customers.

Prior to the second quarter 2016, the Company did not have sufficient historical data to estimate certain revenue deductions. As such, it could not accurately estimate the ultimate net selling price of its Éclat portfolio of products and as a result delayed revenue recognition until the wholesaler sold the product through to its customers.

During the second quarter of 2016, the Company determined that it has sufficient evidence, history, data and internal controls to estimate the ultimate selling price of its products upon shipment from its warehouse to its customers, the wholesalers. Accordingly, it discontinued the sell through revenue approach and now recognizes revenue once the product is shipped from its warehouse. As a result of this change in accounting estimate, the Company recognized $5,981 in additional revenue, or $0.05 in additional diluted net earnings (loss) per share, for the nine months ended September 30, 2016 that previously would have been deferred until sold by the wholesalers to the hospitals.

License and Research Revenue

The Company's license and research revenues consist of fees and milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over our projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. As of September 30, 2016, the Company has not recognized any revenue from milestone payments.

NOTE 2 : Newly Issued Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-15, *"Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*." ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the Company for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. ASU 2016-15 should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of ASU 2016-15 on its consolidated financial statements.

In May 2014, the FASB issued 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. Through May 2016, the FASB issued ASU 2016-08 "*Principal versus Agent Considerations (Reporting Revenue Gross versus Net),"* ASU 2016-10 "*Identifying Performance Obligations and Licensing,"* and ASU 2016-12, "*Narrow-Scope Improvements and Practical Expedients,"* 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 condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09 "*Improvements to Employee Share-Based Payment Accounting"* which amends Accounting Standards Codification ("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 does not believe this standard will materially impact its condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 "*Lease*s" 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 condensed consolidated financial statements.

In September 2015, the FASB issued ASU 2015-16 "*Business Combinations*" which requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This ASU is effective for interim and annual reporting periods beginning after December 15, 2016, with the option to early adopt for financial statements that have not been issued. The Company early adopted the provisions of ASU 2015-16 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. The new standard is to be applied prospectively and early adoption is permitted. The Company does not expect ASU 2015-11 to have a material impact on its condensed 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:

Marketable Securities:	September 30, 2016	December 31, 2015
Value at cost	$ 131,147	$ 81,395
Gross unrealized holding gains	805	15
Gross unrealized holding losses	(1,065)	(1,672)
Fair value	$ 130,887	$ 79,738

NOTE 4 : Inventories

The principal categories of inventories at September 30, 2016 and December 31, 2015 are as follows:

Inventory:	September 30, 2016	December 31, 2015
Finished goods	$ 2,410	$ 2,545
Raw materials	1,499	1,121
Total	$ 3,909	$ 3,666

NOTE 5 : Acquisitions

On February 5, 2016, the Company completed its acquisition of FSC, previously a Charlotte, North Carolina-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 condensed consolidated financial statements from the date of acquisition. Total consideration to acquire FSC is estimated to be $22,228, and was funded with a combination of the following, partially offset by $467 as a result of a net working capital settlement from the seller:

- $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.
- $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 items is reported in related party payable within the Company's condensed consolidated balance sheet, and is further disclosed at Note 7 – Long-Term Related Party Payable.

The Company determined a preliminary purchase price allocation as noted in the following table. This preliminary allocation could change as the Company completes its final accounting for the acquisition, which may include adjustments to the items noted below. The preliminary fair values assigned to the acquired assets and liabilities have been recognized as follows:

Assigned Fair Value:	2016 Preliminary
Accounts receivable	$ 825
Inventories	2,315
Prepaid expenses and other current assets	1,712
Goodwill	643
Intangible assets:	
Acquired product marketing rights	16,200
Acquired developed technology	4,400
Other assets	277
Accounts payable and other current liabilities	(4,144)
Total	$ 22,228

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 were not material for the three and nine month periods ended September 30, 2016. The useful lives on FSC acquired intangible assets range from seven to ten years.

After its acquisition on February 5, 2016, FSC contributed $389 and $3,026 to the Company's net sales for the three and nine month periods ended September 30, 2016, respectively. FSC incurred a loss of $4,508 and $8,997 for the three and nine month periods ended September 30, 2016, respectively.

Had the FSC acquisition been completed as of the beginning of 2015, the Company's unaudited pro forma net sales and net loss for the nine months ended September 30, 2016 and 2015 would have been as follows:

Pro Forma Net Revenue and Losses	Nine Months Ended	
	September 30, 2016	September 30, 2015
Net revenues	$ 107,636	$ 132,318
Net loss	(47,024)	(40,724)

NOTE 6 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at September 30, 2016 and December 31, 2015 are as follows:

	September 30, 2016			December 31, 2015		
	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets:						
Acquired developed technology - Bloxiverz	$ 35,248	$ (32,311)	$ 2,937	$ 35,248	$ (23,498)	$ 11,750
Acquired developed technology - Vazculep	12,061	(8,597)	3,464	12,061	(7,986)	4,075
Acquired developed technology - Flexichamber	4,400	(293)	4,107	—	—	—
Acquired product marketing rights	16,200	(1,200)	15,000	—	—	—
Total amortizable intangible assets	$ 67,909	$ (42,401)	$ 25,508	$ 47,309	$ (31,484)	$ 15,825
Unamortizable intangible assets:						
Goodwill	$ 19,134	$ —	$ 19,134	$ 18,491	$ —	$ 18,491
Total unamortizable intangible assets	$ 19,134	$ —	$ 19,134	$ 18,491	$ —	$ 18,491

The Company recorded amortization expense related to amortizable intangible assets of $3,702 and $3,141 for the three months ended September 30, 2016 and 2015, respectively. The Company recorded amortization expense related to amortizable intangible assets of $10,918 and $9,423 for the nine months ended September 30, 2016 and 2015, respectively. Accumulated amortization in the above tables includes an impairment charge of $7,171 which was recognized during the year ended December 31, 2012 relative to the "Acquired developed technology – Vazculep" intangible asset.

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
Total	$ 26,840

The change in net goodwill during the nine months ended September 30, 2016 is as follows:

Goodwill:	
Balance, December 31, 2015	$ 18,491
Impact of FSC acquisition	643
Balance, September 30, 2016	$ 19,134

NOTE 7 : Long-Term Related Party Payable

Long-term related party payable and related activity are reported at fair value and consist of the following at September 30, 2016 and June 30, 2016:

		Activity during the Three Months Ended September 30, 2016				
				Changes in Fair Value of Related Party Payable		
	Balance, June 30, 2016	**Additions**	**Payments to Related Parties**	**Operating Expense**	**Other Expense**	**Balance, September 30, 2016**
Acquisition-related contingent consideration:						
Warrants - Éclat Pharmaceuticals (a)	$ 15,462	$ —	$ —	$ 2,058	$ —	$ 17,520
Earn-out payments - Éclat Pharmaceuticals (b)	114,614	—	(6,719)	19,720	—	127,615
Royalty agreement - FSC (c)	6,505	—	(261)	(930)	—	5,314
Financing-related:						
Royalty agreement - Deerfield (d)	9,440	—	(630)	—	1,237	10,047
Royalty agreement - Broadfin (e)	4,500	—	(301)	—	590	4,789
Long-term liability - FSC (f)	15,000	—	—	—	—	15,000
Total related party payable	165,521	$ —	$ (7,911)	$ 20,848	$ 1,827	180,285
Less: Current portion	(29,500)					(33,359)
Total long-term related party payable	$ 136,021					$ 146,926

Long-term related party payable and related activity are reported at fair value and consist of the following at September 30, 2016 and December 31, 2015:

		Activity during the Nine Months Ended September 30, 2016				
				Changes in Fair Value of Related Party Payable		
	Balance, December 31, 2015	Additions	Payments to Related Parties	Operating Expense	Other Expense	Balance, September 30, 2016
Acquisition-related contingent consideration:						
Warrants - Éclat Pharmaceuticals (a)	$ 20,617	$ —	$ —	$ (3,097)	$ —	$ 17,520
Earn-out payments - Éclat Pharmaceuticals (b)	90,468	—	(20,934)	58,081	—	127,615
Royalty agreement - FSC (c)	—	7,695	(386)	(1,995)	—	5,314
Financing-related:						
Royalty agreement - Deerfield (d)	7,862	—	(1,968)	—	4,153	10,047
Royalty agreement - Broadfin (e)	3,746	—	(939)	—	1,982	4,789
Long-term liability - FSC (f)	—	15,000	—	—	—	15,000
Total related party payable	122,693	$ 22,695	$ (24,227)	$ 52,989	$ 6,135	180,285
Less: Current portion	(25,204)					(33,359)
Total long-term related party payable	$ 97,489					$ 146,926

(a) As part of the consideration for the Company's acquisition of Éclat on March 13, 2012, the Company issued two warrants to a related party 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 September 30:

Assumptions for the Warrant Valuation	September 30, 2016	September 30, 2015
Stock price	$ 12.40	$ 16.31
Weighted average exercise price per share	8.63	8.63
Expected term (years)	1.5	2.5
Expected volatility	58.40%	64.87%
Risk-free interest rate	0.68%	0.78%
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 represents the remaining life of the warrants at the balance sheet date.

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 September 30, 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) 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. 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. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity.

(c) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part included a commitment 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.

(d) As part of a February 2013 debt financing transaction conducted with Deerfield, 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 products until December 31, 2024.

(e) 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 products until December 31, 2024.

(f) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part consists of payments totaling $1,050 annually for five years with a final payment in January 2021 of $15,000.

At September 30, 2016, the fair value of each related party payable listed 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 and FSC products using an appropriate risk-adjusted discount rate ranging from 15% to 32%. 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 contingent consideration payable, resulting primarily from management's revision of key assumptions, will be recorded in the 'Changes in fair value of related party contingent consideration' line within the Company's condensed consolidated statements of loss.

The Company has chosen to make a fair value election pursuant to ASC 825, "Financial Instruments" for its royalty agreements detailed in items (d) and (e) above. These financing-related liabilities are recorded at fair market value on the condensed consolidated balance sheets and the periodic change in fair market value is recorded as a component of "Other expense – change in fair value of related party payable" on the condensed consolidated statements of loss.

NOTE 8 : Income Taxes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
United States	$ (6,814)	$ (9,581)	$ 4,948	$ 11,192
France	(6,244)	(5,568)	(15,333)	3,545
Ireland	(3,485)	(5,624)	(17,413)	(21,941)
Total loss before income taxes	$ (16,543)	$ (20,773)	$ (27,798)	$ (7,204)

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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Statutory tax rate	33.3 %	33.3 %	33.3 %	33.3 %
International tax rates differential	(3.6)%	(4.8)%	(13.3)%	(66.0)%
Valuation allowance on net operating losses	(2.0)%	10.2 %	(15.3)%	24.8 %
Nondeductible contingent consideration	(38.9)%	(67.9)%	(62.0)%	(367.0)%
Nondeductible stock-based compensation	(4.8)%	1.7 %	(4.4)%	54.6 %
Deferred charge from IP transfer	(1.5)%	(2.7)%	(2.7)%	(8.8)%
State and local income taxes	(1.7)%	(1.3)%	(2.7)%	(7.1)%
Other	(1.7)%	(3.7)%	1.6 %	(4.1)%
Effective income tax rate	(20.9)%	(35.2)%	(65.5)%	(340.3)%

Income tax benefit - at statutory tax rate	$ (5,509)	$ (6,917)	$ (9,257)	$ (2,399)
International tax rates differential	591	1,006	3,706	4,754
Valuation allowance on net operating losses	339	(2,116)	4,252	(1,784)
Nondeductible contingent consideration	6,436	14,109	17,236	26,438
Nondeductible stock-based compensation	788	(357)	1,222	(3,936)
Deferred charge from IP transfer	246	568	739	637
State and local income taxes	280	260	757	515
Other	280	749	(443)	291
Income tax provision - at effective income tax rate	$ 3,451	$ 7,302	$ 18,212	$ 24,516

The income tax provision for the three months ended September 30, 2016 and 2015 was $3,451 and $7,302, respectively. The decrease in the income tax provision for the three months ended September 30, 2016 is primarily the result of a decrease in the amount of nondeductible contingent consideration when compared to the same period in 2015. The decrease in the income tax provision for the three months ended September 30, 2016 would have been larger, but release of $3,360 in valuation allowances recorded in the same period in 2015 did not repeat in 2016.

The income tax provision for the nine months ended September 30, 2016 and 2015 was $18,212 and $24,516. The decrease in the income tax provision for the nine months ended September 30, 2016 is primarily the result of a decrease in the amount of nondeductible contingent consideration and decreases in the amount of pre-tax income recorded in the United States and France, when compared to the same period in 2015. These benefits were partially offset by an increase of $3,343 in valuation allowances recorded against net operating losses during the nine months ended September 30, 2016.

NOTE 9 : Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	**September 30, 2016**	**December 31, 2015**
Valued-added tax recoverable	$ 305	$ 1,099
Prepaid expenses	4,456	2,921
Advance to suppliers and other current assets	1,603	518
Income tax receivable	2,519	3,526
Total	$ 8,883	$ 8,064

Other Non-Current Assets:	September 30, 2016	December 31, 2015
Deferred tax assets	$ 6,715	$ —
Other	105	167
Total	$ 6,820	$ 167

Accrued Expenses:	September 30, 2016	December 31, 2015
Compensation	$ 2,797	$ 1,888
Social charges	1,556	1,710
Customer allowances	8,094	5,710
Other	585	—
Total	$ 13,032	$ 9,308

Other Current Liabilities:	September 30, 2016	December 31, 2015
Valued-added tax payable	$ 91	$ —
Other	336	133
Total	$ 427	$ 133

Other Non-Current Liabilities:	September 30, 2016	December 31, 2015
Provision for retirement indemnity	$ 2,324	$ 2,170
Customer allowances	1,556	—
Other	427	356
Total	$ 4,307	$ 2,526

NOTE 10 : Net Loss Per Share

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

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

Loss Per Share	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net loss	$ (19,994)	$ (28,075)	$ (46,010)	$ (31,720)
Weighted average shares:				
Basic shares	41,241	40,625	41,241	40,397
Effect of dilutive securities—options and warrants outstanding	—	—	—	—
Diluted shares	41,241	40,625	41,241	40,397
Net loss per share - basic	$ (0.48)	$ (0.69)	$ (1.12)	$ (0.79)
Net loss per share - diluted	$ (0.48)	$ (0.69)	$ (1.12)	$ (0.79)

Potential common shares of 6,860 and 6,088 were excluded from the calculation of weighted average shares for the three and nine months ended September 30, 2016 and 2015, respectively, because their effect was considered to be anti-dilutive.

NOTE 11 : Comprehensive Income (Loss)

The following table shows the components of accumulated other comprehensive loss for the three and nine months ended September 30, 2016 and 2015, net of tax effects:

Accumulated Other Comprehensive Loss	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Foreign currency translation adjustment:				
Beginning balance	$ (19,952)	$ (18,612)	$ (22,312)	$ (7,225)
Net other comprehensive (loss) income	1,567	102	3,927	(11,285)
Balance at September 30	$ (18,385)	$ (18,510)	$ (18,385)	$ (18,510)
Unrealized gain (loss) on marketable securities, net				
Beginning balance	$ 1,102	$ (198)	$ (345)	$ (198)
Net other comprehensive (loss) income, net of $152, ($9), ($49), ($9) tax, respectively	(2,405)	(365)	(958)	(365)
Balance at September 30	$ (1,303)	$ (563)	$ (1,303)	$ (563)
Accumulated other comprehensive loss at September 30	$ (19,688)	$ (19,073)	$ (19,688)	$ (19,073)

The effect on the Company’s condensed consolidated financial statements of amounts reclassified out of accumulated other comprehensive loss was immaterial for all periods presented.

NOTE 12 : Shareholders' Equity

The following table presents a reconciliation of the Company's beginning and ending balances in shareholders' equity for the nine months ended September 30, 2016:

Shareholders' Equity	Nine Months Ended September 30, 2016
Shareholders' equity - January 1	$ 69,134
Net loss	(46,010)
Other comprehensive income	2,969
Subscription of warrants	199
Stock-based compensation expense	10,541
Shareholders' equity - September 30	$ 36,833

NOTE 13 : Company Operations by Product

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:

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

NOTE 14 : Commitments and Contingencies

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 September 30, 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 condensed 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 Related Party Payable, to the Company's condensed 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 condensed 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 quarterly 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'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 currently able to self-fund the development of most product development opportunities. Flamel has a business model consisting of:

- an Unapproved Marketed Drugs ("UMDs") business with three approved products in the United States: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulphate injection). On May 2, 2016, the company announced that the U.S. Food and Drug Administration (FDA) had 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 on April 29, 2016. We began marketing Akovaz in a strength of 50mg/mL in the third quarter of 2016. We are also currently studying a fourth unapproved drug for possible submission for review by the FDA in early 2017. The UMD business was obtained through the acquisition of Éclat on March 13, 2012;
- a branded pediatric specialty pharmaceutical business, with three FDA approved products and one FDA approved medical device, acquired through the acquisition of FSC on February 5, 2016; and
- a technology business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. The products that are based on Flamel's proprietary drug delivery platforms target high-value solid and liquid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company is able to develop strong intellectual property positions and deliver meaningful patient benefits.

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 derives a majority of its sales and cash flow from its UMD products. During the three and nine months ended September 30, 2016 the Company generated $30,499 and $100,693 of sales from the UMD products compared to $46,848 and $126,831 in the same period of 2015, respectively.

    - The first UMD product, Bloxiverz, which had sales of $15,591 and $65,958 for the three and nine months ended September 30, 2016, respectively, was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S.

    - The second UMD product, Vazculep, which had sales of $9,340 and $29,167 for the three and nine months ended September 30, 2016, respectively, was approved by the FDA on September 27, 2014 and launched in October 2014 in the U.S.

    - The third UMD product, Akovaz, which had sales of $5,568 for the three and nine months ended September 30, 2016, respectively, was approved by the FDA April 29, 2016. The Company began marketing this product in August 2016.

Each of the above products is currently sold in the United States by Flamel's subsidiary Éclat. These products 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 E.U. 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 E.U. The revenues from these UMD products generate cash flow which we 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:

    - **Micropump®** is a microparticulate system that allows the development and marketing of modified and/or controlled release solid oral dosage formulations of drugs (Micropump®-carvedilol and Micropump®-aspirin formulations have been approved in the U.S. and in the E.U., respectively).

    - **LiquiTime®** allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or patients having issues swallowing tablets or capsules.

    - **Trigger Lock™** allows development of abuse-deterrent modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse.

    - **Medusa™** 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. In particular, the Company has started a Phase III trial, titled "A Double-blind, Randomized, Placebo Controlled, Two Arm Multi-center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy," On October 6, 2016 the Company announced that its Irish subsidiary, Flamel Ireland Holdings, has reached agreement with the U.S. Food and Drug Administration (FDA) for the design and planned analysis of the noted Phase III clinical trial of FT218, a once nightly formulation of sodium oxybate utilizing the Company's proprietary drug delivery platform, Micropump®. The agreement was reached through the

Special Protocol Assessment (SPA) process. A SPA is an acknowledgment by FDA that the design and planned analysis of the Company's pivotal clinical trial of FT218 adequately addresses the objectives necessary to support a regulatory submission.

The key elements of our pipeline strategy include:

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

- ***Inorganic growth through Acquisitions and/or Partnerships***: The Company maintains a strong balance sheet with substantial liquidity and no 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, a 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 U.S. 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 E.U. 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 political spotlight in the U.S. 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 U.S. 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 availability and cost of raising capital may create challenges for the Company if it were to have the need. Currently, the Company has no need to raise capital.

Highlights of our condensed consolidated results for the nine months ended September 30, 2016 are as follows:

- Revenue was $32,087 and $107,161 for the three and nine months ended September 30, 2016, respectively, compared to $47,313 and $128,441 in the same periods last year. This decrease was primarily the result of a decrease in Bloxiverz sales volume as a result of additional competition, partially offset by an increase in sales volume and pricing of Vazculep and additional Akovaz revenue which was launched in August 2016.
- Operating loss was $16,190 and $22,029 for the three and nine months ended September 30, 2016, respectively, compared to operating loss of $14,486 and $6,842 for the three and nine months ended September 30, 2015, respectively. These increases in operating losses were largely driven by a decrease in sales, increases in selling, general and administrative expenses in the current year, partially offset by lower changes in the fair value of contingent consideration.

- Net loss was $19,994 and $46,010 for the three and nine months ended September 30, 2016, respectively, compared to $28,075 and $31,720 in the same periods last year.
- Diluted net loss per share was $0.48 and $1.12 for the three and nine months ended September 30, 2016, respectively, compared to $0.69 and $0.79 in the same periods last year.
- Cash and marketable securities increased $4,865 to $149,667 from $144,802 at December 31, 2015.

Critical Accounting Estimates

The Company's condensed 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, with the exception of changes made to our revenue recognition policy disclosed below, during the nine months ended September 30, 2016.

Revenue. Revenue includes sales of pharmaceutical products, amortization of licensing fees, and, if any, milestone payments for R&D achievements.

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. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

For generic products and branded products sold in mature markets where the ultimate net selling price to customer is estimable, the Company recognizes revenues upon shipment to the wholesaler. 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. As part of the third quarter 2016 launch of Akovaz, the Company determined that sufficient data was available to determine the ultimate net selling price to the customer and therefore recognized revenue upon shipment to its wholesaler customers.

Prior to the second quarter 2016, the Company did not have sufficient historical data to estimate certain revenue deductions. As such, it could not accurately estimate the ultimate net selling price of its Éclat portfolio of products and as a result delayed revenue recognition until the wholesaler sold the product through to its customers.

During the second quarter of 2016, the Company determined that it has sufficient evidence, history, data and internal controls to estimate the ultimate selling price of its products upon shipment from its warehouse to its customers, the wholesalers. Accordingly, it discontinued the sell through revenue approach and now recognizes revenue once the product is shipped from its warehouse. As a result of this change in accounting estimate, the Company recognized $5,981 in additional revenue for the three and nine months ended September 30, 2016 that previously would have been deferred until sold by the wholesalers to the hospitals. The impact of this change is reflected as revenue in the Company's condensed consolidated statements of loss for the nine months ended September 30, 2016.

Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended September 30, 2016 and 2015, respectively:

			Three Months Ended *Increase / (Decrease)*	
	Three Months Ended September 30,		2016 vs. 2015	
Comparative Statements of Loss	**2016**	**2015**	**$**	**%**
Product sales and services	$ 31,340	$ 47,313	$ (15,973)	(33.8)%
License and research revenue	747	—	747	n/a
Total revenues	32,087	47,313	(15,226)	(32.2)%
Cost of products and services sold	2,844	2,087	757	36.3 %
Research and development expenses	8,143	7,221	922	12.8 %
Selling, general and administrative expenses	12,740	4,568	8,172	178.9 %
Intangible asset amortization	3,702	3,141	561	17.9 %
Changes in fair value of related party contingent consideration	20,848	44,782	(23,934)	(53.4)%
Total operating expenses	48,277	61,799	(13,522)	(21.9)%
Operating loss	(16,190)	(14,486)	(1,704)	(11.8)%
Investment income	490	197	293	148.7 %
Interest expense	(264)	—	(264)	n/a
Other expense - changes in fair value of related party payable	(1,828)	(6,644)	4,816	72.5 %
Foreign exchange gain	1,249	160	1,089	680.6 %
Loss before income taxes	(16,543)	(20,773)	4,230	20.4 %
Income tax provision	3,451	7,302	(3,851)	(52.7)%
Net loss	$ (19,994)	$ (28,075)	$ 8,081	28.8 %
Loss per share - diluted	$ (0.48)	$ (0.69)	$ 0.21	30.4 %

The following is a summary of our financial results (in thousands, except per share amounts) for the nine months ended September 30, 2016 and 2015, respectively:

Comparative Statements of Loss	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Product sales and services	$ 104,858	$ 128,441	$ (23,583)	(18.4)%
License and research revenue	2,303	—	2,303	n/a
Total revenues	107,161	128,441	(21,280)	(16.6)%
Cost of products and services sold	10,657	8,473	2,184	25.8 %
Research and development expenses	21,135	20,447	688	3.4 %
Selling, general and administrative expenses	33,491	14,904	18,587	124.7 %
Intangible asset amortization	10,918	9,423	1,495	15.9 %
Changes in fair value of related party contingent consideration	52,989	82,036	(29,047)	(35.4)%
Total operating expenses	129,190	135,283	(6,093)	(4.5)%
Operating loss	(22,029)	(6,842)	(15,187)	(222.0)%
Investment income	1,080	1,171	(91)	(7.8)%
Interest expense	(702)	—	(702)	n/a
Other expense - changes in fair value of related party payable	(6,135)	(9,629)	3,494	36.3 %
Foreign exchange (loss) gain	(12)	8,096	(8,108)	(100.1)%
Loss before income taxes	(27,798)	(7,204)	(20,594)	(285.9)%
Income tax provision	18,212	24,516	(6,304)	(25.7)%
Net loss	$ (46,010)	$ (31,720)	$ (14,290)	(45.1)%
Loss per share - diluted	$ (1.12)	$ (0.79)	$ (0.33)	(41.8)%

Revenues

The revenues for each of the Company's significant products for the three months ended September 30, 2016 were as follows:

Revenues:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Bloxiverz	$ 15,591	$ 41,243	$ (25,652)	(62.2)%
Vazculep	9,340	5,605	3,735	66.6 %
Akovaz	5,568	—	5,568	n/a
Other	841	465	376	80.9 %
Total product sales and services	31,340	47,313	(15,973)	(33.8)%
License and research revenue	747	—	747	n/a
Total revenues	$ 32,087	$ 47,313	$ (15,226)	(32.2)%

Product sales and services revenues were $31,340 for the three months ended September 30, 2016, compared to $47,313 for the same prior year period. Bloxiverz's revenue declined $25,652 quarter over quarter, primarily due to a loss of market share and net selling price driven largely by two new competitors that entered the market subsequent to the first quarter of 2015. Vazculep's revenue increased $3,735 quarter over quarter due primarily to slightly higher market share. The launch of Akovaz

in August 2016 contributed $5,568 to product sales for the three months ended September 30, 2016. The acquisition of FSC in February 2016 contributed $389 to product sales for the three months ended September 30, 2016.

License and research revenues increased $747 during the quarter ended September 30, 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.

The revenues for each of the Company's significant products for the nine months ended September 30, 2016 were as follows:

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2016 vs. 2015	
Revenues:	**2016**	**2015**	**$**	**%**
Bloxiverz	$ 65,958	$ 114,074	$ (48,116)	(42.2)%
Vazculep	29,167	12,757	16,410	128.6 %
Akovaz	5,568	—	5,568	n/a
Other	4,165	1,610	2,555	158.7 %
Total product sales and services	104,858	128,441	(23,583)	(18.4)%
License and research revenue	2,303	—	2,303	n/a
Total revenues	$ 107,161	$ 128,441	$ (21,280)	(16.6)%

Product sales and services revenues were $104,858 for the nine months ended September 30, 2016, compared to $128,441 for the same prior year period. Revenues for the nine months ended September 30, 2016 included $5,981 in additional revenue as a result of our change in accounting estimate as previously described under "Critical Accounting Estimates." Excluding the impact of this revenue change, total product sales and services for the nine months ended September 30, 2016 would have been $98,877, a decline of $29,564 when compared to the same period last year. Bloxiverz's revenue declined $48,116 when compared to the same period last year, primarily due to a $52,713 loss of market share and net selling price in Bloxiverz driven largely by two new competitors that entered the market subsequent to the first quarter of 2015, partially offset by an increase of $4,597 related to the change in revenue estimate noted above. Vazculep's revenue increased $16,410 when compared to the same period last year due primarily to higher market share resulting from its launch in late 2014, which was further increased by $1,384 related to the change in revenue estimate noted above. The launch of Akovaz in August 2016 contributed $5,568 to product sales for the nine months ended September 30, 2016. The acquisition of FSC in February 2016 contributed $3,026 in revenues for the nine months ended September 30, 2016.

License and research revenues increased $2,303 during the nine months ended September 30, 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)*	
	Three Months Ended September 30,		2016 vs. 2015	
Cost of Products and Services Sold:	**2016**	**2015**	**$**	**%**
Cost of products and services sold	$ 2,844	$ 2,087	$ 757	36.3%
Percentage of sales	8.9%	4.4%		

Cost of products and services sold increased $757 or 36.3% during the three months ended September 30, 2016 compared to the same prior year period primarily due to the consolidation of FSC which added approximately $1,648 in cost of products sold, offset partially by lower cost of products sold resulting from the lower product sales in our portfolio of products. As a percentage of sales, cost of products sold was higher than the prior year period due to unfavorable product mix, largely related to the acquisition of FSC and lower net selling prices in Bloxiverz.

Cost of Products and Services Sold:	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Cost of products and services sold	$ 10,657	$ 8,473	$ 2,184	25.8%
Percentage of sales	9.9%	6.6%		

Cost of products and services sold increased $2,184 or 25.8% during the nine months ended September 30, 2016 compared to the same prior year period primarily due to the consolidation of FSC which added approximately $3,734 in cost of products sold offset partially by lower cost of products sold resulting from the lower sales levels in our Éclat portfolio of products. As a percentage of sales, cost of products sold was higher than the prior year period due to unfavorable product mix, largely related to the acquisition of FSC and lower net selling prices in Bloxiverz.

Research and Development Expenses

Research and Development Expenses:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Research and development expenses	$ 8,143	$ 7,221	$ 922	12.8%
Percentage of sales	25.4%	15.3%		

Research and development expenses increased $922 or 12.8% during the three months ended September 30, 2016 as compared to the same period in 2015 primarily due to higher payroll and outside services costs related to feasibility studies and clinical programs primarily associated sodium oxybate.

Research and Development Expenses:	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Research and development expenses	$ 21,135	$ 20,447	$ 688	3.4%
Percentage of sales	19.7%	15.9%		

Research and development expenses increased $688 or 3.4% during the nine months ended September 30, 2016 as compared to the same prior year period primarily due to higher payroll and outside services costs related to feasibility studies and clinical programs primarily associated sodium oxybate.

Selling, General and Administrative Expenses

Selling, General and Administrative Expenses:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Selling, general and administrative expenses	$ 12,740	$ 4,568	$ 8,172	178.9%
Percentage of sales	39.7%	9.7%		

Selling, general and administrative expenses increased $8,172 or 178.9% during the three months ended September 30, 2016 as compared to the same prior year period primarily due to increases in payroll and benefit costs to reinforce the Company's management team and higher professional fees, including legal, tax and audit.

Selling, General and Administrative Expenses:	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Selling, general and administrative expenses	$ 33,491	$ 14,904	$ 18,587	124.7%
Percentage of sales	31.3%	11.6%		

Selling, general and administrative expenses increased $18,587 or 124.7% during the nine months ended September 30, 2016 as compared to the same prior year period primarily due to increases in payroll and benefit costs to reinforce the Company's management team and higher professional fees, including legal, tax and audit.

Intangible Asset Amortization

Intangibles Asset Amortization:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Intangible asset amortization	$ 3,702	$ 3,141	$ 561	17.9%
Percentage of sales	11.5%	6.6%		

Intangible asset amortization expense increased $561 or 17.9% during the three months ended September 30, 2016 as compared to the same prior year period due to the commencement of amortization related to the acquired intangible assets of FSC.

Intangibles Asset Amortization:	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Intangible asset amortization	$ 10,918	$ 9,423	$ 1,495	15.9%
Percentage of sales	10.2%	7.3%		

Intangible asset amortization expense increased $1,495 or 15.9% during the nine months ended September 30, 2016 as compared to the same prior year period due to the commencement of amortization related to the acquired intangible assets of FSC.

Changes in Fair Value of Related Party Contingent Consideration

Changes in Fair Value of Related Party Contingent Consideration:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Changes in fair value of related party contingent consideration	$ 20,848	$ 44,782	$ (23,934)	(53.4)%
Percentage of sales	65.0%	94.7%		

Changes in fair value of related party contingent consideration decreased $23,934 or 53.4% during the three months ended September 30, 2016 as compared to the same prior year period primarily due to changes in the underlying assumptions of the long-term Éclat product sales and gross profit forecasts associated with our acquisition-related long-term related party liabilities.

Changes in Fair Value of Related Party Contingent Consideration:	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Changes in fair value of related party contingent consideration	$ 52,989	$ 82,036	$ (29,047)	(35.4)%
Percentage of sales	49.4%	63.9%		

Changes in fair value of related party contingent consideration decreased $29,047 or 35.4% during the nine months ended September 30, 2016 as compared to the same prior year period primarily due to changes in the underlying assumptions of the long-term Éclat product sales and gross profit forecasts associated with our acquisition-related long-term related party liabilities.

Other Expense - Changes in Fair Value of Related Party Payable

Other Expense - Changes in Fair Value of Related Party Payable	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Changes in fair value of related party contingent consideration	$ (1,828)	$ (6,644)	$ 4,816	72.5%
Percentage of sales	(5.7)%	(14.0)%		

Changes in fair value of related party payable increased $4,816 or 72.5% during the three months ended September 30, 2016 as compared to the same prior year period primarily due to changes in the underlying assumptions of the long-term Éclat product sales and gross profit forecasts associated with our acquisition-related long-term related party liabilities.

Other Expense - Changes in Fair Value of Related Party Payable	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 $	Nine Months Ended Increase / (Decrease) 2016 vs. 2015 %
Changes in fair value of related party contingent consideration	$ (6,135)	$ (9,629)	$ 3,494	36.3%
Percentage of sales	(5.7)%	(7.5)%		

Changes in fair value of related party payable increased $3,494 or 36.3% during the nine months ended September 30, 2016 as compared to the same prior year period primarily due to changes in the underlying assumptions of the long-term Éclat product sales and gross profit forecasts associated with our acquisition-related long-term related party liabilities.

Income Taxes

Income Tax Provision:	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Three Months Ended Increase / (Decrease) 2016 vs. 2015 $	Three Months Ended Increase / (Decrease) 2016 vs. 2015 %
Income tax provision	$ 3,451	$ 7,302	$ (3,851)	(52.7)%
Percentage of income (loss) before income taxes	20.9%	35.2%		

The items accounting for the difference between the income tax provision computed at the French statutory rates and the Company's effective tax rate for the three months ended September 30, 2016 and 2015, are as follows:

	Three Months Ended September 30,	
	2016	2015
Statutory tax rate	33.3 %	33.3 %
International tax rates differential	(3.6)%	(4.8)%
Valuation allowance on net operating losses	(2.0)%	10.2 %
Nondeductible contingent consideration	(38.9)%	(67.9)%
Nondeductible stock-based compensation	(4.8)%	1.7 %
Deferred charge from IP transfer	—	(2.7)%
State and local income taxes	(1.7)%	(1.3)%
Other	(1.7)%	(3.7)%
Effective income tax rate	(20.9)%	(35.2)%

Income tax benefit - at statutory tax rate	$ (5,509)	$ (6,917)
International tax rates differential	591	1,006
Valuation allowance on net operating losses	339	(2,116)
Nondeductible contingent consideration	6,436	14,109
Nondeductible stock-based compensation	788	(357)
Deferred charge from IP transfer	246	568
State and local income taxes	280	260
Other	280	749
Income tax provision - at effective income tax rate	$ 3,451	$ 7,302

The income tax provision for the three months ended September 30, 2016 and 2015 was $3,451 and $7,302, respectively. The decrease in the income tax provision for the three months ended September 30, 2016 is primarily the result of a decrease in the amount of nondeductible contingent consideration when compared to the same period in 2015. The decrease in the income tax provision for the three months ended September 30, 2016 would have been larger, but release of $3,360 in valuation allowances recorded in the same period in 2015 did not repeat in 2016.

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2016 vs. 2015	
Income Tax Provision:	**2016**	**2015**	**$**	**%**
Income tax provision	$ 18,212	$ 24,516	$ (6,304)	(25.7)%
Percentage of income (loss) before income taxes	65.5%	340.3%		

The items accounting for the difference between the income tax provision computed at the French statutory rates and the Company's effective tax rate for the nine months ended September 30, 2016 and 2015, are as follows:

	Nine Months Ended September 30,	
	2016	**2015**
Statutory tax rate	33.3 %	33.3 %
International tax rates differential	(13.3)%	(66.0)%
Valuation allowance on net operating losses	(15.3)%	24.8 %
Nondeductible contingent consideration	(62.0)%	(367.0)%
Nondeductible stock-based compensation	(4.4)%	54.6 %
Deferred charge from IP transfer	(2.7)%	(8.8)%
State and local income taxes	(2.7)%	(7.1)%
Other	1.6 %	(4.1)%
Effective income tax rate	(65.5)%	(340.3)%

Income tax benefit - at statutory tax rate	$ (9,257)	$ (2,399)
International tax rates differential	3,706	4,754
Valuation allowance on net operating losses	4,252	(1,784)
Nondeductible contingent consideration	17,236	26,438
Nondeductible stock-based compensation	1,222	(3,936)
Deferred charge from IP transfer	739	637
State and local income taxes	757	515
Other	(443)	291
Income tax provision - at effective income tax rate	$ 18,212	$ 24,516

The income tax provision for the nine months ended September 30, 2016 and 2015 was $18,212 and $24,516. The decrease in the income tax provision for the nine months ended September 30, 2016 is primarily the result of a decrease in the amount of nondeductible contingent consideration and decreases in the amount of pre-tax income recorded in the United States and France, when compared to the same period in 2015. These benefits were partially offset by an increase of $3,343 in valuation allowances recorded against net operating losses during the nine months ended September 30, 2016.

Liquidity and Capital Resources

The Company's cash flows from operating, investing and financing activities, as reflected in the condensed consolidated statements of cash flows, are summarized in the following table:

			Nine Months Ended *Increase / (Decrease)*	
	Nine Months Ended September 30,		2016 vs. 2015	
Net cash provided by (used in):	**2016**	**2015**	**$**	**%**
Operating activities	$ 11,160	$ 57,895	$ (46,735)	(80.7)%
Investing activities	(50,088)	(23,128)	(26,960)	(116.6)%
Financing activities	(8,012)	(16,250)	8,238	50.7 %

Operating Activities

Net cash provided by operating activities of $11,160 for the nine months ended September 30, 2016 decreased $46,735 compared to the same prior year period. This decline in operating cash flow is primarily due to lower cash earnings largely driven from lower revenues for the nine months ended September 30, 2016 when compared to the same period last year. Additionally, contributing to the lower operating cash flows was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During the first half of 2016, the cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments in excess of the original fair value totaling $16,276 were classified within operating activities for the nine months ended September 30, 2016, compared to the same period in 2015 during which all such cash payments were classified as financing activities.

Investing Activities

Cash used in investing activities of $50,088 for the nine months ended September 30, 2016 increased $26,960 compared to the same prior year period. This increase was primarily driven by higher use of cash for net purchases of marketable securities of $49,716.

Financing Activities

Cash used in financing activities of $8,012 for the nine months ended September 30, 2016 decreased $8,238 compared to the same prior year period. The decrease in the usage of cash for financing activities was primarily related to lower earn out payments for related party contingent consideration. As noted in the discussion of cash flows from operating activities contributing to the lower uses of cash for financing activities was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During the first half of 2016, the cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments made before the Company exceeded the original fair value of the related liabilities are classified as financing activities and amounted to $7,951 for the nine months ended September 30, 2016 compared to $17,655 in the same period last year, during which all such cash payments were classified as financing activities. Additionally the Company made $4,904 in debt repayments during the nine months ended September 30, 2015. No such payments were made in 2016 as the related debt was repaid in full. Cash proceeds from the issuance of ordinary shares and warrants were $6,990 during the nine months ended September 30, 2015, which did not repeat during the nine months ended September 30, 2016.

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.

Proposed Reincorporation as an Irish Public Limited Company (plc)

At our shareholders meeting on August 10, 2016, our shareholders approved resolutions to change our jurisdiction of incorporation from France to Ireland. Based on such approval, we intend to give effect to this reincorporation on December 31, 2016 by merging with and into our wholly owned Irish corporate subsidiary, Avadel Pharmaceuticals Limited (the “Merger”). Prior to completing the Merger, Avadel Pharmaceuticals Limited will re-register as an Irish public limited company, or plc, and at the time of the

Merger and thereafter our shareholders (and holders of our American Depositary Shares (ADSs)) will own shares (or ADSs, as applicable) in a company known as Avadel Pharmaceuticals plc. Our definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016 contains additional information about the proposed reincorporation. The company continues to assess the impact of any potential tax consequences as a result of this intended reincorporation.

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 September 30, 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 condensed 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 Related Party Payable, to the Company's condensed 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 condensed 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. In addition, our marketable securities are subject to credit and market risk. Our investment policy specifies credit quality standards for our investments and limits the amount of credit and market risk 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 and as a result we are exposed to foreign currency exchange risk as the functional currency financial statements of our foreign subsidiaries are translated to U.S. dollars. The functional currency of each of our foreign subsidiaries is generally the local currency. 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 exchange gain (loss) in the condensed consolidated statements of loss. As of September 30, 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. The Company realized foreign exchange gain from transactional exposure of $1,249 for the three

months ended September 30, 2016 and foreign exchange loss from transactional exposure of $12 for the nine months ended September 30, 2016.

ITEM 4. 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 September 30, 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 as described in Item 9A in our Annual Report on Form 10-K as of December 31, 2015.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the three months ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for the Company's continued implementation of action plans to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures under the leadership of 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. While we have made progress in all areas of our remediation plan relating to the material weaknesses described in our Form 10-K as of December 31, 2015, we specifically focused on the revenue recognition process and the strengthening of the Finance team. In the area of revenue recognition, we assessed and enhanced the design and documentation of our revenue controls and developed a plan for testing their operating effectiveness. Further, we continue to add to our finance staff, which included hiring a senior tax professional with the appropriate amount of experience related to accounting for income taxes and additional employees responsible for financial reporting. Additionally, we implemented a new information technology system and designed more robust and effective general computer access controls and developed a plan for testing their operating effectiveness. Our Audit Committee contributes to establishing the appropriate tone at the top by emphasizing to senior leadership the importance of a sound internal control environment and also by approving our remediation plan and the subsequent monitoring of its progress.

PART II – OTHER INFORMATION

ITEM 1.LEGAL PROCEEDINGS.

The information contained in Note 14 – Commitments and Contingencies to the Company's condensed 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.

Exhibit No.	Description
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)

Date: November 14, 2016

By: /s/ Michael F. Kanan

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

Exhibit 31.1

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: November 14, 2016

/s/ Michael S. Anderson

Michael S. Anderson

Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: November 14, 2016

/s/ Michael F. Kanan

Michael F. Kanan

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

Exhibit 32.1

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 September 30, 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: November 14, 2016

/s/ Michael S. Anderson

Michael S. Anderson
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 September 30, 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: November 14, 2016

/s/ Michael F. Kanan

Michael F. Kanan

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