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

FORM 20-F/A

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

OR

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

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

Date of event requiring this shell company report_____
For the transition period from_____ to _____

Commission file number: 000-28508

Flamel Technologies S.A.

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Republic of France

(Jurisdiction of incorporation or organization)

Parc Club du Moulin à Vent
33, avenue du Docteur Georges Levy
69693 Vénissieux Cedex France

(Address of principal executive offices)

Siân Crouzet
Principal Financial Officer
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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of Exchange on which Registered
Ordinary Shares, nominal value 0.122 Euros per share, represented by American Depositary Shares (as evidenced by American Depositary Receipts), each representing one Ordinary Share	**NASDAQ Global Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

25,612,550 Ordinary Shares, nominal value 0.122 Euros per Ordinary Share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒
International Financial Reporting Standards as issued by the International Accounting Standards Board ☐
Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

TABLE OF CONTENTS

As used herein, references to the Company, “we,” ‘us,” “our,” the Registrant and Flamel refer to Flamel Technologies S.A. and its subsidiaries on a consolidated basis, unless the context indicates otherwise. References to Shares herein refer to (i) the Ordinary Shares of Flamel, nominal value 0.122 Euros per Ordinary Share (the “Ordinary Shares”) and (ii) Flamel’s American Depositary Shares, each of which represents one Ordinary Share (“ADSs”). The ADSs are evidenced by American Depositary Receipts (“ADRs”). Ordinary Shares and ADSs are referred to herein as “Shares.”

The following product or drug delivery platforms designations are trademarks of the Company: Flamel Technologies®, Bloxiverz™, Micropump®, LiquiTime®, Trigger Lock™, Medusa™, DeliVax®, and Vazculep™.

Flamel publishes its financial statements in U.S. dollars. In this annual report, references to “dollars” or “$” are to U.S. dollars and references to “Euros” or “EUR” or “€” are to the currency of the European Union as used in the Republic of France. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in dollars. Solely for the convenience of the reader, this annual report contains translations of certain Euro amounts into dollars at specified rates. See “Item 3. *Key Information - Exchange Rates*” for information regarding the rates of exchange between the Euro and the dollar in each of the previous five years.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Although we believe that our expectations 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 development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations include, among others, those specified in "Risk Factors" beginning on page 2, including:

- we depend on a small number of customers for the majority of our revenues related to our drug delivery platforms and drug products (e.g. Coreg CR® microparticles and Éclat products), and the loss of any one of these customers could reduce our revenues significantly.

- our focus on (i) the development and licensing of versatile, proprietary drug delivery platforms, (ii) the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat Pharmaceuticals, LLC, or Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S., rather than primarily on collaborative agreements with pharmaceutical and biotechnology companies, may not be successful.

- our current revenues from our drug delivery business primarily depend on third party pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery platforms.

- we must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.

- we currently depend upon a single site to manufacture some of our drug products and our drug delivery product, Coreg CR® microparticles, and any interruption of operations could have a material adverse effect on our business.

- we depend upon a limited number of suppliers for certain raw materials used in our drug delivery technologies and for the manufacture of certain drug products in development, and any failure to deliver sufficient quantities of supplies of these raw materials or product could interrupt our production process and could have a material adverse effect on our business.

- if our competitors develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.

- we may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of late-stage products pipeline products, and any new and complementary businesses, products and technologies we may acquire in the future.

- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms and products could become obsolete or noncompetitive.

- if we cannot adequately protect our drug delivery platforms and proprietary information, we may be unable to sustain a competitive advantage.

- even if we and our partners obtain necessary regulatory approvals, our products and drug delivery platforms, or our partners' products (incorporating our platforms) may not gain market acceptance.

- our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of intellectual property and may adversely affect the commercial success of the products developed under those partnerships.

- third parties may claim, that our drug delivery platforms, or the products in which they are used, or our other products infringe on their rights and we may incur significant costs resolving these claims or may not be able to resolve.

- if we or our third party collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

- if our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.

- healthcare reform and restrictions on reimbursements may limit our financial returns.

- fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may clause fluctuations in our financial results.

- products that incorporate our drug delivery platforms and our late-stage development products acquired from Éclat and other products we may develop are subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.

- commercial products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology companies partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.

- we are subject to U.S. federal and state laws prohibiting “kickbacks” and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, causing harm to our business.

- regulatory reforms may adversely affect our ability to sell our products or technologies drug delivery platforms profitably.

- we and companies to which we have licensed our drug delivery platforms and subcontractors we engage for services related to our inthe development of our products are subject to extensive regulation by the FDA and other regulatory authorities. Their failure to meet these regulatory requirements could adversely affect our business.

- we may face product liability claims related to participation in clinical trials or the use or misuse of our products or third party products that incorporate our drug delivery platforms.

- if we use hazardous biological and/or chemical materials in a manner that causes injury, we may be liable for significant damages.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements. Statements in this annual report including those set forth above and in “Risk Factors” in this report, describe factors, among others, that could contribute to or cause such differences.

PART I

ITEM 1. Identity of Directors, Senior Management and Advisers

Not applicable.

ITEM 2. Offer Statistics and Expected Timetable

Not applicable.

ITEM 3. Key Information

Selected Financial Data

The selected consolidated financial data as of and for each of the five years ended December 31, 2013 are derived from the Consolidated Financial Statements of the Company, which have been prepared in accordance with U.S. GAAP and audited by an independent registered accounting firm with the Public Company Accounting Oversight Board (United States). The selected consolidated financial data of the Company set forth below are qualified by reference to, and should be read in conjunction with, "Item 5. *Operating and Financial Review and Prospects*" and the Consolidated Financial Statements and the Notes related thereto appearing elsewhere in this annual report.

Statement of Operations Data[1]:

	2009	2010	2011	2012	2013
Revenues	42,118	37,094	32,600	26,101	22,443
Cost and Expenses	(53,871)	(46,934)	(42,183)	(34,464)	(72,476)
Income (Loss) from Operations	(11,753)	(9,840)	(9,583)	(8,363)	(50,033)
Interest and foreign exchange gain (loss), net	342	549	867	331	(4,635)
Other income	(28)	525	134	102	573
Income (loss) before income tax	(11,439)	(8,766)	(8,582)	(7,930)	(54,095)
Income tax benefit (expense)	-	(209)	(192)	4,702	11,170
Net income (loss)	(11,439)	(8,975)	(8,774)	(3,228)	(42,925)
Income (Loss) from Operations per ordinary share	$ (0.49)	$ (0.40)	$ (0.39)	$ (0.33)	(1.97)
Basic earnings (loss) per ordinary share.	$ (0.47)	$ (0.37)	$ (0.36)	($ 0.13)	(1.69)
Diluted earnings (loss) per ordinary share	$ (0.47)	$ (0.37)	$ (0.36)	($ 0.13)	(1.69)
Basic weighted average number of shares outstanding (in thousands).	24,225	24,411	24,669	25,135	25,449
Diluted weighted average number of shares outstanding (in thousands)	24,225	24,411	24,669	25,135	25,449
Dividends per share	-	-	-	-	

[1] in thousands of U.S. dollars, except share and per share data.

Balance Sheet Data[2]:

	2009	2010	2011	2012	2013
Cash, Cash equivalents & marketable securities	44,068	31,344	24,491	9,155	7,037
Working capital**[3]**	44,185	25,941	18,338	10,726	(6,972)
Total assets	94,296	74,614	69,402	117,311	116,252
Long term liabilities (excluding deferred revenues)	20,744	15,641	19,763	72,267	85,169
Shareholders' equity	44,863	36,305	29,794	30,504	(9,512)

[2] in thousands of U.S. dollars

[3] working capital is calculated by subtracting current liabilities from current assets

Exchange Rates:

Flamel publishes its financial statements in U.S. dollars. The reporting currency of the Company and its wholly-owned subsidiaries is the U.S. dollar as permitted by the SEC for a foreign private issuer (S-X Rule 3-20(a)). All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiary whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Currently a significant portion of the Company's expenses are denominated in Euros. For information regarding the effects of currency fluctuations on the Company's results, see "Item 5. *Operating and Financial Review and Prospects*."

The following table sets forth the high, low and average exchange rates for the Euro against the U.S. dollar in each of the last five years and in each of the previous six months.

Year Ended December 31, Euro to U.S. Dollar:	**High**	**Low**	**Average Rate [1]**
2013	1.3814	1.2768	1.3282
2012	1.3454	1.2089	1.2856
2011	1.4882	1.2889	1.3917
2010	1.4563	1.1942	1.3268
2009	1.512	1.2555	1.3933

Previous Six Months, Euro to U.S. Dollar:	High	Low	Average Rate[1]
March 2014	1.3942	1.3732	1.3823
February 2014	1.3813	1.3495	1.3659
January 2014	1.3687	1.3516	1.3610
December 2013	1.3814	1.3536	1.3704
November 2013	1.3611	1.3365	1.3493
October 2013	1.3805	1.3493	1.3635

[1] Annual totals represent the average of the noon buying rates for Euros of each business day during the relevant period, according to the "Banque de France". Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month according to the "Banque de France".

The exchange rate for the Euro against the U.S. dollar as of April 29, 2014, was $1.3826 to € 1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into dollars at any of the exchange rates referred to herein as of a given date.

Risk Factors

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, and the trading price of our securities could decline. As a result, you should consider all of the following risks, together with all of the other information in this Annual Report on Form 20-F, before making an investment decision regarding our securities.

Risks Relating to Our Business and Industry

We depend on a small number of customers for the majority of the revenues related to our drug delivery platforms, and the loss of any one of these customers could reduce our revenues significantly.

We depend on a small number of customers for the majority of our revenues from our drug delivery platforms and drug products. Revenue from GlaxoSmithKline plc (GSK) in relation to Coreg CR® generated 66% of total revenues in 2013. With respect to the Éclat products, four customers, AmeriSource Bergen, Cardinal, McKesson and Morris & Dickson accounted for 95% of revenues from sales of these products in 2013. The termination of our relationship with any of these customers and our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

Our focus on (i) the development and licensing of versatile, proprietary drug delivery platforms, (ii) the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat Pharmaceuticals, LLC, or Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S., rather than primarily on collaborative agreements with pharmaceutical and biotechnology companies, may not be successful.

We have relied primarily over past years on our collaborative agreements and relationships with pharmaceutical and biotechnology companies as partners with respect to our drug delivery platforms and our strategic change in focus to the development of novel, high-value products based on our drug delivery platforms and, as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S. may not be successful in the near or long term and may negatively impact our business, financial condition, and results of operations, and further increase our research and development expenses.

Our current revenues from our drug delivery business primarily depend on third party pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery platforms.

We market and sell our drug delivery platforms to third parties who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GSKand other pharmaceutical and biotechnology companies whose identities remain confidential.

The products that our partners successfully develop under these collaborative agreements will affect our revenues. We cannot control the timing or other aspects of the development or marketing by our partners of their products that incorporate our drug delivery platforms and may not be informed by our partners concerning the timing and other aspects of their development or marketing efforts. The failure of one or more of our partners to develop successful products that incorporate our drug delivery platforms or to perform as we expect under our agreements with them could have a material adverse effect on our drug delivery business, financial condition and results of operations. We face risks relating to our collaborative agreements, including risks that:

- our collaborative agreements may not result in any new commercial products;
- our pharmaceutical and biotechnology company partners may not successfully obtain regulatory approval in a timely manner, or at all, and may not market any commercial products;
- the products developed under our collaborative agreements may not be successful commercially;
- we cannot control the amount and timing of resources that our pharmaceutical and biotechnology company partners devote to the development or commercialization of products using our drug delivery platforms or to the marketing and distribution of those products;
- we may not be able to meet the milestones established in current or future collaborative agreements;
- we may not be able to successfully develop products based on current drug delivery platforms and/or new drug delivery platforms that would be attractive to develop new products with potential pharmaceutical or biotechnology company partners;
- our collaborative partners may terminate their relationships with us; and
- our collaborative partners may enter bankruptcy or otherwise dissolve.

Although products that incorporate our drug delivery platforms and late-stage development products acquired through our acquisition of Éclat may appear promising, in particular, at their early stages of development and in clinical trials, none of these potential platforms or products may reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. We intend to continue to enhance our current technologies and pursue additional or complementary proprietary drug delivery platforms. Our success will depend on the development and the successful commercialization of products that can utilize our drug delivery platforms and development products from Éclat. If products incorporating our drug delivery platforms or our development products fail to reach the commercial market, our future revenues would be adversely affected.

Even if our products and current drug delivery platforms appear promising during various stages of development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the competent authority of an EU Member State or an Institutional Review Board ("IRB"), or an Ethics Committee (EU equivalent to IRB), or our pharmaceutical or biotechnology partners may delay or halt applicable clinical trials;

- we or our pharmaceutical or biotechnology partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;

- we or our current drug delivery platforms and drug products or our pharmaceutical and biotechnology company partners' products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;

- we may not find additional pharmaceutical or biotechnology companies to adopt our technologies or, if partnered, the business strategy of our partners may change;

- we or our pharmaceutical and biotechnology company partners may find certain products using our current drug delivery platforms cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;

- we or our partners may determine that managed care providers are unwilling or unable to reimburse patients at an economically attractive level for products under development; or

- products that use our current drug delivery platforms and products in development acquired from Éclat could fail to obtain regulatory approval or, if approved, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop technologies and new products. In 2013, we spent $26.7 million on research and development. Our ongoing investments in research and development for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The research and development process is lengthy and carries a substantial risk of failure. If our research and development does not yield sufficient new technologies and products that achieve commercial success, our future operating results will be adversely affected.

We depend upon a single site to manufacture some of our drug products and our drug delivery products, Coreg CR® microparticles, and any interruption of operations could have a material adverse effect on our business.

All of our manufacturing for some of our drug products and our drug delivery products, Coreg CR® microparticles, currently takes place in our production facilities located in Pessac, France. A significant interruption of operations at this facility for any reason, such as fire, flood, labor disruptions or other manmade or natural disaster or a failure to obtain or maintain required regulatory approvals, could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory obligations, including undergoing a successful inspection by the FDA, EMA, the competent authorities of EU Member States or our clients and obtaining the required regulatory approvals with respect to our drug delivery products. If this occurs, we may be unable to demonstrate compliance with applicable regulatory requirements governing manufacturing and to satisfy contractual obligations related to our drug delivery products with our pharmaceutical or biotechnology partners in a timely manner.

We depend on a limited number of suppliers for certain raw materials used in our drug delivery platforms and for the manufacture of certain drug products in development, and any failure of such suppliers to deliver sufficient quantities of supplies of these raw materials or product could interrupt our production process and could have a material adverse effect on our business.

We purchase a number of raw materials used in our current drug delivery platforms and drug products in development from a limited number of suppliers, including a single supplier for certain key ingredients. These raw materials include excipients such as, microsphere starting materials (e.g. cellulose beads) and active ingredients, such as, neostigmine methylsulfate for the production of Bloxiverz™ and carvedilol phosphate used for the production of Coreg CR® microparticles and other drug substances. Specialized ingredients, such as polyglutamate are used in the production of our Medusa polymers. We use contract manufacturing organizations for the supply of our products in development and the manufacture of Bloxiverz™, currently takes place in a single third party manufacturing facility. We have contracts in place with these suppliers, which are reviewed based on future forecast requirements. We determine minimum inventory levels based on our goal of holding at least three months of future requirements in inventory. If the supplies of these materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current Good Manufacturing Practices ("cGMP") requirements before we may incorporate that supplier's ingredients into our manufacturing. We expect to continue relying on our current suppliers for the foreseeable future, but failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Company to a relatively small number of individuals, each of whom has played key roles in executing various important components of our business. We do not maintain material key person life insurance for any of our key personnel. If we lose the services of Mr. Anderson, our Chief Executive Officer, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

If our competitors develop and market technologies or products that are safer or more effective than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including other companies developing niche brand or generic specialty pharmaceutical products or drug delivery platforms. Some of these competitors may be also our business partners. Our drug delivery platforms all compete with technologies provided by several other companies (for details see "Item 4. *Competition and Market Opportunities*"). There could be new biological or chemical entities that are being developed that, if successful, could compete against the drug delivery platforms or products we are developing. Further, unless and until the FDA has removed the "unapproved marketed products", the Éclat products may compete with products of companies such as, for Bloxiverz™, West-Ward Pharmaceutical Corp., APP (a division of Fresenius Kabi USA, LLC), American Regent Inc., and others. Additionally, the FDA could also approve generic versions of our marketed products. For any partnerships Flamel has with other companies, our collaborators could choose a competing drug delivery platform to use with their drugs instead of one of our drug delivery platforms.

Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Additionally, New Biological or Chemical Entities ("NBEs" or "NCEs") could be developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These new biological or chemical products may be safer or may work better than our technologies-based products.

We may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of late-stage products pipeline and any new and complementary businesses, products and technologies we may acquire in the future.

With the acquisition of Éclat, a new part of our business strategy is to obtain FDA approval and commercialize its portfolio of potential niche brand and generic specialty pharmaceutical products. We also are aiming to transition to a more vertically integrated business model that adds increased commercial capabilities in the U.S. to our existing drug delivery platforms. There can be no assurance that this strategy will be successful or that we will be able to successfully integrate and grow these two businesses, which could negatively impact our business and operating results.

If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to market demands, competitive pressures and evolving technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we would be able to successfully complete any acquisitions, or whether we would be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact our operating results.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms could become obsolete or noncompetitive.

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical and biotechnology company partners may choose to adopt the drug delivery platforms of our competitors. Our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

If we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and drug delivery platforms and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Any patent applications that we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is continually evolving and can be the subject of some uncertainty. The laws providing patent protection may change in a way that would limit protection. Our current patents may not be exclusive, valid or enforceable. They may not protect us against competitors that challenge our patents, such as companies that submit drug marketing applications to the FDA, the EMA, or the competent authorities of EU Member States that rely, at least in part, on safety and efficacy data from our products or our business partners' products (e.g., abbreviated new drug applications), obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our products or to exclude competing products. Our collaborations with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We may not have the necessary financial resources to enforce our patents. Further, patent protection once obtained is limited in time, after which competitors may use the covered technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shortened.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position. To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with our employees, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or techniques, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

Third parties may claim, that our drug delivery platforms, or the products in which they are used, or our other products infringe on their rights, and we may incur significant costs resolving these claims.

Third parties may claim, that the manufacture, use, import, offer for sale or sale of our drug delivery platforms or our products infringes on their patent rights. In response to such claims, we may have to seek licenses, defend infringement actions or challenge the validity of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

Any claims that our products or drug delivery platforms infringe or may infringe proprietary rights of third parties, with or without merit, could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our operating results.

The implementation of the Leahy-Smith America Invents Act of 2011 may adversely affect our business.

The Leahy-Smith America Invents Act of 2011 ("AIA"), which was signed into law on September 16, 2011, includes several provisions that may impact our business and patent protection in the United States. The AIA changes the current U.S. "first-to-invent" system to a system that awards a patent to the "first-inventor-to-file" for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and eliminates the ability to rely on prior research to lay claim to patent rights. Disputes will be resolved through new derivation proceedings and the AIA creates mechanisms to allow challenges to newly issued patents in reexamination proceedings. Although many of the changes bring U.S. law into closer harmony with EU and other national patent laws, the new bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S. may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

Even if we and our partners obtain necessary regulatory approvals, our products and our drug delivery platforms or our partners' products (incorporating our platforms) may not gain market acceptance.

Even if we and our pharmaceutical and biotechnology company partners obtain the necessary regulatory approval to market products or products that incorporate our platforms, such products, technologies and product candidates may not gain market acceptance among physicians, patients, healthcare payers and medical communities. The degree of market acceptance of any product, technology or product candidate will depend on a number of factors, including:

- the scope of regulatory approvals, including limitations or warnings in a product's regulatory-approved labeling;
- demonstration of the clinical efficacy and safety of the product or technology;
- the absence of evidence of undesirable side effects that delay or extend trials;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement; and
- the marketing and distribution support it receives.

If any of our products or drug delivery platforms or our partners' products fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business. In addition, even if we gain regulatory market acceptance, further delays due to, for example, the FDA not removing unapproved products from the market in a timely manner, may affect our ability to generate revenue quickly after market acceptance.

Our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of our intellectual property and may adversely affect the commercial success of the products developed under those partnerships.

While we are currently shifting our business model, our business currently remains dependent on our ability to work with customers and partners in collaborative relationships to develop products using our drug delivery platforms. While, we now have marketed products and products in late stage development that are not dependent on these collaborative relationships, most of our current revenues come from those partnerships. Therefore, as we have in the past, we are still exploring to enter into new collaborative arrangements, some of which are not evidenced by formal or executed definitive agreements, but rather by memoranda of understanding, material transfer agreements, options or feasibility agreements. If those collaborative relationships give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, such disputes may delay collaborative research, development or commercialization of potential products and may lead to lengthy and expensive litigation or arbitration. In some cases, the terms of our collaborative arrangements, particularly feasibility studies, may preclude us from disclosing the identity of the partners and/or of the products we are co-developing with them. The terms of collaborative arrangements may also limit or preclude us from fully developing other related products or specific applications of our drug delivery platforms used under such partnerships. Such arrangements generally include also termination provisions in the event either party decides that, for strategic or other reasons, it does not wish to pursue the partnership. Additionally, the partners under these arrangements may breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to agree to less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs or the development of our products and technologies.

We may be unable to enter into future collaborative arrangements on acceptable terms, which could also adversely affect our ability to develop and commercialize our current and potential future products. Further, even if we do enter into acceptable collaboration arrangements, it is possible that our collaborative partners may not choose to develop and commercialize products using our technologies or may not devote sufficient resources to the development and commercial sales of products using our technologies. Our collaborative arrangements may also limit or preclude us with respect to the development of our products or technologies that may compete with those of our collaborators, but may not necessarily restrict our collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us or may terminate their relationships with us or otherwise decide not to proceed with development and commercialization of products containing our drug delivery platforms.

We enter into collaborative agreements with pharmaceutical and biotechnology companies to apply our drug delivery platforms to drugs developed by others. Ultimately, we receive license revenues and product development fees, as well as revenues from royalties and the sale of products incorporating our technology. The drugs to which our drug delivery platforms are applied are generally the property of, or controlled by, our pharmaceutical and biotechnology company partners. Those drugs may be the subject of patents or patent applications and other forms of protection owned by such companies or third parties. If those patents or other forms of protection expire, are challenged or become ineffective, sales of the drugs by such companies may be restricted or may cease and adversely affect our revenues.

If we or our third party collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

The development of some of our drug delivery platforms-based products may require the use of raw materials (e.g. proprietary excipient), active ingredients or drugs (e.g. proprietary proteins), technologies/processes, etc. developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses, which could reduce the revenues and royalties we may receive on commercialized products that incorporate our drug delivery platforms.

If our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.

Some of our third party collaborative partners may utilize our drug delivery platforms in products with exclusive rights secured by patents or other means. These rights are limited in time and do not always provide effective protection for the developed products. If our collaborative partners are unable to protect the developed products' exclusivity or patent rights, generic competition may erode their market share, undermine the profitability of their products and limit the royalties we could collect from product sales. The expiration of the Hatch Waxman exclusivity for Coreg CR in April 2010 opens Coreg CR to potential generic competition, which may negatively affect further milestone payments and the royalties we could collect in the future. Abbreviated New Drug Applications (ANDA) have been submitted to the FDA by Mutual Pharmaceuticals Co. (now Caraco Pharmaceutical Laboratories, Ltd.), Lupin Pharmaceuticals, Inc. and Impax Laboratories, Inc. requesting marketing approval of generic formulations of Coreg CR and by Anchen Pharmaceuticals, Inc. regarding only 40 mg dosage strength. Should the FDA grant approval to any of these applications, our royalty income from sales of Coreg CR and further milestone payments would be negatively affected. To date, we have generated (i) $23 million in milestone payments and (ii) $56.2 million in royalty revenue from Coreg CR, the sole product sold in the U.S. using our Micropump drug delivery platform.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payers are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our products depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. In particular, it is difficult to predict the effect of health care reform legislation enacted in the U.S. in 2010, certain provisions of which are still subject to regulatory implementation, further legislative change and ongoing judicial review. Any such changes or changes due to future legislation governing the pricing and reimbursement of healthcare products in the EU Member States may adversely affect our business.

Security breaches and other disruptions could compromise confidential information and expose us to liability and cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store proprietary data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.

The costs of compliance with these laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

Fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may cause fluctuations in our financial results.

For the year ended December 31, 2013, we derived 46% of our total revenues from transactions in U.S. dollars, but have 35% of our cash and cash equivalents, all of our marketable securities, and the majority of our expenses denominated in Euros. Our functional currency is the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although we do, from time to time, purchase Euros against invoiced Dollar receivables.

Recent developments in the EU have created uncertainty about the ability of certain EU Member States to continue to service their sovereign debt obligations. This debt crisis and the related financial restructuring efforts may cause the value of the Euro to deteriorate, reducing the value of the Euro relative to the U.S. Dollar. Any strengthening in the U.S. Dollar relative to the Euro would have a negative effect on our balance sheet while a weakening in the U.S. Dollar relative to the Euro would have a positive effect. In addition, the sovereign debt crisis affecting some EU Member States is contributing to instability in global credit markets. If global economic and market conditions, or economic conditions in the European Union, the U.S. or other key markets, remain uncertain, persist or deteriorate further, our business, financial condition, results of operations and cash flows may be adversely affected.

Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery platforms and our late-stage development products acquired from Éclat and other products we may develop are subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.

Although products that incorporate our drug delivery platforms and late-stage development products acquired through our acquisition of Éclat, and other products we may develop may appear promising, in particular at their early stages of development and in clinical trials, none of these potential platforms or products may gain regulatory approval and reach the commercial market for any number of reasons.

In the U.S., federal state and local government agencies, primarily the FDA, regulate all pharmaceutical products, including existing products and those under development. We, or our pharmaceutical and biotechnology company partners, may experience significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If we, or our partners, are not successful, our revenues and profitability may decline. We cannot control, and our pharmaceutical and biotechnology company partners cannot control, the timing of regulatory approval for any of these products, or if approval is obtained at all.

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as, information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners, to conduct additional pre-clinical studies or clinical trials. For instance, we do not anticipate the necessity to conduct individual toxicity and carcinogenicity tests for each product that we develop using the Medusa's polymers developed and have been extensively studied previously. However, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of Medusa-based product candidates, which would impact development plans for product candidates. In addition, although Flamel has submitted a Drug Master File ("DMF") for its lead Medusa polymer, the FDA may require additional information prior to the conduct of clinical trials or for commercialization of any product that uses our Medusa polymers and cross-references our DMF.

Similarly, although we anticipate submitting applications for approval for the development products acquired from Éclat that rely on existing data to demonstrate safety and effectiveness, FDA may determine that additional studies particular to our products are necessary. If FDA requires such additional data, it would impact development plans for those products.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or result in rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), we or our partners may be required to develop Risk Evaluations and Mitigation Strategies, or REMS, to ensure the safe use of their product candidates. If the FDA disagrees with our or our partners' REMS proposals, it may be more difficult and costly for us, or our partners, to obtain regulatory approval for product candidates. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the wait time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which a product may be marketed, restrict distribution of the product or require further studies. With respect to the Éclat product Bloxiverz™, the FDA has required the Company to conduct post-marketing non-clinical, toxicity studies by December 2016.

The FDA may also withdraw product clearances and approvals for failure to comply with regulatory requirements or if problems follow initial marketing. In the same way, medicinal products for supply on the EU market are subject to marketing authorization by either the European Commission, following an opinion by the EMA, or by the competent authorities of EU Member States. Applicants for marketing authorization must submit extensive technical and clinical data essentially in the form of the ICH Common Technical Document. The data is subject to extensive review by the competent authorities and may be considered inappropriate or insufficient. If applications for marketing authorization by pharmaceutical and biotechnology company partners are delayed, or rejected, if the therapeutic indications for which the product is approved are limited, or if conditional marketing authorization imposing post-marketing clinical trials or surveillance is imposed, our revenues may decline and earnings may be negatively impacted.

Manufacturers of drugs, including the active pharmaceutical ingredients, also must comply with applicable cGMP requirements, both as a condition of approval and for continued authority to manufacture and distribute products. Our manufacturing facilities, and those of our pharmaceutical and biotechnology company partners, may be required to pass a pre-approval inspection by the FDA, the EMA, the competent authorities of EU Member States or our customers, and will be subject to periodic inspection after that, all intended to ensure compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our pharmaceutical and biotechnology company partners will need to ensure that all of our processes, methods and equipment are compliant with cGMP. We will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we, our pharmaceutical and biotechnology company partners or suppliers of key ingredients cannot comply with these practices, the sale of our products or products developed by our partners that incorporate our technologies may be suspended. This would reduce our revenues and gross profits.

Commercial products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology companies partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.

We on our own and in conjunction with our pharmaceutical and biotechnology companies partners will be subject to extensive regulatory requirements for our and the co-developed products and product candidates that incorporate our drug delivery platforms, even if the products receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required post-marketing studies or clinical trials;
- authorization renewal procedures;
- authorization variation procedures;
- compliance with any required REMS;
- updating safety and efficacy information;
- processing of personal data;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

If we or our partners, including any contract manufacturers that we use, fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of our products and products that incorporate our technologies. If the FDA, the European Commission or competent authorities of EU Member States determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

We are subject to U.S. federal and state laws prohibiting "kickbacks" and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

We are subject to extensive and complex U.S. federal and state and international laws and regulations, including but not limited to, health care "fraud and abuse" laws, such as anti-kickback and false claims laws and regulations pertaining to government benefit program reimbursement, price reporting and regulations, and sales and marketing practices. These laws and regulations are broad in scope and they are subject to evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our revenues, profitability, and financial condition. In the current environment, there appears to be a greater risk of investigations of possible violations of these laws and regulations. This is reflected by recent enforcement activity and pronouncements by the US Office of Inspector General of the Department of Health and Human Services that it intends to continue to vigorously pursue fraud and abuse violations by pharmaceutical companies, including through the potential to impose criminal penalties on pharmaceutical company executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Regulatory reforms may adversely affect our ability to sell our products or drug delivery platforms profitably.

From time to time, the US Congress, the Council of the European Union and the European Parliament, as well as the legislators of the EU Member States, adopt changes to the statutes that the FDA, the European Commission and the competent authorities of the EU Member States enforce in ways that could significantly affect our business. In addition, the FDA, the European Commission and the competent authorities of the EU Member States often issue new regulations or guidance, or revise or reinterpret their current regulations and guidance in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA, EU or EU Member State's regulations, guidance or interpretations changed, and what the impact of any such changes may be.

It is possible, however, that such changes could have a significant impact on the path to approval of products incorporating our drug delivery platforms, our products or of competing products, and to our obligations and those of our pharmaceutical and biotechnology company partners.

We and companies to which we have licensed our drug delivery platform and subcontractors we engage for services related to the development of our products are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.

We, and companies to which we license our technology, as well as, companies acting as subcontractors for our products are subject to extensive regulation by the FDA, other domestic regulatory authorities and equivalent foreign regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including: warning letters or untitled letters; fines and civil penalties; delays in clearing or approving, or refusal to clear or approve, products; withdrawal, suspension or variation of approval of products; product recall or seizure; orders to the competent authorities of EU Member States to withdraw or vary national authorization; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair the ability to produce and market applicable products, which could significantly impact our revenues and royalties that we receive from our customers.

We may face product liability claims related to clinical trials we may sponsor or for which we provide investigational products or technologies or the use or misuse of our products or products that incorporate our drug delivery platforms.

The testing, including through clinical trials, manufacturing and marketing of our products or products that incorporate our drug delivery platforms may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance with a limit of €8 million and product liability and recall insurance with a limit of €10 million for products incorporating our drug delivery platforms, and coverage of $5 million for products marketed by Éclat. Although we believe the amounts to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing our drug delivery platforms may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or be sufficient to reimburse us, for any expenses or losses we may suffer. A successful product liability claim against us, if not covered by, or if in excess of, our product liability insurance, may require us to make significant compensation payments. These payments would be reflected as expenses on our statement of operations and reduce our earnings.

If we use hazardous biological and/or chemical materials in a manner that causes injury, we may be liable for significant damages.

Our research and development activities involve the controlled use of potentially harmful biological and/or chemical materials, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain environmental liability, property, business interruption and casualty insurance with aggregate maximum limits of €115 million, which are limits that we believe to be commercially reasonable, but may be inadequate to cover any actual liability or damages. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any such liability could be significant.

Risks Relating to Ownership of Our Securities

Our share price has been volatile and may continue to be volatile.

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2013, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $3.25 to $8.21. During the year ended December 31, 2012, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $2.99 to $7.67. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery platforms developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery platforms;
- lack of efficacy of our products;
- litigation;

- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA, the EMA or national authorities of EU Member States in connection with submissions related to the products incorporating our technologies;
- the perception by the market of biotechnology and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

Because we have limited commercial sales, evaluating our prospects may be difficult.

Our primary commercial sales currently include only Coreg CR®. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited history of commercial sales, which may make it difficult to evaluate our prospects. The difficulty in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors and holders react to information about our prospects. Since 1995, we have generated revenues from product development fees and licensing arrangements and royalties. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with limited commercial sales of products and only two currently marketed products, Coreg CR® and Bloxiverz™).

If we are not profitable in the future, the value of our shares may fall.

We have a history of operating losses and have accumulated aggregate net loss from inception of approximately $236 million through December 31, 2013. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for research and product development of our drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our technologies and products;
- the level of product and price competition;
- our ability to develop new collaborative partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;
- the effectiveness of our marketing strategy;
- the effectiveness of our partners' marketing strategy for products that use our technology; and
- general economic conditions.

We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of our shareholders' equity interest.

We may require additional financing to fund the development and possible acquisition of new drug products and delivery platforms and to increase our production capacity beyond what is currently anticipated. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery platforms. We also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery platforms. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and technologies;
- the progress of our research and product development programs;
- results of our collaborative efforts with current and potential pharmaceutical and biotechnology company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues.

Our operating results may fluctuate, which may adversely affect our share price.

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by consumers for the products we and our partners produce;
- new product introductions;
- pharmaceutical and biotechnology company ordering patterns;
- the number of new collaborative agreements into which we enter;
- the number and timing of product development milestones that we achieve under collaborative agreements;
- the level of our development activity conducted for, and at the direction of, pharmaceutical and biotechnology companies under collaborative agreements; and
- the level of our spending on new drug delivery platform development and technology acquisition, and internal product development.

Variations in the timing of our revenue and expenses also could cause significant fluctuations in our operating results from period to period and may result in greater than expected losses or more difficulty achieving earnings.

We are subject to different corporate disclosure standards than U.S based companies that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Exchange Act, relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-U.S. issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

We currently do not intend to pay dividends and cannot assure shareholders that we will make dividend payments in the future.

We have never declared or paid a cash dividend on any of our capital stock and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

Judgments of United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.

An investor in the U.S. may find it difficult to:

- effect service of process within the U.S. against us and our non-U.S. resident directors and officers;
- enforce United States court judgments based upon the civil liability provisions of the United States federal securities laws against us and our non-U.S. resident directors and officers in France; or
- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary, or the "Depositary", is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

Preferential subscription rights may not be available for U.S. persons.

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. U.S. holders of our securities (which might not be shares but ADRs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, United States holders of our securities will be unable to exercise any preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.

For holders of our shares in the form of ADSs, the Depositary may make these rights or other distributions available to holders in the United States if we instruct it to do so. If we fail to issue such instruction and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, the holders will receive no value for them.

Our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

On March 31, 2014, Deerfield Capital and certain of its affiliates beneficially owned approximately 11.3% of our outstanding shares (in the form of ADRs) and Broadfin Capital. and certain of its affiliates beneficially owned approximately 9.9% of our outstanding shares (in the form of ADRs). See "Item 7. *Major Shareholders and Related Party Transactions — A. Major Shareholders*." To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, including change of control transactions.

ITEM 4. Information on the Company

General Overview

Flamel Technologies SA, or Flamel, is a specialty pharmaceutical company with a long history of expertise in drug delivery, focusing on the development of safer and more efficacious formulations, tackling unmet medical needs in the process. The acquisition of Éclat Pharmaceuticals, LLC, or Éclat, on March 13, 2012 (for more details on the Éclat acquisition and its debt financing, see "Item 7. *Major Shareholders and Related Party Transactions*" and "Item 10. *Additional Information – Material Contracts*") has created a more vertically integrated company, benefiting from greater development and commercial expertise, best in class drug delivery platforms and more near-term and mid-term potential value creating catalysts (for more details, see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*").

Corporate Information

The Company was incorporated as a *Société Anonyme (or SA)*, a form of corporation under the laws of the Republic of France, in August 1990 as Flamel Technologies S.A. and its shares, represented by American Depositary Shares, began to be quoted on the NASDAQ National Market in 1996 and are now quoted on the NASDAQ Global Market. As per the Company's by-laws, its legal existence expires in 2099, unless extended. Flamel's principal place of business is located at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy, 69693 Venissieux Cedex, France; phone number +33 472 78 34 34, fax number +33 472 78 34 35 and website www.flamel.com.

The Company currently has one direct wholly owned operating subsidiary: Flamel US Holdings, Inc., a Delaware corporation, created for the acquisition of Éclat in March 2012. Éclat Pharmaceuticals, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Flamel US Holdings, Inc. Talec Pharma, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Éclat Pharmaceuticals, LLC. A complete list of the Company's subsidiaries can be found in Exhibit 8.1 to this Annual Report.

Our Business Model

As a result of our acquisition of Éclat, we have implemented an altered business model allowing Flamel to blend novel, high-value internally developed products with its leading drug delivery capabilities and to commercialize niche branded and generic pharmaceutical products in the U.S. and other countries as appropriate. Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) regulatory pathway (see "Item 4. *Patent Restoration and Exclusivity*"), adds marketing and licensing knowledge of the commercial and regulatory process in the U.S and EU, which we believe will enhance the ability of the Company to identify potential product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and to license and market products in the U.S and EU.

By adopting this revised strategy, the Company makes itself less dependent on the often changing strategies of its partners, in the future. Nevertheless, Flamel is still exploring development, supply and licensing opportunities for its drug delivery platforms with carefully selected third parties, but, unlike our historical operations, will not rely completely on those partnerships to create revenue and profit opportunities.

Since our acquisition of Éclat, the Company is now focusing not only on (i) the development and licensing of versatile, proprietary drug delivery platforms (Micropump® oral sustained release platform and its derivatives LiquiTime® and Trigger Lock™ and, the long acting injectable platform, Medusa™; see "Item 4. *Flamel's Drug Delivery Platforms Overview*" for details) but also on (ii) the development of novel, high-value products based on those delivery platforms (for more details, see "Item 4. *Other Products Under Development*"), most of which are self-funded, and, (iii) the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S. acquired from Éclat (for more details, see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*").

On October 18, 2012, Flamel received U.S. Food and Drug Administration ("FDA") acceptance for its first New Drug Application ("NDA") with a Prescription Drug User Fee Act ("PDUFA") date of May 31, 2013. The product - later identified as Bloxiverz™ (Neostigmine Methylsulfate Injection for the reversal of effects of blocking agents after surgery) - was approved on May 31, 2013 and launched in the U.S. in July 2013 (for more details, see "Item 4. *Lead Products*"). Flamel believes that Bloxiverz™ could have a significant impact on the Company's revenue generation and favorably impact its progression to profitability. This launch is an important milestone for our business and we believe it demonstrates the expanded capabilities of Flamel. This is the first of what we expect to be multiple new product successful development to come from our internal pipeline over the next few years.

Business Strengths and Strategies

The acquisition of Éclat provides the Company with additional competencies and business strengths. To complement the historical science-oriented strengths of Flamel as an innovator of drug delivery platforms, we now have enhanced our ability to pursue commercial opportunities and identify new product candidates (see "Item 4. *Other Products Under Development*") and have gained a four products portfolio in various stages of development. The first product from the acquired Éclat's portfolio, Bloxiverz™, was approved by the FDA, and is currently being marketed in the U.S. (see "Item 4. *Lead Products*"). The second product from the acquired Éclat's portfolio was accepted for review NDA with a PDUFA date of April 28, 2014 (see "Item 4. *Other Products Under Development*").

We anticipate this enhanced commercialization capability will allow us to retain a greater portion of the economic benefits associated with sales not only of those potentially three (3) additional "Unapproved to Approved" products developed using the Unapproved Marketed Drug (or UMD) strategy (see "Item 4. *Other Products Under Development - Three (3) "Unapproved to Approved" Products using the Unapproved Marketed Drug (or UMD) Strategy*"), but also, in some instances, of new products developed using our drug delivery platforms (see "Item 4. *Other Products Under Development - Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2017*"). We also benefit from the addition of a different perspective on the business (including, but not limited to, the regulatory and commercial environments in the U.S.) and products to be developed in the future.

Our versatile, proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™, Medusa™) allow us to select unique product development opportunities, representing "life cycle" opportunities for marketed chemical and biological drugs (via 505(b)(2) or ANDA regulatory paths), to the development of innovative formulations for NCEs or NBEs (via NDA regulatory path). Our drug delivery platforms allow us to generate competitive differentiated product profiles (e.g. improvement of pharmacokinetics, efficacy and/or safety). These product development opportunities offer the ability to grow market share and to protect market position, through patent protection and/or product differentiation in multiple marketplaces. Indeed, as part of our new business model, and the building-up of an internal product portfolio, several products formulated using our proprietary drug delivery platforms are currently under development at Flamel, in various stages of development and using a variety of registration pathways. These products will be marketed either by the Company and/or by partners via licensing/distribution agreements (see "Item 4. *Other Products Under Development - Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2017*").

Altogether, the key elements of our strategy that enable us to build upon our strengths are:

- to maximize the commercial potential of our "Unapproved to Approved" products acquired from Éclat;
- to continue to build the efficacy and utility of Micropump®;
- to identify and optimize time-to-market for our (not yet approved) drug delivery platforms, i.e. LiquiTime®, Trigger Lock™ and Medusa™.
- to maximize the technical potential of our existing drug delivery platform for developing new and proprietary products with the appropriated development pathway (as identified above);
- to develop and validate additional drug delivery platforms for unmet applications with our current platforms; and,
- to leverage the capabilities of our existing (and additional, in the future) drug delivery platforms with pharmaceutical and biotechnology partners.

Developments in 2013 and early 2014

On May 7, 2013, we announced that the Company had filed a NDA for the second product from the portfolio of Éclat products acquired in March 2012 with the FDA in the first quarter. However, the Company received shortly thereafter a "refusal to file" letter from the FDA, citing the need to reformat parts of certain datasets in the application. The Company announced that it was working closely with the FDA to provide - in the requested format - the information requested for resubmission of this application as quickly as possible. This represented the second NDA filing after the first one accepted by the FDA for Bloxiverz™ in October 2012, which is Flamel's first NDA approval (see "Item 4. *Lead Products*").

On May 23, 2013, we announced that the Company had exercised its right to regain control of two drugs that use its Trigger Lock™ delivery platform that were formerly being developed in partnership with an undisclosed partner.

On June 3, 2013, we announced that the FDA had approved the Company's NDA for Bloxiverz™, the first product from the portfolio of Éclat products acquired in March 2012 (see "Item 4. *Lead Products*").

On June 6, 2013, we announced that the Company had entered into a multi-year development partnership agreement with an undisclosed, large international pharmaceutical company. The development work, which will be done in Flamel's Pessac facility.

On July 1, 2013, we announced that the Company had resubmitted to FDA its second NDA the second undisclosed drug acquired from Éclat. As Flamel previously announced on May 7, 2013, this second NDA had been filed with the FDA in the first quarter of 2013 and the Company received a "refusal to file" letter from the FDA, citing the need to reformat parts of certain datasets in the application. The resubmission of the NDA is consistent with the Company's planned timetable.

On July 29, 2013, we announced that launch of Bloxiverz™ (0.5 and 1.0 mg/mL strengths) had commenced.

On September 11, 2013, we announced that FDA had accepted for review the Company's second new drug NDA the second product from the portfolio of Éclat products acquired in March 2012. Flamel has received a PDUFA date, the target date for the FDA to complete its review of the NDA, of April 28, 2014. For competitive reasons, the Company has decided not to identify the product at this time, but intends to provide additional information at a later date. Flamel anticipates the potential filing of two (2) additional NDAs from the Éclat pipeline in 2014.

On October 31, 2013, we announced that Company completed preclinical studies with its proprietary extended-release Medusa hGH XL product, a customized version of recombinant human growth hormone (rhGH) based upon Flamel's proprietary Medusa platform. The study was conducted on hypophysectomized ("hypoX") rats, e.g. animals that have had their pituitary glands removed. This animal model is relevant for assessing efficacy evaluation of the condition of growth hormone deficiency. Flamel's study data provided significant evidence to move this proprietary drug forward into a human clinical trial in 2015 with once weekly dosing.

On December 4, 2013, we announced that Company had established a $15.0 million secured line of credit with Broadfin Capital, a current Flamel shareholder, to support our operations. The Company drew $5.0 million initially upon closing of the facility. The interest rate on any outstanding loan was 12.5% and the loan was required to be repaid on or before November 15, 2015. There was no cost for undrawn capital or any penalty or premium for early repayment. Broadfin Capital also received a royalty of less than 1.0% on net sales of Bloxiverz and the other products resulting from the R&D projects of the former Éclat until December 31, 2024, subject to required regulatory approvals and sales of these products. The outstanding loan was repaid in March 2014, using the net proceeds of ADSs sold by the Company described below; however, the royalty obligation remains in place.

On February 14, 2014, we announced the voting results of the resolutions with regards to the issuance of ADSs, presented at the Extraordinary General Meeting of the holders of its ordinary shares held on February 11, 2014. The resolutions related to the Company's ability to raise additional capital, an initiative that has to be approved by shareholders. Approximately 96% of the outstanding ordinary shares were represented at the meeting and granted to the Board of Directors the authorization for carrying out the resulting capital increases. A description of each resolution presented at the meeting was previously provided as Exhibit 99.2 to Form 6-K filed by the Company on January 31, 2014.

On March 6, 2014, we announced we had offered to sell 10.8 million ADSs, representing Company's ordinary shares, in an underwritten public offering. In connection with the offering, Company granted the underwriters a 30-day option to purchase up to an additional 15% (1.6 million) of the ADSs offered in the public offering to cover over-allotments, if any. The offering closed on March 12, 2014. The ADSs described were offered by Company pursuant to a shelf registration statement on Form F-3 previously filed with the SEC. The ADSs were sold at a price to the public of $9.75 per ADS. All of the ADSs in this offering are to be sold by Flamel. The underwriters subsequently exercised the over-allotment option in full. As a result we sold a total of 12.4 million ADSs (representing an equal number of our ordinary shares) for total net proceeds (after deducting commission) of approximately $113 million.

We used some of the net proceeds from the offering for the repayment of all outstanding amounts under the secured lines of credit previously provided by our shareholders Deerfield Capital L.P and Broadfin Capital LLC, as well as the notes issued in connection with our acquisition of Éclat. The Company intends to use the remaining net proceeds for the continued development of its product pipeline, including possible clinical trials, and general corporate purposes, including working capital.

On April 7, 2014, we announced that our proprietary Micropump® platform applied to sodium oxybate has achieved, in a First-in-Man (FIM) clinical study in healthy volunteers, the objective of one single dose before bedtime for patients suffering from narcolepsy, eliminating the need for a second dose. The current dosing regimen for the standard of care, Xyrem® (sodium oxybate), in the United States is two equal, divided doses: the first dose at bedtime and the second dose 2.5 to 4 hours later. The FIM clinical study was designed as a 16 subject four-way crossover evaluating three different formulations of Micropump® sodium oxybate and Xyrem at a nightly dose of 4.5g (two doses of 2.25g for Xyrem) with an extension phase at 6g for successful Micropump® formulations. The key data for the 14 evaluable subjects at 4.5g are: onset of action similar to Xyrem®, Cmax lower than Xyrem® and, mean blood concentration (mg/ml) at hours 7 and 8 similar to Xyrem®. For the extension phase of the study, two formulations were moved forward for dosing at 6g. Thirteen subjects were evaluable as one subject dropped out for a reason unrelated to drug. The profiles for both formulations were consistent with expectations. The current study will continue to treat subjects at higher doses. Given these results, the Company plans to begin a new clinical study before the end of 2014 in a larger number of subjects.

On April 29, 2014, the Company announced the receipt of a complete response letter (CRL) from the FDA for its second application from the Eclat Portfolio.

Lead Products

Bloxiverz™, Flamel's first NDA approval from the portfolio of Éclat products acquired in March 2012. Bloxiverz's NDA was filed in August 2012 and approved by the FDA on May 2013. The launch of Bloxiverz (10mL multiple dose vial at 0.5 and 1.0 mg/mL strengths) commenced in July 2013. Bloxiverz (Neostigmine Methylsulfate Injection) is a drug used intravenously in the operating room for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz is the first and only FDA-approved version of neostigmine methylsulfate, even though other versions of neostigmine have been on the market as unapproved, grandfathered products under the Food, Drug and Cosmetic Act of 1938. Compared with the remaining unapproved marketed products, Bloxiverz has proven and approved safety, efficacy and quality. Today, neostigmine is the most common agent used for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately 5 million vials sold annually in the U.S. The volume of sales of Bloxiverz is dependent upon, as per FDA guidance (see "Item 4. *Other Products Under Development - Unapproved Marketed Drug (or UMD) Strategy*"), the FDA removing all unapproved products from the market in a timely manner (typically one year post approval) and the Company enjoying a period of defacto exclusivity through the 505(b)(2) approval pathway (see "Item 4. *Patent Restoration and Exclusivity*").

Coreg CR®, the lead product using our Micropump drug delivery platform. Coreg CR is an extended-release formulation (once-a-day) of Coreg (i.e. carvedilol phosphate), a non-selective antagonist of Beta 1, Beta 2 adrenergic receptors and a selective antagonist of Alpha 1 adrenergic receptors. Coreg and Coreg CR are the only beta blockers indicated for the treatment of moderate to severe heart failure and left ventricular dysfunction following myocardial infarction. Coreg CR has been developed in partnership with GlaxoSmithKline (or GSK; for more details, see "Item 4. *Strategic Alliances*") and is approved, marketed and sold in the U.S since 2007. To date, we have generated (i) $23 million in milestone payments and (ii) $56.2 million in royalty revenue from Coreg CR. Flamel still is eligible to receive additional payments, which are not expected to be material, if certain milestones are achieved. In 2013, we recognized royalty revenue of $6.8 million. Since the Hatch-Waxman exclusivity period for Coreg CR ended on April 20, 2010, it is possible that Coreg CR may experience generic competition from one or more competitors following approval of an Abbreviated New Drug Application (ANDA), which may negatively affect the milestone payments and royalties we could collect in the future. We have submitted a Citizen's Petition to the FDA requesting the FDA to require that any generic formulations of Coreg CR should meet the same requirements that the FDA required for the approval of Coreg CR, which is a higher standard than is otherwise required under the minimum bioequivalence regulations. In October 2010, the FDA granted our petition in part and denied it in part. In addition, US Patent 8,101,209 covering Coreg CR formulation has been granted in the US and listed in the FDA Orange Book by our partner GSK on February 23, 2012. To date, no generic formulation of Coreg CR has received tentative or final approval.

Other Products Under Development

Three "Unapproved to Approved" Products using the Unapproved Marketed Drug (or UMD) Strategy. We are pursuing the development and will seek FDA approval (NDA) of drugs that are currently marketed, as yet still "unapproved" products, but with well-established medical efficacy. This should create opportunities, which may offer significant economic returns, to have the only "branded" products in niche markets, enjoying a period of defacto exclusivity through the 505(b)(2) approval pathway. Indeed, many products are marketed in the U.S., but have never received FDA approval and are not covered by DESI (Drug Efficacy Study Implementation). This strategy has, however, a limited number of opportunities where a meaningful return on investment is possible. Through Éclat, Flamel has acquired three additional opportunities beyond Bloxiverz with expected launches in the U.S. by the end of 2015.

- The Company's second NDA has a PDUFA date, the target date for the FDA to complete its review of the NDA, of April 28, 2014. For competitive reasons, the Company has decided not to identify the product at this time, but intends to provide additional information at a later date.

- Flamel anticipates the potential filing of two additional NDAs in 2014.

- Those products will be marketed by Flamel's subsidiary, Éclat Pharmaceuticals.

Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2017. Using the acquired marketing and commercial capability of Éclat, six new products development opportunities (i.e. four using Micropump® or LiquiTime® or Trigger Lock™, and two using Medusa™) have been selected for internal development. After setting differentiated targeted product profiles and establishing development plans, pharmaceutical development activities have been initiated.

- **Sodium oxybate**, a Micropump®-based formulation for one single dose before bedtime for patients suffering from narcolepsy, eliminating the need for a second dose. Flamel's results of its FIM clinical study in healthy volunteers, published in April 2014, demonstrated the elimination of the second nighttime dose. The elimination of the second dose for narcolepsy patients not only provides more convenience, but may improve the benefit sodium oxybate provides as there will be no disruption to nighttime sleep. The potential for additional benefits, including improved safety, will be studied. The current study will continue to treat subjects at higher doses. Given these results, the Company plans to begin a new clinical study before the end of 2014 in a larger number of subjects further evaluating its formulations as well as certain pharmacodynamic endpoints. This study is not expected to be a registration study. Flamel plans to meet with regulatory authorities prior to embarking upon registration studies which are expected to begin prior to the end of 2015.

- **hGH XL**, a once-a week Medusa™-based injectable formulation of recombinant human growth hormone (rhGH). Flamel's pharmacodynamics pre-clinical data, published in October 2013, provided significant evidence to move this proprietary drug forward into a human clinical trial in 2015.

- We have several other products based on our proprietary drug delivery platforms at various stages of development, i.e. two LiquiTime®-based (for pain or respiratory indications), and one Trigger Lock™-based (for pain indication), and an additional Medusa™-based (for metabolic indication). For competitive reasons, the Company has decided not to identify those products for the time being, but intends to provide additional information upon the achievement of pre-clinical, clinical and regulatory milestones.

- Those products will be marketed either by Flamel (and/or its subsidiary Éclat) and/or by partners via licensing/distribution agreements (e.g. after clinical proof of concept is achieved).

As part of the rationalization of the Company's products pipeline initiated in 2012, considering the evolution of the Hepatitis (HCV but also HBV) market in developing countries towards IFN-alpha free treatments, we have discontinued the development of IFN-alpha XL (a once-a week Medusa-based formulation of recombinant human interferon alpha-2b IFN-alpha XL (long-acting interferon alpha-2b which has completed a Phase 2 trial in HCV patients; Study "ANRS HC23 COAT-IFN"). The Company believes the commercial opportunity to be very limited, even in emerging markets.

Products in development with partners. Although our business model has changed, we still have partnerships (e.g. feasibility study and/or license agreements) with pharmaceutical and biotechnology partners. These alliances involve both novel and already-marketed drugs. Flamel expects some of these co-developed products to reach the marketplace as a function of many factors. These include the promise of the drug itself (particularly with respect to NCEs/NBEs there is a high rate of attrition); the success of formulation development activities that we conduct for our partners; the evolving strategy and marketing focus of our partners; and the pharmaco-economics associated with the eventual product and the indication(s) for which it is being developed. In particular, among those partnerships, we are developing a Micropump®-based once-daily formulation of a drug that is currently being marketed by undisclosed specialty pharmaceutical company (for more details see "Item 4. *Strategic Alliances*"). Flamel intends to provide additional information on the development progress of these co-developed products once the Company has obtained clearance from the partners.

Proprietary and Partnered Product Pipeline. The status of Flamel's proprietary and partnered product pipelines is detailed in the followings table:

Proprietary Product Pipeline				
Development Strategy/Platform	**Drug/Product**	**Indication**	**Stage**	**Sales Forces**
UMD[1]	Neostigmine Methylsulfate Injection/**Bloxiverz**™	Anesthesia	Marketed in the U.S.	Flamel (via Éclat)
	Undisclosed (UD)**[2]**	UD	NDA under review by FDA (PDUFA date April 28, 2014)	
	UD	UD	NDA filing expected in 2014	
	UD	UD		
Micropump®	Sodium oxybate	CNS (narcolepsy)	FIM clinical study completed (pivotal clinical study initiation could be expected in 2015)	To be determined**[3]**
LiquiTime®	UD	Pain	Proof of concept (pivotal clinical study initiation could be expected in 2015)	
	UD	Respiratory		
Trigger Lock™	UD	Pain		
Medusa™	Recombinant human growth hormone/**hGH XL**	Short stature	Proof of concept (dose ranging clinical study initiation expected in 2015)	
	UD	Metabolic	Pre-clinical(dose ranging clinical study initiation expected in 2014)	
Partnered Product Pipeline				
Micropump®	Coreg CR®	Cardiovascular	Marketed in the U.S.	GSK
Micropump®	UD	CNS	Dose ranging clinical study	Partner
Medusa™	UD	Cardiovascular	Proof of concept	

[1] Company's "Unapproved to Approved" products using the Unapproved Marketed Drug (or UMD) strategy.

[2] For competitive reasons, Flamel has decided not to identify those products for the time being, but intends to provide additional information upon the achievement of pre-clinical, clinical and regulatory milestones.

[3] Those products will be marketed either by Flamel (and/or its subsidiary Éclat) and/or by partners via licensing/distribution agreements (e.g. after clinical proof of concept is achieved).

Competition and Market Opportunities

Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche brand or generic specialty pharmaceutical products or drug delivery platforms. Some of these competitors may be also our business partners. There can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Further, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

The drug delivery industry landscape has dramatically changed over the past decade and even more so during the past five years, largely as a function of the growing importance of generic drugs. The growth of generics (typically small molecules) and of large molecules (biosimilars) have accelerated the demand for drug delivery solutions while, at the same time, reducing the overall market for drug delivery formulations due to reduced pricing power.

In addition, the overall landscape of the Pharma/Biotech industry has changed, as consolidation has reduced our pool of potential partners and further accelerated the competition among drug delivery companies. Over the past ten years, numerous stand-alone drug delivery companies have been acquired (partly or entirely) by pharmaceutical, biotech, generic or other drug delivery companies. By acquiring drug delivery platforms, those companies are internalizing their previously outsourced R&D efforts while potentially preventing competitors from accessing the acquired technologies. In the meantime, certain drug delivery companies have consolidated their existing positioning or have entered new markets via M&A transactions and/or restructuring.

Very few of Flamel's "historical" competitors still pursue a sole drug delivery business model as many other have moved or are moving to the Specialty Pharma model, e.g. Actavis (acquisition of Forest Laboratories in February 2014 which acquired Aptalis (formerly Eurand) in January 2014), Alkermes, BioAlliance Pharma, Depomed, Ethypharm, Octoplus (acquired by Dr. Reddy's Laboratories Ltd. in February 2013), Veloxis Pharmaceuticals (formerly LifeCycle Pharma), or to the fully integrated biotech model, e.g. Human Genome Sciences International (or HGSI), developing human serum albumin (HSA) biotherapeutic fusions acquired by GSK in July 2012 (note that before GSK's acquisition, HGSI spun-out in 2005 CoGenesys (which had a license to develop and commercialize certain HSA-fusions), which was acquired by Teva in 2008), Nektar Therapeutics developing PEGylation technology which is used e.g. in UCB's Cimzia® approved by the FDA for Crohn's disease.

Our drug delivery platforms primarily compete with technologies from companies such as:

Flamel's Drug Delivery Platforms	Competition category*	Selected Competitive Companies*
Micropump® (oral)	**Solid sustained release**	Alkermes (*Elan's drug delivery technologies*), COSMO Pharmaceuticals SpA, Depomed, Inc., Durect Corp., Actavis (*acquisition of Forest Laboratories, Inc. which previously acquired Aptalis* (*formerly Eurand*)), Supernus Pharmaceuticals, Inc., Tris Pharma, Inc., Veloxis Pharmaceuticals A/S (*formerly LifeCycle Pharma*)
LiquiTime® (oral)	**Liquid sustained release**	Neos Therapeutics, Inc. ("Neos"), Tris Pharma, Inc. ("Tris")
Trigger-Lock™ (oral)	**Abuse deterrence**	Acura Pharmaceuticals, Inc., Atlantic Pharmaceuticals, Inc., Cima, Collegium Pharmaceutical, Inc., Durect Corp., Egalet Corporation, Elite Pharmaceuticals, Inc., Ethypharm, Grünenthal Group, Inspirion Delivery Technologies, Intellipharmaceutics International, Inc., Paladin Labs Inc. (*acquired Labopharm*; acq. offer by Endo Health Solutions in November 2013), QRx Pharma, Ltd., Signature Therapeutics, Supernus Pharmaceuticals, Inc., Tris Pharma, Inc.
Medusa™ (injectable)	**Protein Engineering** (PEGylation, Protein fusion and other conjugation technologies)	Affibody AB, Ambrx, Inc., Ascendis Pharma A/S, Bolder Biotechnology, Inc., Enzon Pharmaceuticals, Inc., Fresenius Kabi AG, Nektar Therapeutics, Novozymes A/S, PharmaIN Corporation, Polytherics Ltd., Prolor Biotech Inc., Versartis, Inc., Xenetic Biosciences plc (*formerly Lipoxen plc*), XL-protein GmbH
	Depot (PLA/PLGA microspheres, liposomes and other technologies)	Alkermes plc., BioAlliance Pharma, Biodel Inc., Debiopharm Group, Durect Corp., LG Life Sciences, InnoCore Pharmaceuticals, Marina Biotech, Inc. (*Novosom AG technology*), MedinCell SA, Octoplus N.V. (*subsidiary of Dr. Reddy's)*, Pacira Pharmaceuticals, Inc., Q Chip Ltd., REcoly N.V., Soligenix, Inc. (*formerly DOR BioPharma Inc*), Surmodics, Inc. (PR Pharmaceuticals technologies), Xenetic Biosciences plc. (formerly Lipoxen plc)

***** From companies' web site and/or press releases.

"New" Flamel's Specialty Pharma's model (focusing on optimized re-formulations development capabilities) primarily competes with the one of other public companies such as (non-exhaustive list):

		"New" Flamel's capabilities		
Companies*	**Focus***	505(b)(2) regulatory pathway*	Life Cycle Management (drug delivery platforms) *	Commercialization (Rx and/or OTC and/or hospital)*
Actavis	Global	Y	Y	Y
Salix Pharmaceuticals	Gastrointestinal (GI) disorders	Y	Y	Y
H. Lundbeck A/S	Brain diseases	Y	N	Y
Impax Laboratories	Generic (high value, ANDA) and branded (CNS)	Y	Y	Y
Cadence Pharmaceuticals	Products principally for use in the hospital setting	Y	N	Y
Idenix Pharmaceuticals	Human viral and other infectious diseases	Y	N	N
Emergent BioSolutions	Medical needs and emerging health threats	Y	Y	Y
Insmed	Lung diseases	Y	Y	N
Horizon Pharma	Arthritis, pain and inflammatory diseases	Y	N	N

***** From companies' web site and/or press releases.

Until the FDA has removed the "unapproved marketed products", the Éclat products may compete with products of companies such as, for Bloxiverz, APP (a division of Fresenius Kabi USA, LLC) and West-Ward Pharmaceuticals Corp.

Market Opportunities

Drug delivery platforms are of particular interest for managing the life cycle of medicines, as they offer many advantages: i.e., improvement of drug characteristics such as bioavailability, pharmacokinetics, efficacy, compliance, and side effects; protection of market position through patent extension or differentiation; and extension of market to new indications thanks to improvement of the drug's characteristics. The global drug delivery market was estimated by BCC Research at $181.9 billion in 2013. The increased number of geriatric patients and the demand for convenient drug delivery options offer major opportunities for the development of innovative and easy-to-use drug delivery platforms. However, the industry faces many challenges.

There are four main forces currently affecting all standalone drug delivery companies and forcing the industry to adapt and to change: (i) the rise of generics (customers need to fill their drug pipelines with patent-protected reformulations to mitigate generics impact ("life cycle")), (ii) the rise in costs for new product development (increasing development costs for new chemicals or biological entities is in favor of developing new formulations of already approved drugs at lower costs, (iii) the commoditization and acquisition of drug delivery technologies (more and more drug delivery customers (mainly "Big Pharmas") have developed internal drug delivery capabilities; the integration of the drug delivery-based formulation development occurs at much earlier stage in the overall pharmaceutical development and (iv) the higher regulatory and reimbursement hurdles ("as good as" with increased convenience is now insufficient to get approved and reimbursed for drug products; therefore, technology-based drugs need to show improved efficacy too).

These forces have affected the small molecule space to a greater extent, as biologics enjoy higher barriers to entry and have been sheltered as a consequence. But they are at work in the biologics space as well. In particular, in today's environment, a drug has to demonstrate significant therapeutic efficacy advantage over current standard of care in order to successfully solicit third party payer coverage. Alternately, changes in the delivery of a drug must create a demonstrable reduction in costs. Dosing convenience, by itself, is no longer sufficient to gain reimbursement acceptance. It has a serious impact on drug delivery companies as they have to now demonstrate, through costly phase 3 trials, therapeutic efficacy of their new formulations. Interestingly, this trend directly contradicts the "improvement in patients' convenience first" approach supported in the past by drug delivery companies. More positively, in parallel, the FDA has encouraged drug companies developing enhanced formulations to use an abbreviated regulatory pathway: the 505(b)(2) NDA. Most drug delivery companies today are using this approach or the supplemental NDA pathway (sNDA). An NDA or sNDA is necessary to market an already approved drug for a new indication, or in a different dosage form or formulation. However, the sNDA approach requires cross-referencing the originator's drug dossier, and eventually, an alliance with the originator's company for commercialization.

Because the drug delivery industry is highly competitive, participants must find ways to lessen the pressure and increase profitability. The "new" Flamel, resulting from the combination of its existing proprietary drug delivery platforms with the established commercial capability of Éclat, is evolving into a Specialty Pharma company focusing on re-formulations and requiring shorter product development cycles by using a "fast track" NDA mechanism (505(b)(2)). The pharmaceutical and biotechnology sectors, with an impending "patent cliff", are forcing Big Pharma/Biotech to reorganize and creating niche opportunities for Specialty Pharma companies like the "new" Flamel.

Flamel's Drug Delivery Platforms

Overview

Flamel owns and develops outstanding drug delivery platforms that are able to tackle key challenges in the formulation, in various dosage forms (e.g. capsules, tablets, sachets or oral liquid suspensions; or injectable for subcutaneous administration) of a broad range of drugs (novel, already-marketed, or off-patent):

- **Micropump**® allows generating and marketing modified and/or controlled release of solid, oral dosage formulations of drugs (Micropump-carvedilol and Micropump-aspirin formulations have been approved in the U.S. and in E.U., respectively; see "Item 4. *Strategic Alliances*").

- Micropump's derivative **LiquiTime**® allows developing modified/controlled release of liquid formulations for patients having issues swallowing tablets or capsules such as children and the elderly.

- Micropump's derivative **Trigger Lock**™ allows developing tamper-resistant modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse.

We believe in the competitive advantages represented by the versatility of Micropump which permits us to develop differentiated product profiles (modified/controlled release formulations) under various dosage forms e.g. capsules, tablets, sachets or oral liquid suspensions (LiquiTime). With Trigger Lock potentially addressing the issue of narcotic/opioid analgesics tampering, we have broad and versatile presentations to serve most markets from pediatric to geriatric.

- **Medusa**™ allows developing extended/modified release of injectable dosage formulations of drugs (e.g. peptides, polypeptides, proteins, vaccines, and small molecules).

We believe also that our Medusa-based formulations give us a competitive advantage in developing differentiated product profiles. Indeed, Medusa-based formulations permit drugs' full activity to be preserved and, extended release, as well as other advantages, such as, improved solubility, stability, and resistance to aggregation. Overall, Medusa improves the patient experience though a change in the route of administration (e.g. switching from intravenous to subcutaneous injection) and compliance (e.g. from once-a-day to once-a-week) while potentially improving efficacy and/or safety.

The Company is developing specific applications of its proprietary, versatile drug delivery platforms with its exiting pharmaceutical and biotechnology partners (see "Item 4. *Strategic Alliances*"). In addition, Flamel will continue to partner its proprietary formulations capabilities and will seek to commercialize and/or partner internally developed novel products after clinical proof of concept is achieved (see "Item 4. *Other Products Under Development*").

Micropump®: Delivery Platform for the Modified and/or Controlled Release of Solid, Oral Dosage Formulations of Drugs

The oral drug delivery market was valued at $49 billion in 2010, and is forecast to grow at a Compound Annual Growth Rate ("CAGR") of 10.3% until reaching $97 billion by 2017. The market is expected to show this increase due to continuing upswing in demand for innovative oral drugs (contractpharma.com, 2012). In 2009, the FDA has approved more reformulations (75) than NCEs (26) (contractpharma.com, 2012); 27 NCEs were approved by the FDA in 2013 (fda.gov).

Flamel's Micropump® platform permits either extended, or both delayed and extended, delivery of small molecule drugs via the oral route. It is particularly suitable for drugs with a narrow window of absorption in the upper part of the small intestine. Micropump consists of a multiple-particulate system containing 5,000 to 10,000 microparticles per capsule or tablet. The 200-500 microns diameter-sized microparticles are released in the stomach and pass into the small intestine, where each microparticle, operating as a miniature delivery platform, releases the drug by osmotic pressure at an adjustable rate and over an extended period of time. The design of the Micropump microparticles allows an extended transit time in the small intestine with a mean plasma residence time extended up to 24 hours, which is especially suitable for short-lived drugs known to be absorbed only in the small intestine. The microparticles' design can be potentially adapted to each drug's specific characteristics by modifying the coating thickness and composition (including "Generally Regarded as Safe" (GRAS) excipients encapsulated with the drug) for improved efficacy (i.e., extending therapeutic coverage), reduced toxicity and/or side effects (i.e., reduced C_{max} or peak drug concentration in the plasma; with also reduced intra- and inter-patient variability) and improved patient compliance (once-a-day regimen). It is applicable to poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) and to low dose (4 mg) or high dose (1,000 mg) of drugs, while providing good mouth feel and taste masking. Micropump allows the development of extremely precise pharmacokinetic profiles [extended (and/or delayed) release] of single or combination of drugs, in a variety of formats (tablet, capsule, sachet, or liquid), while preserving the targeted release rate over the shelf-life of the product.

Considering R&D costs for reformulating a drug are typically lower than for developing NCEs, "reformulation approvals" provide an opportunity to extend the exclusivity period of an already marketed or create new market exclusivity for off-patent drug. The Micropump drug delivery platform has successfully transitioned to commercial stage with Coreg CR®, (see "Item 4. *Lead Products*"). Coreg CR Micropump-based microparticles are being manufactured for GSK by Flamel at the Company's cGMP FDA-approved manufacturing site in Pessac, France (for more details, see "Item 4. *Manufacturing*"). Flamel has one Micropump®-based internal product in development (i.e. Micropump®-Sodium oxybate successfully tested in FIM for narcolepsy) and a pivotal clinical study is expected to begin prior to the end of 2015 (see "Item 4. *Proprietary Product Pipeline*").

Micropump® is being utilized in collaborations with pharmaceutical and specialty pharma companies (see "Item 4. *Strategic Alliances*") Micropump® (and related products) is patented (see "Item 4. *Proprietary Intellectual Property*").

LiquiTime®: Delivery Platform for the Modified/Controlled Release of Liquid, Oral Dosage Formulations of Drugs

The U.S. sales of drugs (Rx and OTC) in liquid form for oral administration exceeded $ 5.3 billion for the year 2013 (IMS Health). Amongst marketed "extended release" (twice-a-day or once-daily) liquid products are Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex combo based on Neos' Dynamic Time Release Suspension Technology® and sold by UCB), three generic of Tussionex (one sold by Aristos Pharmaceuticals, one sold by Par Pharmaceuticals (developed using Tris' LiquiXR™ technology) and one sold by Kremers Urban Pharmaceuticals Inc.), Delsym® and Delsym Children® (dextromethorphan polistirex developed and sold by Reckitt Benckiser plc.) and Quillivant XR (an a priori "true" once daily methylphenidate, approved by the FDA in January 2013, developed using Tris' LiquiXR™ technology and marketed by Pfizer; 2013 sales were $25.1 M). These products totaled $206 million sales in 2013 (IMS Health).

Flamel's LiquiTime® platform uses Micropump®'s competitive advantages to allow us to develop modified/controlled release (e.g. zero-order kinetics) of liquid formulations for patients having issues swallowing tablets or capsules such as children and the elderly. LiquiTime may *a priori* not have the limitation of working solely with ionic drugs as for resin-complex based technologies. As with Micopump®, LiquiTime® is easy to scale-up to commercial quantities.

The increased number of geriatric patients and the demand for convenient drug delivery options for children offer striking opportunities for the development LiquiTime®-based formulations. LiquiTime has reached, with an undisclosed partner, clinical proof of concept in humans for a liquid suspension of an undisclosed drug for treatment of children (confidential). Flamel has two LiquiTime®-based and self-funded products at various stages of development; first pivotal clinical study could be expected to be initiated as early as in 2015 (see "Item 4. *Proprietary Product Pipeline*").

LiquiTime® (and related products) is patented (see "Item 4. *Proprietary Intellectual Property*").

Trigger Lock™: Delivery Platform for the Tamper-Resistant Modified/Controlled Release Formulations of Narcotic/Opioid Analgesics

A major problem faced by the industry is the growing abuse and misuse of opioids by drug abusers, who extract the opioids from the drugs and achieve their immediate release. The proportion of narcotic/opioid analgesics abuse associated with emergency room admissions has more than tripled, from 6.8% in 1998 to 26.5% in 2008 (TEDS report, July 15, 2010). Narcotic/opioid analgesics abuse continues to increase as current products remain easy to abuse. In 2010, enough prescription painkillers were prescribed to medicate every American adult every 4 hours for one month (PBS 2013). The number of prescription medicine abusers in 2010 was 8.76 million, 5.1 million of which abused painkillers (drugabuse.com 2013). The market for opioid drugs, used to treat patients suffering from severe and chronic pain in the seven major markets (USA, Japan, and five European countries) was estimated to exceed $7.4 billion in 2010, dominated by oxycodone. In 2013, the U.S. opioids containing market was evaluated to be $4.6 billion (IMS Health).

Flamel's Trigger Lock™ platform is using Micropump's competitive advantages to allow us developing tamper-resistant modified/controlled release formulations of narcotics and other drugs susceptible to abuse:

- Micropump particles are extremely difficult to crush to extract the narcotic/opioid analgesics;
- Additional modifications tailored to prevent other less publicized methods of foiling controlled release technologies; and,
- Provides either bioequivalent or improved pharmacokinetics to marketed narcotic/opioid analgesics.

The FDA's move to restrict prescribing extended-release opioid analgesics should benefit tamper-resistant formulations, such as, Trigger Lock-based formulations of opioids. The FDA has issued a "Draft Guidance for Abuse Deterrent Opioids" on January 9, 2013. Recent FDA decisions on drug abuse are as follows:

- April 16, 2013 – US FDA will not accept or approved ANDAs for generic version of Purdue's OxyContin (oxycodone) that lack abuse-deterrent properties. FDA had approved abuse-deterrent labeling for reformulated OxyContin (oxycodone hydrochloride controlled-release tablets from Purdue Pharma L.P.). Additionally, because original OxyContin provides the same therapeutic benefits as reformulated OxyContin, but poses an increased potential for certain types of abuse, the FDA has determined that the benefits of original OxyContin no longer outweigh its risks and that original OxyContin was withdrawn from sale for reasons of safety or effectiveness. Consequently, the FDA will not accept or approve ANDAs for generic versions of OxyContin that lack abuse-deterrent properties. OxyContin sales made comprised about $2.81 billion of the $9.38 billion U.S. market for prescription painkillers in 2012 (IMS Health).
- May 10, 2013 – US FDA denied Endo's citizen petition to block generic forms of its widely abuse prescription pain drug Opana ER (oxymorphone; non-crush resistant formulation of Opana ER was discontinued from sale for safety reasons and thus can no longer serve as a reference listed drug).
- September 10, 2013 – FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics; New boxed warning to include neonatal opioid withdrawal syndrome.

It is thought that Trigger Lock™ has the potential to satisfy the FDA Draft Guidance for Abuse Deterrent Opioids:

- Laboratory-based in vitro manipulation and extraction studies (Category 1) – Success with Trigger Lock™
- Pharmacokinetic studies (Category 2) – Success with Trigger Lock™
- Clinical abuse potential studies (Category 3) – To be performed prior marketing
- Analysis of post marketing data to assess the impact of an abuse-deterrent formulation on actual abuse in a community setting (Category 4) – To be performed post marketing

Flamel has one Trigger Lock™-based internal product under development for which a pivotal clinical study is expected to be initiated in 2015 (see "Item 4. *Proprietary Product Pipeline*").

On May 2013, the Company exercised its right to regain control of two drugs that use its Trigger Lock™ delivery technology that were formerly being developed in partnership with an undisclosed partner (see "Item 4. *Recent Developments*" and "Item 4. *Strategic Alliances*").

Trigger Lock™ (and related products) is patented (see "Item 4. *Proprietary Intellectual Property*").

Medusa™ Delivery Platform for the Modified/Controlled Release of Injectable Dosage Formulations of Drugs

The injectable drug delivery market could be worth $43.3 billion by 2017 (MarketsandMarkets). Conversely, global sales of biologics were approximately $178 billion in 2013, and are expected to reach $252 billion by 2017, which represents a CAGR of 9% (BCC Research). By comparison, in 2016 biosimilars will be worth only about $5 billion in an even larger biologics business (IMS Health).

Flamel's Medusa, a hydrogel depot formulation approach that does not alter the drug substance, enables the modified/controlled delivery from one day up to one week of drugs (e.g. peptides, polypeptides, proteins, vaccines (DeliVax's application(s)), and small molecules) while remaining fully active (as distinguished from chemical modification (e.g. PEGylation) or protein engineering or other conjugation (e.g. HSA-fusion) approaches). Particularly suited for the development of subcutaneously administered formulations of small molecule drugs that are otherwise given intravenously, this platform may be used also to solve threshold issues for biological drugs, such as solubility/aggregation/poor stability issues.

The Medusa™ platform consists of proprietary, a versatile drug carrier polymer that forms a hydrogel depot after injection. Medusa™ polymers are made of glutamic acid, a naturally occurring aminoacid, and alpha tocopherol (Vitamin E). These polymers are amphiphilic and spontaneously form stable hydrogels in water. These hydrogels contain hydrophobic nanodomains rich in Vitamin E and hydrophilic polyglutamate that are exposed to water. The hydrogels are robust over a wide range of pH values and can be stored, in particular as a stable freeze-dry form, that can be easily reconstituted in Water for Injection. Those polymers, which are fairly easy and cost effective to produce under cGMP requirements, have been proven to be safe and biodegradable. A comprehensive ADME and regulatory toxicology package for key Medusa polymer is being completed in order to update the Type IV Drug Master File ("DMF") filed with the FDA in February 2011 (assigned number 024634).

The drug is loaded in Medusa™'s hydrogel (nano- or micro-gel) via non-covalent, hydrophobic and electrostatic, bonds. Once in the body, the hydrogel releases the drugs in a controlled manner with potentially no burst effect, lower initial C_{max} and uniform plasma concentration, over an extended period of time. Both drug loading (in fully aqueous solution, and usually, under solvent- and surfactant-free conditions) and release (essentially by displacement of the loaded drug by circulating endogenous proteins) are non-denaturing, which preserves structural integrity - and hence the activity - of the drug. The transient, non-covalent interactions dictate the pharmacokinetic parameters (C_{max} and bioavailability in particular) of the released drugs.

The Company is focusing on Medusa™-based "biobetters" development opportunities, which can be summarized as follows:

- Validated drugs, established market and proven clinical development approaches as starting points;
- Product differentiation e.g. improvement of pharmacokinetic (and potentially pharmacodynamics) parameters;
- Protection of market position through product differentiation and/or patent extension; and,
- Ability to grow market share and resist price competition.

Flamel has two Medusa™-based internal products at various stages of development. The first, hGH XL, has achieved pharmacodynamics pre-clinical proof of concept; human clinical trial is expected to be initiated in 2015 (see "Item 4. *Proprietary Product Pipeline*"). The second Medusa-based (for metabolic indication) is at pre-clinical stage; dose ranging clinical study could be expected in 2014.

Medusa™ (and related products) is patented (see "Item 4. *Proprietary Intellectual Property*"). It is being utilized in collaborations with pharmaceutical and biotechnology companies (see "Item 4. *Strategic Alliances*").

Proprietary Intellectual Property

Patents and other proprietary rights are essential to our business. Our proprietary product pipeline and our strategic alliances are dependent on our drug delivery platforms and related products (formulation, process, etc.) being patent protected. As a matter of policy, we seek patent protection of our inventions and trademarks (see key trademarks listed on page ii herein) and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop our competitive position.

Generally, we first file a patent application covering an invention in France and in the United States (provisional application). Within one year, we file a U.S. non-provisional patent application for that invention, together with an international patent application, pursuant to the Patent Cooperation Treaty (PCT). In addition to seeking patent protection in the United States and France, to further protect the inventions that we consider important to the development of our business, from the PCT we will usually prosecute patent applications in Europe, Japan, Canada, and key foreign markets on a selective basis. Therefore, in addition to the above-named countries, we also have patents granted or patent applications pending in a number of other countries, including, for example, Mexico, Brazil, China, India, Australia, Israel, South Africa and South Korea.

On a case-by-case basis, an invention developed jointly by Flamel and a partner may be assigned to and prosecuted by the partner. The information provided in this section herein, does not refer to such patent applications.

During 2013, we were granted fifty-seven new patents. In addition, in 2013, we filed two patent applications, one provisional application in the U.S. and one PCT international application. Altogether, as of December 31, 2013, we owned approximately the following patent and patent applications:

	US	EUROPE	ROW[1]	TOTAL
Granted patents	23	252**[2]**	120	395
Pending patent applications	26	28	121	175
Patents granted in 2013	3	28	26	57
Patent applications filed in 2013	1	0	1	2

[1] ROW: Rest of the Word;
[2] 252 national patents corresponding to 25 granted European Patents

The Company's patents protecting its drug delivery platforms have the following dates of expiration:

Drug Delivery Platforms	Date of expiration of granted patents	
	U.S.	Europe
Micropump®	November 2025	July 2023
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026 (pending)
Medusa™	December 2029	May 2028 (pending)

Flamel's key patents include protection for the following:

- **Micropump® platform** is patented under multiple patents. Among them is Flamel's Micropump-related key patent, WO 2003/030878, which discloses an efficacious coating formulation for providing delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract. It is granted in the U.S. as US Patent 8,101,209 and will expire on October 2025. It covers Coreg CR formulation and, as such, has been listed at the FDA Orange Book by our partner GSK on February 23, 2012. Equivalent patents are granted in China, Hong Kong, Israel, India, Singapore, Japan, South Korea, Canada, South Africa, Mexico (expiry date: October 2022) and in France (expiry date: October 2021). Patent applications are pending in Brazil and Europe and would expire on October 2022.

- **LiquiTime® platform** is protected by a Flamel's patent granted in the U.S. (US 7,906,145; expiry date: September 2025) and in South Korea, Canada, Israel, Japan, Australia, China, Austria, Belgium, Switzerland, Liechtenstein, Germany, Spain, France, United Kingdom, Italy, Ireland, Luxembourg, Netherlands, Portugal, Sweden, Turkey, India, Mexico, South Africa that expire on April 2023. A patent application is pending in Brazil and a continuation application is pending in the U.S.

- **Trigger Lock™ platform** is protected by seven Flamel's patent application families. Six patents are granted in the U.S., Europe and Japan; twenty-six (26) patent applications are pending including other countries and will expire between November 2025 and December 2033.

- **Medusa™ platform** is patented under Flamel's key patent WO 2000/30618 and WO 2003/104303, granted in the U.S. and which will expire on November 2019 and July 2023, respectively. Equivalent patents to WO 2003/104303 are granted in China, Israel, Mexico, Australia, Japan, South Korea, Canada and South Africa. Patent applications are pending in Brazil, Europe and India. These patents will expire on June 2023.

    - Medusa-based nanogels are protected by issued patents from WO 2005/051416' family in the U.S., Australia, China, Israel, Japan, South Korea, Mexico, South Africa, India, Canada and Europe expiring on November 2024. Corresponding patent applications are pending in Brazil and Thailand.

    - Medusa-based microgels are protected by granted patents from WO 2007/141344' patents family in the U.S., Australia, Japan and South Africa. Applications are pending in Europe and other countries. This patents family will expire on June 2027.

Strategic Alliances

As focus shifts to a more "specialty pharma" model the Company's business is becoming less dependent on its ability to work with partners in collaborative relationships to develop products using our drug delivery platforms. Indeed, we have now marketed product and products in late stage development that are not dependent on these collaborative relationships (see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*"). As part of the rationalization of the Company's products pipeline initiated in 2012, we have continued our efforts to streamline and optimize existing partnerships, as follows:

- In January 2013: Effective termination of the development and license agreement with Merck Serono (Medusa-based formulation of interferon beta-1a (Rebif));

- In April 2013: Monetization of our controlled release Micropump-based formulation of aspirin to New Haven Pharmaceuticals (second Micropump-based product approved in EU, noticeably U.K.).

- In May 2013: Regained control of two drugs that use our Trigger Lock platform that were formerly being developed in partnership with an undisclosed specialty pharmaceutical company; and,

- In July 2013: Termination of joint development partnerships with Digna Biotech SL (Medusa-based formulations of P144 and P17) and with Theralpha SAS (Medusa-based formulation of THA902).

While we are moving to a specialty pharma model, currently most of our revenues come from partnerships. Therefore, as we have in the past, we are still exploring to enter into new partnerships, in particular, with pharmaceutical and biotechnology companies providing new formulation development opportunities (especially, based on partners' proprietary or controlled therapeutic compounds) and access to complementary expertise (regulatory, medical and commercial).

Under our partnership agreements, our partners typically assume responsibility for all formulation development, manufacturing, polymer supply, clinical, regulatory and marketing costs and make payments to us at the time the agreement is signed and upon the achievement of significant technical, pre-clinical, clinical and regulatory milestones. We also typically are entitled to receive royalty payments on the sales of products that incorporate our drug delivery platforms.

A summary of our major existing agreements is provided below.

GlaxoSmithKline (or GSK)

We began work with GSK on a Micropump-based formulation of Coreg in 2003 when we entered into a license agreement for use of our Micropump platform for an extended release formulation of carvedilol phosphate. The product was approved by the FDA in October 2006 and launched in the U.S. in March 2007. We are eligible to receive low to mid-single digit royalty payments on net sales of Coreg CR. To date, we have generated (i) $23 million in milestone payments and (ii) $56.2 million in royalty revenue from Coreg CR. Flamel still is eligible to receive additional payments, which are not expected to be material, if certain milestones are achieved. In 2013, we recognized royalty revenue of $6.8 million. This agreement expires on the later of: (i) ten (10) years from the date of the first commercial sale of product in such country, or (ii) the expiration of the last to expire Flamel patent right in such country. Prior to 2011, we produced Coreg CR microparticles in our Pessac cGMP facility on a cost plus basis pursuant to a separate supply agreement that expired on December 31, 2010. In October, 2011, we announced that we signed a new supply agreement with GSK for the production of Coreg CR microparticles and remain the sole supplier of Coreg CR microparticles for GSK. Under this new supply agreement, we will receive guaranteed minimum payments to supply Coreg CR microparticles over a minimum period of five years. GSK may terminate the agreement at their sole discretion by giving six months written notice. Pursuant to this new supply agreement, we received a payment of €1.3 million ($1.8 million) during the third quarter of 2011 and a further €1.3 million ($1.8 million) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel for GSK since January 1, 2011. For 2012, the Company recognized as revenues from product sales a total amount of $9,097,000 of which $852,000 relates to the €2,600,000 received in 2011. For 2013, the Company recognized as revenues from product sales a total amount of $7,969,000 (for more details, see "Item 18. *Financial Statements – Notes to Consolidated Financial Statements*, "*Subcontracting agreements F-17*"").

Undisclosed specialty pharmaceutical company (Micropump formulation of marketed drug)

In May, 2011 we entered into a license and development agreement with an undisclosed specialty pharmaceutical company for the development of a Micropump-based, once-daily formulation of a central nervous system medication that is currently being marketed by that company. Pursuant to the agreement, we received a $0.5 million up-front payment and are entitled to additional payments, which are not expected to be material, upon development and regulatory milestones, as well as, low to mid-single digit royalty payments upon commercial sales of the product. Our partner pays for all formulation development, manufacturing and regulatory costs, as well as sales and marketing.

Undisclosed large international pharmaceutical company (Medusa formulation of new drug for cardiovascular indication)

In July 2013, we entered into a pilot (feasibility) study agreement, including an option for a license to be exercised prior engaging IND-/IMPD-enabling studies, with an undisclosed large international pharmaceutical company for the development of a Medusa-enabled formulation of a partner's controlled compound for cardiovascular indication (confidential).

Undisclosed large international pharmaceutical company (multi-year development and manufacturing partnership)

In June 2013, we entered into a multi-year development partnership agreement with an undisclosed, large international pharmaceutical company. The development work will be done in Flamel's Pessac facility (see "Item 4. *Manufacturing*"). In April 2014, this strategic partner announced its intention to terminate the current product under development, however the overall partnership remains in place and we may agree to develop future products with this partner. As a result, we cannot predict what future revenues, if any, will result from this partnership. In addition, the development of a performing manufacturing process may trigger interest in additional supply agreement. In 2013, we received $556,000 in development fees.

Manufacturing

The manufacturing facilities for our drug delivery platforms are located in Pessac, France, near Bordeaux (hereinafter referred as "Pessac facility"). These facilities provide us with two commercial scale production lines for the manufacture of Coreg CR microparticles, and another production line used for other Micropump-based formulations (i.e. the production of certain pharmaceutical products, including commercial quantities of our microencapsulated drugs). The facility has been audited and is approved by the U.S., the European (EMA) and the French regulatory agencies, ANSM (formerly "AFSSAPS")) and is, we believe, cGMP compliant. Such approval qualifies us to manufacture certain approved pharmaceutical products for sale in most countries in Europe and the U.S.

In the past, in addition to production activities related to our core businesses, we were able to build on our capabilities and experience with GSK and other pharmaceutical customers to engage in toll manufacturing for pharmaceutical partners.

Our Pessac facility equally provides us with one cGMP pilot plant for our Medusa™ platform. We are able to manufacture qualification batches and clinical batches of our polymers. This facility supports the production of polymer for the needs of our projects based on our Medusa platform.

The facility also provides us with non-commercial capabilities for both our Micropump® and Medusa™ platforms. With our experienced workforce and cGMP operations, we are able to perform scale-up activities and clinical batch manufacturing for our Micropump platform, and synthesis of Medusa's polymers specific and pilot batch manufacturing of our Medusa-based formulations.

During 2013, our commercial manufacturing capacity utilization ranged from 50% to 65% of total capacity.

The manufacture of the NDA-submitted products by Éclat is outsourced to contract manufacturing organizations (CMO) in accordance with supply agreements that expire in 2017. Flamel is currently investigating the transfer of the scale up of its own proprietary products to CMOs in the US, in particular for products regulated and sold in the U.S. marketplace.

Government Regulation

The design, testing, manufacturing and marketing of certain new or substantially modified drugs, biological products or medical devices must be approved, cleared or certified by regulatory agencies, regulatory authorities and Notified Bodies under applicable laws and regulations, the requirements of which may vary from country to country. This regulatory process is lengthy, expensive and uncertain. In the United States, the FDA regulates such products under various federal statutes, including the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act. Similar requirements exist in the Member States of the European Union and are imposed by the European Commission and the competent authorities of EU Member States. There can be no assurance that we or our collaborative partners will be able to obtain such regulatory approvals or clearances or certification of conformity on a timely basis, if at all, for any products under development. Delays in receipt or failure to receive such approvals, clearances, or certifications of conformity, the revocation of previously received approvals or clearances, or certifications of conformity, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We believe our delivery platforms, when used in conjunction with therapeutic pharmaceuticals, and development products acquired from Éclat, are subject to drug and biological product approval or marketing authorization requirements. In the United States and the European Union, biological products, such as therapeutic proteins and peptides, generally are subject to the same FDA and EU regulatory requirements as other drugs, although some differences exist. For example, for some biological products a biologic license application (BLA) is submitted for approval for commercialization instead of the New Drug Application (“NDA”) or Abbreviated New Drug Application (“ANDA”) used for other drugs. Also, unlike drug products, some biological products are subject to FDA lot-by-lot release requirements and those approved under a BLA currently cannot be the subject of ANDAs. Insulin, which is regulated as a drug product, typically has not been the subject of ANDAs. However, the FDA is working on a variety of issues pertaining to the possible development of biosimilars and there can be no assurance that this type of submission will continue to be unavailable for insulin. Additionally, our delivery platforms likely will be regulated by the FDA as ‘combination products’ if they are used together with a biologic or medical device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. In the European Union, applications for marketing authorization of innovative drugs, which are essentially products that are neither generics nor biosimilars, are addressed on a case by case basis by the EMA, followed by a decision of the European Commission, or by the competent authorities of the EU Member States.

New Drug and Biological Product Development and Approval Process

United States and European Union

Regulation by governmental authorities in the United States and other countries is a significant impact in the development, manufacture, and marketing of biological and drug products and in ongoing research and product development activities. The products of all of our pharmaceutical and biotechnology partners as well as our own products will require regulatory approval by governmental agencies and regulatory authorities prior to commercialization. In particular, these products are subject to manufacturing according to stringent cGMP quality principles, and rigorous, pre-clinical and clinical testing and other pre-market approval requirements by the FDA, the European Commission and regulatory authorities in other countries. In the United States and the European Union, various statutes and regulations also govern, or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical and biological products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

The FDA and European Union’s statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or drug products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific uses. Approved biological and other drugs, as well as their manufacturers, are subject to ongoing review (including requirements and restrictions related to record keeping and reporting, FDA, European Commission and EU Member States competent authorities' approval of certain changes in manufacturing processes or product labeling, product promotion and advertising, and pharmacovigilance, which includes monitoring and reporting adverse reactions, maintaining safety measures, and conducting dossier reviews for marketing authorization renewal). Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use, or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting the commercial prospects of our pharmaceutical and biotechnology partners' potential products or uses or products that incorporate our technologies. Any failure by our pharmaceutical and biotechnology partners to comply with current or new and changing regulatory obligations, and any failure to obtain and maintain, or any delay in obtaining, regulatory approvals, could materially adversely affect our business.

The process for new drug and biological product development and approval has many steps, including:

Chemical and Formulation Development

Pharmaceutical formulation taking into account the chemistry and physical characteristics of the drug or biological substance is the beginning of a new product. If initial laboratory experiments reveal that the concept for a new drug or biological product looks promising, then, a variety of further development steps and tests complying with internationally recognized guidance documents will have to be continued, in order to provide for a product ready for testing in animals and, after sufficient animal test results, also in humans.

Concurrent with pre-clinical studies and clinical trials, companies must continue to develop information about the properties of the drug product and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product, and the manufacturer must develop and validate methods for testing the quality, purity and potency of the final products. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Pre-Clinical Testing

Once a biological or drug candidate is identified for development, the candidate enters the pre-clinical testing stage. This includes laboratory evaluation of product chemistry and formulation, as well as animal studies of pharmacology (mechanism of action, pharmacokinetics) and toxicology which may have to be conducted over lengthy periods of time, to assess the potential safety and efficacy of the product as formulated. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations, the Animal Welfare Act and its regulations in the US and the Clinical Trials Directive and related national laws and guidelines in the EU Member States. Violations of these laws and regulations can, in some cases, lead to invalidation of the studies, then requiring such studies to be replicated. In some cases, long-term pre-clinical studies are conducted while clinical studies are ongoing.

Investigational New Drug Application

USA: The entire body of chemical or biochemical, pharmaceutical and pre-clinical development work necessary to administer investigational drugs to human volunteers or patients is summarized in an Investigational New Drug ("IND") application to the FDA. The IND becomes effective if not rejected by the FDA within thirty (30) days after filing. There is no assurance that the submission of an IND will eventually allow a company to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations to ensure the quality and integrity of clinical trial results and data. These regulations include the requirement that, with limited exceptions, all subjects provide informed consent. In addition, an institutional review board ("IRB"), composed primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. Failure to adhere to good clinical practices and the protocols, and failure to obtain IRB approval and informed consent, may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

European Union: The European equivalent to the IND is the Investigational Medicinal Product Dossier ("IMPD") which likewise has to contain pharmaceutical, pre-clinical and, if existing, previous clinical information on the drug substance and product. An overall risk-benefit assessment critically analyzing the non-clinical and clinical data in relation to the potential risks and benefits of the proposed trial must also be included. The intended clinical trial must be submitted for authorization by the regulatory authority(ies) of each EU Member States in which the trial is intended to be conducted prior to its commencement. The trial shall be conducted on the basis of the protocol as approved by an Ethics Committee(s) in each EU Member State (EU equivalent to IRBs) before the trial commences. Before submitting an application to the competent authority, the sponsor must register the trial in the EudraCT database where it will be provided with a unique EudraCT number from the EudraCT database.

Clinical Trials

Typically, clinical testing involves the administration of the drug or biological product first to healthy human volunteers and then to patients with conditions needing treatment under the supervision of a qualified principal investigator, usually a physician, pursuant to a 'protocol' or clinical plan reviewed by the FDA- and the competent authorities of the EU Member States along with the IRB or Ethics Committee (via the IND or IMPD submission). The protocol details matters such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study and the parameters to be used to monitor safety and efficacy.

Clinical trials are time-consuming and costly, and typically are conducted in three sequential phases, which sometimes may overlap. Phase I trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In phase II, in addition to safety, the product is studied in a patient population to evaluate the product's efficacy for the specific, targeted indications and to determine dosage tolerance and optimal dosage. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. With limited exceptions, all patients involved in a clinical trial must provide informed consent prior to their participation. Meeting clinical endpoints in early stage clinical trials does not assure success in later stage clinical trials. Phase I, II, and III testing may not be completed successfully within any specified time period, if at all.

The FDA and the competent authorities of EU Member States monitor the progress of each clinical trial phase conducted under an IND or IMPD and may, at their discretion, reevaluate, alter, suspend or terminate clinical trials at any point in this process for various reasons, including a finding that patients are being exposed to an unacceptable health risk or a determination that it is unethical to continue the study. The FDA, the European Commission and the competent authorities of EU Member States can also request additional clinical trials be conducted as a condition to product approval. The IRB, the Ethics Committee, and sponsor also may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns arise. Such holds can cause substantial delay and in some cases may require abandonment of product development. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations, the Clinical Trials Directive and/or internationally recognized guidance (such as "ICH", or "International Conference on Harmonization").

New Drug Application or Biological License Application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug or biological candidate is effective and that the drug is safe for its intended use, an NDA or "BLA" ("Biological License Application") may be submitted to the FDA. The application must contain all of the information on the drug or biological candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability (shelf-life). NDAs and BLAs are often over 100,000 pages in length. If FDA determines that a Risk Evaluation And Mitigation Strategy ("REMS") is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits. Submission of an NDA or BLA does not assure FDA approval for marketing.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing (the U.S. prerequisite for dossier review). It may refuse to file the application and request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. There is a strong presumption for advisory committee review for any drug containing an active ingredient not previously approved. The FDA is not bound by the recommendation of an advisory committee. Under the Prescription Drug User Fee Act (PDUFA), submission of an NDA or BLA with clinical data requires payment of a fee. In return, the FDA assigns an action date of 10 months from acceptance of the application to return of a first 'complete response,' in which the FDA may approve the product or request additional information. (Although PDUFA also provides for a six-month "priority review" process, we do not anticipate it applying to any of our products or our partners' products.) There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA, if at all. If the FDA's evaluation of the NDA or BLA is not favorable, the FDA usually will outline the deficiencies in the submission and request additional testing or information. Notwithstanding the submission of any requested additional information, or even in lieu of asking for additional information, the FDA may decide that the marketing application does not satisfy the regulatory criteria for approval and issue a complete response letter, communicating the agency's decision not to approve the application.

FDA approval of an NDA or BLA will be based, among other factors, on the agency's review of the pre-clinical and clinical data submitted, a risk/benefit analysis of the product, and an evaluation of the manufacturing processes and facilities. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA or BLA. For instance, FDA may require us to provide data from additional preclinical studies or clinical trials to support approval of certain development products acquired from Éclat. Among the conditions for NDA or BLA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to cGMP standards and requirements. Manufacturing establishments often are subject to inspections prior to NDA or BLA approval to assure compliance with cGMPs and with manufacturing commitments made in the relevant marketing application.

Patent Restoration and Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an Abbreviated New Drug Application, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the "Reference Listed Drug," or "RLD". Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective. .

505(b)(2) NDAs. If a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under Section 505(b)(2) of the Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on published scientific literature and the FDA's finding that the RLD is safe and effective, and must submit its own data of safety and effectiveness to an extent necessary because of the differences between the products. With regard to certain development products acquired from Éclat, we intend to submit 505(b)(2) NDAs, relying solely on published scientific literature. We do not plan to conduct additional preclinical studies or clinical trials for these 505(b)(2) NDAs.

RLD Patents. An NDA sponsor must advise the FDA about patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner file suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months from the date of receipt of the notice. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Regulatory Exclusivities. The Hatch-Waxman Act may provide periods of regulatory exclusivity for products that would serve as RLDs. If a product is a "new chemical entity," or NCE, – generally meaning that the active moiety has never before been approved in any drug – there may be a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent. Because it takes time for the FDA to review and approve an application once it has been accepted for filing, five-year NCE exclusivity usually effectively means the ANDA or 505(b)(2) application is not approved for a period well beyond five years from approval of the RLD.

A product that is not an NCE may qualify for a three-year period of exclusivity, if the NDA contains clinical data that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for a product that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use. For example, Coreg CR received three-year exclusivity for the clinical trials that demonstrated the safety and efficacy of the new, controlled-release dosage form; that exclusivity, which has expired, blocked other controlled-release products.

Patent Term Restoration. Under the Hatch-Waxman Act, a portion of the patent term lost during product development and FDA review of an NDA or 505(b)(2) application is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate.

Other Marketing Exclusivity

Pediatric Exclusivity. Section 505A of the FDC Act provides for six months of additional exclusivity and patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. Coreg CR received such pediatric exclusivity, which extended the three-year new clinical trial exclusivity it previously obtained, as well as the protection of the listed patents. The statutory provision permitting the award of pediatric exclusivity expired on October 1, 2012, and there can be no guarantee that Congress will reauthorize this provision, or do so without significant changes.

Other Countries

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by regulatory authorities must be obtained in any other country prior to the commencement of marketing of the product in that country. The approval procedure may vary from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Under European Union legislation, product authorization is granted for an initial period of five years. The authorization may subsequently be renewed for an unlimited period on the basis of a re-evaluation of the risk-benefit balance by the competent authorizing authority. In the EU, marketing authorization of drugs is according to either a centralized, decentralized or mutual recognition procedure, generally depending on the nature and type of drug. Certain designated drugs may be authorized only in accordance with the centralized procedure by the European Commission following an opinion by the European Medicines Agency ("EMA"). The centralized procedure is mandatory for pharmaceutical products developed by means of biotechnological processes (recombinant DNA, controlled expression of genes coding, hybridoma and monoclonal antibody methods), products containing new actives substances indicated for the treatment of AIDS, cancer, diabetes and neuro-degenerative diseases, orphan designated medicinal products and advanced therapy products. Other pharmaceutical products may be authorized in accordance with the centralized procedure where it is demonstrated that they contain new active substances or are demonstrated to have a significant therapeutic benefit, or where they constitute a scientific or technical innovation, or are in the interest of patients at Community level. Where authorization is in accordance with the decentralized or mutual recognition procedures, approval is either by "mutual recognition," whereby the authorization granted by the competent authorities of one EU Member States are recognized by the authorities of other EU Member States, or where the competent authorities of each EU Member State authorize a product on the basis of an identical dossier, with one national authority taking care of the dossier intensively and coordinating activities. To the extent possible, clinical trials of our products are designed to develop a regulatory package sufficient for the grant of marketing authorization in the EU approval according to the Community Code on medicinal products.

Regulatory approval of prices for certain drugs is required in France and in many other countries outside the United States. In particular, many EU Member States make the reimbursement of a product within the national social security system conditional on the agreement by the seller not to sell the product above a fixed price in that country. Also common is the unilateral establishment of a reimbursement price by the national authorities, often accompanied by the inclusion of the product on a list of reimbursable products. Related pricing discussions and ultimate governmental approvals can take several months to years. Some countries require periodic pricing updates and renewals at intervals ranging from two to five years. Some countries also impose price freezes or obligatory price reductions. We cannot assure you that, if regulatory authorities establish lower prices for any product incorporating our technology in any one EU Member State, this will not have the practical effect of requiring our collaborative partner correspondingly to reduce its prices in other EU Member States. We can offer no assurance that the resulting prices would be sufficient to generate an acceptable return on our investment in our products.

Regulation of Combination Drugs

Medical products containing a combination of drugs or biological products may be regulated as 'combination products' in the United States. A combination product generally is defined as a product comprising components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device.

To determine which FDA center or centers will review a combination product submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. It is possible that our delivery platforms, when coupled with a drug, biologic or medical device component, could be considered and regulated by the FDA as a combination product.

If the primary mode of action is determined to be a drug, the product will be reviewed by the Center for Drug Evaluation and Research ("CDER") either in consultation with another center or independently. If the primary mode of action is determined to be a medical device, the product would be reviewed by Center for Devices and Radiological Health ("CDRH") either in consultation with another center, such as CDER, or independently. In addition, FDA could determine that the product is a biologic and subject to the jurisdiction of the Center for Biologic Evaluation and Research ("CBER"), although it is also possible that a biological product will be regulated by CDER.

In the European Union, drug combinations, that is, drug products containing two or more drug substances each of which has to contribute a proven advantage of therapy (e.g., synergism, less adverse reactions), are subject to drug regulations like all others. Products combining drug substances or drugs with a device may be subject to device and/or drug regulations, or may be classified as medical devices, depending on the individual case.

Marketing Approval and Reporting Requirements

If the FDA approves an NDA or BLA, the product becomes available for physicians to prescribe. The FDA may require post-marketing studies, also known as phase IV studies, as a condition of approval to develop additional information regarding the safety of a product. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA may require post-marketing studies or clinical trials, as well as periodic status reports, if new safety information develops. These post-marketing studies may include clinical trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks. Failure to conduct these studies in a timely manner may result in substantial civil fines and can result in withdrawal of approval.

In addition, the FDA may require distribution to patients of a medication guide or impose other requirements under a REMS for prescription products that the agency determines pose a serious and significant health concern in order to provide information necessary to patients' safe and effective use of such products.

In the European Union, the marketing authorization of a medicinal product may be made conditional on the conduct of phase IV post-marketing studies. Failure to conduct these studies in relation to centrally authorized products can lead to the imposition of substantial fines. Moreover, phase IV studies are often run by companies in order to obtain further information on product efficacy and positioning on the market in view of competitors and to assist in application for pricing and reimbursement.

Post-Marketing Obligations

Any products manufactured and/or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. For example, with respect to the Éclat product Bloxiverz™, the FDA has required the Company to conduct post-marketing non-clinical, toxicity studies by December 2016.

Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to expend time, money and effort in recordkeeping and quality control to assure that the product meets applicable specifications and other post-marketing requirements. Failure of the Company or our licensees to comply with FDA's cGMP regulations or other requirements could have a significant adverse effect on the Company's business, financial condition and results of operations.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and NDA or BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA or BLA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

The Food and Drug Administration Amendments Act of 2007 provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require additional post-marketing studies or clinical trials, labeling changes as a result of safety findings, registering clinical trials, and making clinical trial results publicly available.

In the European Union, stringent pharmacovigilance regulations oblige companies to appoint a suitably qualified and experienced Qualified Person resident in the European Economic Area, to prepare and submit to the competent authorities adverse event reports within specific time lines, prepare Periodic Safety Update Reports (PSURs) and provide other supplementary information, report to authorities at regular intervals and take adequate safety measures agreed with regulatory agencies as necessary. Failure to undertake these obligations can lead to the imposition of substantial fines.

Biologics Price Competition and Innovation Act of 2009

The Hatch-Waxman construct applies only to conventional chemical drug compounds, sometimes referred to as small molecule compounds approved under an NDA. On March 23, 2010, however, the "Biologics Price Competition and Innovation Act" of 2009, or "BPCIA", was signed into law. It creates an abbreviated approval pathway for biological products that are "biosimilar" to a previously approved biological product, which is called the "reference product." This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a "full" BLA were submitted, by relying to some extent on FDA's previous review and approval of the reference product to which the proposed product is similar. If a proposed biosimilar product meets the statutory standards for approval (which include demonstrating that it is highly similar to the reference product and there are no clinically meaningful differences in safety, purity or potency between the products), the proposed biosimilar may be approved on the basis of an application that is different than the standard BLA. In addition, a biosimilar product may be approved as interchangeable with the reference product if the proposed product application meets standards intended to ensure that the biosimilar product can be expected to produce the same clinical result as the reference product.

Regulation of Medical Devices

United States

In the United States, medical devices are classified into Class I, II or III on the basis of the controls deemed by the FDA to be reasonably necessary to ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, and adherence to cGMPs) and Class II devices are subject to special controls (e.g., performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must require premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices or those found not to be substantially equivalent to legally marketed devices).

Other Countries

The marketing of medical devices in the EU is governed by a variety of EU legislative provisions and related guidance documents commonly referred to as MEDDEVs, the consequences of which depend on the intended use and the classification of the device. Although medical devices are not subject to authorization by the national authorities of EU Member States, manufacturers must ensure that the device complies with Essential Requirements established in applicable EU legislation with respect to design, safety, performance and manufacture. Medical Devices are, in addition, often subject to existing or future national regulation on pricing and reimbursement, which varies from country to country.

The manufacturer of a medical device cannot add a CE mark, which is a mandatory mark for medical devices sold in the EU, to the device unless the devices are demonstrated to comply with the obligations concerning safety and performance requirements of the EU medical device legislation. For devices other than those falling within Class I, the manufacturing facility and the medical device must undergo conformity assessment by a notified body in order to demonstrate compliance. The nature of this assessment will depend on the class of the product. Once all the necessary conformity assessment tasks have been completed, the notified body shall issue certificates of conformity, and the CE Mark may be affixed on the medical devices concerned by its manufacturer as that term is defined in applicable EU legislation. Although EU Member States must accept for marketing medical devices bearing a CE Marking without imposing further requirements related to product safety and performance, national regulatory authorities who are required to enforce compliance with requirements of the EU medical device legislation may restrict, prohibit and recall CE Marked medical devices if they consider, on the basis of available information that they are unsafe. EU Member States can impose additional requirements as long as they do not exceed the obligations provided for in EU medical device legislation or constitute technical barriers to trade. They can also dispute the classification of the device chosen by the device manufacturer. Within the EU, pre CE marking compliance for all medical devices must be supported by clinical data of a type and to the extent set out by the EU directives. When the CE mark has been placed on a medical device its manufacturer must comply with a strict vigilance system. This includes establishment of a vigilance reporting system in accordance with the MEDDEVs provided by the European Commission, which are intended to ensure that reportable adverse events are reported to the competent authority, that information is collected and maintained and that regular reporting obligations are fulfilled.

Other Regulation

Controlled Substances Act. Our Trigger Lock™ delivery platform is designed to control the release of narcotics and other active ingredients subject to abuse. Narcotics are “controlled substances” under the Controlled Substances Act. The federal “Controlled Substances Act” (“CSA”), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, regulates the manufacture and distribution of narcotics and other controlled substances, including stimulants, depressants and hallucinogens. The CSA is administered by the “Drug Enforcement Administration” (“DEA”), a division of the U.S. Department of Justice, and is intended to prevent the abuse or diversion of controlled substances into illicit channels of commerce.

Any person or firm that manufactures, distributes, dispenses, imports, or exports any controlled substance (or proposes to do so) must register with the DEA. The applicant must register for a specific business activity related to controlled substances, including manufacturing or distributing, and may engage in only the activity or activities for which it is registered. The DEA conducts periodic inspections of registered establishments that handle controlled substances and allots quotas of controlled drugs to manufacturers and marketers’ failure to comply with relevant DEA regulations, particularly as manifested in the loss or diversion of controlled substances, can result in regulatory action including civil penalties, refusal to renew necessary registrations, or proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. In addition to these federal statutory and regulatory obligations, there may be state and local laws and regulations relevant to the handling of controlled substances or listed chemicals.

cGMP. Current Good Manufacturing Practices rules apply to the manufacturing of drugs and medical devices. Our manufacturing facilities and laboratories are subject to inspection and regulation by French regulatory authorities in accordance with applicable EU provisions governing cGMP and may also be subject to the United States’ and other countries’ regulatory agencies. Mutual recognition agreements for government inspections exist between the United States, the EU, Canada, Australia and New Zealand.

In addition to regulations enforced by the FDA, we are also subject to French, U.S. and other countries’ rules and regulations governing permissible laboratory activities, waste disposal, handling of toxic, dangerous or radioactive materials and other matters. Our research and development involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by French, EU, U.S. and other foreign rules and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

Health Care Fraud and Abuse. We are subject to a number of federal and state laws pertaining to health care “fraud and abuse,” such as anti-kickback and false claims laws. Under anti-kickback laws, it is illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance via regulations and that there are few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (such as the Medicare and Medicaid programs) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our sales and marketing activities relating to our products could be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. In addition, similar sanctions and penalties can be imposed upon executive officers and employees, including criminal sanctions against executive officers. As a result of the potential penalties that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. In addition to the reasons noted above, our activities could be subject to challenge due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. There also are an increasing number of federal and state laws that require manufacturers to make reports to states on pricing, marketing information, and payments and other transfers of value to healthcare providers. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent authorities.

Healthcare Reimbursement

In both U.S. and foreign markets, sales of our potential products as well as products of pharmaceutical and biotechnology companies that incorporate our technology into their products, if any, will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. The U.S. market for pharmaceutical products is increasingly being shaped by managed care organizations, pharmacy benefit managers, cooperative buying organizations and large drugstore chains. Third-party payers are challenging the price and cost effectiveness of medical products and services. Uncertainty particularly exists as to the reimbursement status of newly approved healthcare products. There can be no assurance reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

Description of Property

Our corporate headquarters and the research center are located in Venissieux, France (a suburb of Lyon) in four adjacent leased facilities totaling approximately 58,000 square feet. One building of approximately 12,800 square feet houses administrative offices and research laboratories, including equipment dedicated to polymer characterization and analytical research. The lease on this facility expires in 2016. A second facility comprising approximately 12,800 square feet houses equipment dedicated to our Micropump technology has a lease which expires in 2015. The third facility of approximately 6,800 square feet houses analytical laboratories and quality control and the lease expires in 2016. The fourth facility of approximately 26,000 square feet houses a biological laboratory and research laboratories with equipment for organic synthesis and polymerization, polymer formulation and small scale processing. The lease on this facility expires at the end of 2014 and is expected to be renewed. The facility has been audited by U.S., the European (EMA) and the French regulatory agencies, ANSM (formerly “AFSSAPS”) and is, we believe, cGMP compliant. Such approval qualifies us to manufacture certain approved pharmaceutical products for sale in most countries in Europe and the U.S (see “Item 4. *Manufacturing*”).

We own manufacturing facilities, of approximately 103,900 square feet, located in Pessac, France, which are housed on a 470,000 square foot lot in an industrial park not far from the Bordeaux airport (“Pessac Facility”). The facilities include manufacturing capabilities with spray-coating equipment and a clean room for the synthesis of Medusa’s polymers (see “Item 4. *Manufacturing*”).

The initial value of the facility is recorded in our financial books at the value of the liabilities corresponding to the retirement indemnities of the plant staff that we assumed at the time of the plant purchase in 1996, plus the additional investments made by us, less the depreciation and appropriate amortization.

We built a a new building on the site in 2004, which includes 8,600 square feet dedicated to our Medusa platform with a cGMP pilot plant, extended synthesis capacity and increased capacity to manufacture qualification batches and clinical batches of our polymers. This facility supports the production of polymer for the needs of our projects based on our Medusa platform. This facility was successfully inspected by the French Agency, ANSM (formerly “AFSSAPS”) in June 2008 and recorded officially as a GMP excipient manufacturing facility.

Our manufacturing facility of approximately 6,800 square feet is used for the manufacture of Coreg CR microparticles for GSK as well as other Micropump-based formulations (i.e. the production of certain pharmaceutical products, including commercial quantities of our microencapsulated drugs)and houses two suites of equipment, as well as a dedicated warehouse, analytical control laboratory and a technical area with air compressor units, refrigeration units for solvents, and heat boiler. In 2008 we expanded our Micropump Pilot Development facilities of this site increasing the available area by 14,300 square feet and renovating a further 4,500 square feet. The new facility houses administrative offices and process development areas which can be utilized for the production of both clinical and commercial batches, thus increasing our production capacity from two lines to three.

We have commercial and administrative activities located in St. Louis, Missouri. The office space consists of 5,300 square feet, and the lease expires in 2018.

During 2013, we expended $1.0 million on property and equipment.

See "Item 5, *Operations and Financial Review and Prospects*" for more information regarding our investment activities and principal capital expenditures over the last three years.

ITEM 4A. Unresolved Staff Comments

Not applicable

ITEM 5. Operating and Financial Review and Prospects

The following should be read in conjunction with "Item 3. *Key Information*" and the Company's Financial Statements and the Notes related thereto appearing elsewhere in this Annual Report. See also "Item 11. *Quantitative and Qualitative Disclosures About Market Risk*".

Overview

We are a specialty pharmaceutical company with a long history of expertise in drug delivery, focusing on the development of safer and more efficacious formulations, tackling unmet medical needs in the process. The acquisition of Éclat on March 13, 2012 has created a more vertically integrated company, benefiting from greater development and commercial expertise, best in class drug delivery platforms and more near-term and mid-term potential value creating catalysts. Since our acquisition of Éclat, Flamel is now focusing not only on the development and licensing of versatile, proprietary drug delivery platforms but also on the development of novel, high-value products based on those delivery platforms. Flamel's new model allows us now to select, develop, seek approval for, and commercialize niche branded and generic products in the U.S. and most of the opportunities are self-funded. For more details, see "Item 4. *Information on the Company*".

The addition of Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) regulatory pathway, adds marketing and licensing knowledge of the commercial and regulatory process in the U.S. and EU, which we believe will enhance the ability of Flamel to identify potential product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and to license and market products in the U.S and EU. By adopting this revised strategy, the Company makes itself less dependent on the often, changing strategies of its partners, in the future. Revenues generated by Coreg CR remain a significant portion of our revenue and total revenues from GSK contributed to 66% of our revenues in 2013. However, we now have marketed product and products in late stage development that are not dependent on these collaborative relationships. The first product from the acquired Éclat's portfolio, Bloxiverz is currently marketed in the U.S and could have a significant impact on the Company's revenue generation and favorably impact its progression to profitability.

To complement the historical science-oriented strengths of Flamel as an innovator of drug delivery platforms, we now have enhanced our ability to pursue commercial opportunities and identify new product candidates. Our drug delivery platforms allow us to generate competitive differentiated product profiles (e.g. improvement of pharmacokinetics, efficacy and/or safety). These product development opportunities offer the ability to grow market share and to protect market position, through patent protection and/or product differentiation in multiple marketplaces. In 2013, we have specifically focused our Research and Development (R&D) efforts towards building-up an internal product portfolio; several products formulated using our proprietary drug delivery platforms are currently under development at Flamel in various stages of development. These products will be marketed either by the Company and/or by partners via licensing/distribution agreements. For more details, see "Item 4. Lead Products" and "Item 4. Other Products Under Development".

As a result of the shift to a specialty pharma model, Flamel's business is now becoming less dependent on its ability to work with partners in collaborative relationships to develop products using our drug delivery platforms. Nevertheless, Flamel is still exploring development, supply and licensing opportunities for its drug delivery platforms with carefully selected third parties, but does not intend to rely completely on those partnerships to create revenue and profit opportunities. As part of the rationalization of the Company's products pipeline initiated in 2012, we have continued our efforts to streamline and optimize existing partnerships (see "Item 4. *Strategic Alliances*"). Consequently, over 2013, our external project portfolio continued to reduce resulting in the decrease in R&D revenues.

Operating expenses increased in 2013 largely as a result of an unfavorable non-cash line item of $28.1 million resulting from the change in fair-value measurement of the liabilities outstanding for the acquisition of Éclat (see 16 and 22 to the Consolidated Financial Statements) as of December 31, 2013 compared with 2012. These commitments were valued at $31.9 million as of December 31, 2012 and at $58.9 million as of December 31, 2013. The valuations are based on current information and data, including financial projections related to the potential of the Éclat products, as well as the share price and interest rate in so far as they influence the value of the warrants. Absent the effects of the fair value measurement and impairment of assets, operating expenses decreased by $1.8 million in 2013. Our investment in research and development, or R&D, has increased as we pursue the development of the Éclat product portfolio and maintain our research efforts on our in-house product portfolio. We continue to maintain an aggressive approach to cost controls and are committed to challenging our costs on non-core activities. As projects advance to later stage development we expect to see an increase in R&D expenditure, including regulatory costs and the payment of FDA filing fees, which are expected to be $2 million for each of the Éclat products we expect to file for approval. Non-cash expenses relative to stock based compensation, amounted to $2.0 million in 2013 and $3.0 million in 2012.

In 2013, our investment in property and equipment was comparable with 2012. Investments were limited to maintenance of our property and equipment.

As in previous years, the majority of the Company's expenses were incurred in Euros, since the Company's base of operations is in France. However, a portion of revenues were, and will continue to be, denominated in U.S. dollars, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk". Although our reporting currency is the U.S. dollar, the Company's functional currency is the Euro. Conversion of the Company's financial accounts to U.S. dollars for reporting purposes is calculated in accordance with the value of the Euro to the U.S. dollar. See "Item 3. Key Information – Exchange Rates". As such, the Financial Statements are translated as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at quarterly weighted average exchange rates for the year, (3) cash flow statement quarterly weighted average exchange rates for the year, and (4) shareholders' equity accounts at historical rates. Consequently, the variation in the Euro relative to the U.S. dollar has an impact on the interpretation of the financial statements, which may differ from the underlying variations in the functional currency. For example, the weakening of the U.S. dollar relative to the Euro has resulted in a 3.3% decrease in the average value of the US dollar relative to the Euro between 2012 and 2013. Consequently, Euro denominated expenses will appear to have increased by an equivalent amount year on year simply as a result of the translation from Euro to U.S. dollars for reporting purposes. The closing value of the Euro relative to the U.S. dollar has increased by 4.5% resulting in a corresponding increase in amounts represented in the balance sheet as of December 31, 2013, compared with December 31, 2012. The Company does not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although it does, from time to time, purchase Euros against invoiced Dollar receivables. There is no outstanding hedging agreement as of December 31, 2013.

In certain instances we may compare expenses from one period to another in this Annual Report on Form 20-F using comparable currency exchange rates in order to assess our underlying performance before taking into account exchange fluctuations. To present this information, prior period expenses are converted into U.S. dollars at current year average exchange rates rather than exchange rates for the prior fiscal year. For example, if SG&A expenses were €6.7 million in each of fiscal year 2013 and fiscal year 2012, we would report $9.0 million of SG&A expenses in fiscal year 2013 (based on the quarterly weighted average exchange rates during 2013) and $8.6 million in fiscal year 2012 (based on the quarterly weighted average exchange rates during 2012). The presentation using comparable currency exchange rates would translate the fiscal 2012 expenses using the fiscal 2013 exchange rates and indicate that underlying expenses were flat rather than increasing by $0.4 million, as would be reported in the financial statements under U.S. GAAP. We use figures prepared on a comparable currency basis for internal analysis and communicate similarly externally from time to time, since we believe this appropriate in order to analyze variations in expenditure from one period to another. However, figures provided on a comparable currency basis are unaudited and are not measurements under U.S. GAAP.

Flamel's business is subject to substantial risks, including the uncertainties associated with the research and development of new products or technologies, the length and uncertainty linked to the results of clinical trials and regulatory procedures, uncertainties relating to collaborative arrangements with large companies, difficulties in the scale-up and manufacturing of its products, the uncertainty relating to the market acceptance of new products based on its technologies and uncertainties arising from the Éclat acquisition and the development and commercialization of its portfolio of products. The time required for the Company to achieve sustained profitability, and consequently, the amount of future losses, is highly uncertain. Operating losses may also fluctuate from quarter to quarter as a result of differences in timing of revenues recognized or expenses incurred. See "Item 3. *Key Information - Risk Factors*".

The Company has incurred substantial losses since its inception, and through December 31, 2013, had an accumulated deficit of approximately $236million. Flamel expects to maintain its investment in its research and development activities in line with the projects portfolio, while being vigilant to ensure that investments in non-core activities are limited. Thus, there can be no assurance that the Company will not continue to incur losses. We expect our research and development costs to increase as we pursue the development of our own products. We currently have one approved product on the market and an approval requests is pending with the FDA, with a PDUFA date of April 28 2014. We anticipate generating revenue streams on these products in 2014 and beyond, which will be supplemented by further products from the Éclat business in subsequent years which could have a significant impact on the Company's revenue generation and favorably impact its progression to profitability in the future.. In March 2014 we completed an underwritten public offering which generated $113.6 million in net proceeds. Subsequently; we repaid substantially all of our outstanding long-term debt amounting to $32 million and will use the remaining proceeds along with revenues generated from our Éclat pipeline products to pursue the development of our internal product portfolio, possible including clinical trials.

Critical Accounting Policies

Revenue Recognition

Revenue includes upfront licensing fees, milestone payments for R&D achievements, compensation for the execution of research and development activities.

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

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

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized at the hourly rate for the number of hours worked as the research and development work is performed. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

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. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of its products, an estimate of provision for sales return and allowances is recorded which reduces product sales. These adjustments include estimates for product returns, chargebacks, payment discounts and other sales allowances and rebates. The return allowance, when estimable, is based on an analysis of the historical returns of the product or similar products.

For new product launches the Company recognizes revenue based on net product sales of wholesalers to their customers, until sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, renowned wholesaler inventory tracking service. Net sales of wholesalers to their customers are calculated by deducting estimates for returns for wholesaler customers, chargebacks, payment discounts and other sales or discounts offered from the applicable gross sales value. When the Company has the ability to estimate product returns from wholesalers, product sales are recognized upon shipment, net of discounts, returns and allowances. Estimates for product returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors.

The Company launched Bloxiverz™ in July of 2013 and determined that market acceptance of the product had not occurred given the absence of wholesaler reorders and insufficient data to determine product returns. For the twelve months ended December 31, 2013, the criteria for recognizing the revenue were not met and the Company deferred $1.1M of revenue as of December 31, 2013.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classifies these revenues in 'Other Revenues'.

The Company receives revenue under signed feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

The Company receives financial support for various research and investment projects from governmental agencies. Revenue from conditional grants related to specific development projects is recognized as an offset to operating expenses when all conditions stated in the grant have been met and the funding has been received. Revenue from unconditional grants for research and development projects are recognized as an offset to research and development expense on a pro-rata basis over the duration of the program. Funding can be received to finance certain research and development projects which are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and the funds are recognized in the Income Statement as 'Other Income'.

The Company receives financial support for capital investment programs from partners. Revenue from these operations is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets in the consolidated statement of operations.

The Company benefits from tax credits on a percentage of eligible research and development costs. These tax credits can be refundable in cash and are not contingent upon future taxable income. As explained in note 5 to the Consolidated Financial Statements, the company determined that the research tax credit should be classified as a research and development grant and the tax credit is recognized as an offset to research and development expense.

Research and Development Costs

R&D expenses are comprised of the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical or developmental manufacturing costs, and contract and other outside service fees, filing fees and regulatory support. Research and development expenditures are charged to operations as incurred.

Generally, the Company's research and development efforts are either funded internally or by third-party partners. The Company's research and development efforts are organized to allow internal services to support both internal research programs and partner-sponsored research programs simultaneously, reflecting the Company's approach and belief that internal projects can benefit from the research and development efforts funded by partners and vice versa. Due to this approach, the Company views research and development costs as a whole across the organization and by technological platform. The Company monitors progress on the basis of the actual number of hours/days worked and the cost of outside services for pre-clinical and clinical activities.

Management Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates reflected in the consolidated financial statements include, but are not limited to, purchase price allocation of its acquisitions, remeasurement of liabilities accounted at fair value, the recoverability of the carrying amount and estimated useful lives of long-lived assets, in progress R&D and goodwill, share-based compensation expenses, evaluation of long term personnel compensation, calculation of R&D tax credit, and valuation allowance of deferred tax assets. Management makes these estimates using the best information available at the time the estimates are made; however, actual results could differ from those estimates.

Impairment of Long-Lived Assets

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the asset (or the group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted future cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the asset, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on management assumptions and are subject to risk and uncertainty.

Long-Term Debt

Long Term debt associated with the acquisition liabilities arising from the acquisition of Eclat Pharmaceuticals are accounted at fair-value. Long-term debt associated with the Deerfied Facility and Broadfin Facility agreements are accounted for at amortized cost. The Company elected the fair value option for the measurement of the long-term liability associated with the Deerfield and Broadfin Royalty agreements.

Translation of Financial Statements

The reporting currency of the Company is the U.S. dollar and the functional currency of the Company is the Euro. As such, the Financial Statements are translated for reporting purposes as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Results of Operations

Years Ended December 31, 2013, 2012 and 2011

Operating Revenues

The Company had total revenues of $22.4 million in 2013, $26.1 million in 2012 and $32.6 million in 2011. The following table shows revenues attributable to license and research activities in millions of US dollars:

		2011	2012	2013
LICENSE AND RESEARCH REVENUES		**$ 10.6**	**$ 9.3**	**$ 6.5**
RESEARCH		**$ 6.3**	**$ 5.1**	**$ 5.0**
Research	Merck Serono	2.4	-	-
	Pfizer	0.1	-	-
	Eagle Pharmaceuticals	0.3	0.7	0.0
	Undisclosed Partners	3.5	4.4	5.0
LICENSES		**$ 4.3**	**$ 4.3**	**$ 1.5**
Upfront Payment	Merck Serono	1.4	2.7	-
	Baxter International	0.9	-	-
	Pfizer	0.7	-	-
	Undisclosed Partners	1.3	1.3	0.6
Milestones	Merck Serono	-	-	-
	Undisclosed Partners	-	0.3	0.9
TOTAL		**$ 10.6**	**$ 9.3**	**$ 6.5**
	Merck Serono	3.8	2.7	-
	Baxter International	0.9	-	-
	Pfizer	0.8	-	-
	Eagle Pharmaceuticals	0.3	0.7	-
	Undisclosed Partners	4.8	5.9	6.5

In 2013, license and research revenue totaled $6.5 million. License and research revenue in 2012 and 2011 totaled $9.3 million and $10.6 million, respectively. In 2013 research and development revenue totaled $5.0 million and license revenue totaled $1.5 million. In 2012 research and development revenue totaled $5.1 million and license revenue totaled $4.3 million. In 2011 research and development revenue totaled $6.3 million and license revenue totaled $4.3 million. License and research revenues in 2013 and 2012 have decreased compared with 2011 due to the termination of certain partnership agreements with Merck-Serono, Pfizer and Baxter International. This correlates with our transition from a drug delivery company to a self-funded specialty pharma company.

Research and development revenues in 2013 consisted primarily of $5.0 million from undisclosed partners. Research and development revenues in 2012 consisted primarily of $0.7 million from Eagle Pharmaceuticals and $4.4 million from undisclosed partners. Research and development revenues in 2011 consisted primarily of $2.4 million from Merck Serono, $0.1 million from Pfizer, $0.3 million from Eagle Pharmaceuticals and $3.5 million from undisclosed partners.

License revenues in 2013 consisted primarily of $1.5 million from undisclosed Partners. License revenues in 2012 consisted primarily of $2.7 million from Merck Serono (amortization of up-front payments) and $1.6 million from undisclosed partners. License revenues in 2011 consisted primarily of $1.4 million from Merck Serono (amortization of up-front payments), $0.9 million from Baxter International (amortization of up-front payments), $0.7 million from Pfizer (amortization of up-font payment) and $1.3 million from undisclosed partners.

In 2013, product sales and services revenues totaled $9.0 million, $9.7 million in 2012 and $13.4 million in 2011. In 2011 product sales relate solely to sales of Coreg CR microparticles to GSK. In 2012 and 2013, product sales include sales of Coreg CR microparticles to GSK and product sales of Hycet for a total of respectively $0.6 million and $1.0 million. The license for commercialization of Hycet was divested in November 2013. Revenues from the sale of Coreg CR microparticles have decreased in 2013 as a result of the lower demand. The multi-year supply agreement concluded in 2011 provides for fixed unit pricing, as opposed to a cost-plus arrangement in the previous supply agreement, and guaranteed minimal payments minimum period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at its sole discretion by giving six months written notice.

Other revenues of $6.9 million in 2013, $7.1 million in 2012 and $8.6 million in 2011, consisted primarily of royalties from GSK related to the sale of Coreg CR and to a lesser extent royalties from Corning related to the sale of photochromic lenses that incorporate technology licensed from Flamel.

Operating Expenses

The Company had total costs and expenses of $72.5 million in 2013, $34.5 million in 2012, and $42.2 million in 2011.

The terms of acquisition of Éclat Pharmaceuticals in March 2012 included the issuance of a $12 million note, the repayment of which was tied to the approval and net sales of certain Éclat products, and which was repaid in full in March 2014, 3.3 million warrants and earn-out payments based on the gross profit achieved on the Éclat products (see note 2 to the Consolidated Financial Statements). These commitments are revalued and reassessed at each balance sheet date based on information and data available at that time, including financial projections related to the potential of the Éclat products, as well as the share price and interest rate in so far as they influence the value of the warrants. An unfavorable $28.1 million adjustment was accounted in 2013 and a favorable adjustment of $18.8 million in 2012 from the updated fair-value measurement of these liabilities. In addition, in 2012 a $7.2 million charge was recognized to reflect the impairment of acquired R&D assets, mainly reflecting changes in market opportunities occurring post-acquisition for one of the acquired pipeline products.

As in previous years, in 2013 the majority of costs were incurred on research and development. R&D costs totaled $26.7 million in 2013, $26.1 million in 2012 and $25.1 million in 2011. At comparable currency exchange rates, research and development costs increased marginally by $0.1 million in 2013.

Our total research and development expenditures can be split in the following categories ($in millions):

	2011	2012	2013
Salaries and employee benefits	16.9	16.5	13.4
Materials and Supplies	3.9	3.4	2.6
Pre-clinical, Clinical, Regulatory and Manufacturing outside services	2.5	3.9	8.1
Grants and R&D Tax credit	(7.8)	(6.7)	(6.2)
Depreciation of facilities and equipment	2.0	1.7	2.0
Other Expenses & Taxes	6.4	6.2	6.0
Stock-based Stock Compensation	1.2	1.1	0.8
Total	**25.1**	**26.1**	**26.7**

The human resources allocated to each technological platform over the past three years are as follows:

Full Time Equivalents	**2011**	**2012**	**2013**
Micropump®	25	33	47
LiquiTime®	-	1	27
Trigger Lock™	10	11	1
Medusa™	87	78	50

The cost of outside services borne by the Company for pre-clinical, clinical, contract manufacturing and regulatory activities by technological platform over the past three years are as follows ($USD in millions):

		2011	2012	2013
Pre-Clinical	Micropump®	0.3		
	Medusa™	1.7	0.4	0.2
	Micropump®			0.3
Clinical	Trigger-Lock™	0.3	-	-
	Medusa™	0.2	0.3	
Contract Manufacturing	Éclat	-	1.7	5.5
Regulatory	Éclat	-	1.5	1.9

As of December 31, 2013, Flamel had total research tax credits receivable of $20.6 million. In 2012 the Company obtained an advance secured against the tax credit generated in 2011 valued at $6.1 million as of December 31, 2013. This advance would normally have been received as a cash payment of $6.8 million in 2015. In 2011 the Company obtained an advance secured against the tax credit generated in 2010 valued at $7.1 million as of December 31, 2013. This advance would normally have been received as a cash payment of $7.9 million in 2014. The Company earned a research and development credit of $5.8 million in 2013, $6.5 million in 2012 and$6.1 million in 2011. In 2013, the Company received reimbursement of the 2012 tax credit since it met the criteria to benefit from immediate reimbursement (i.e. considered to be a Small and Medium Enterprise under the EU legislation).

The average number of employees dedicated to research and development activities has decreased year over year. This decrease was driven by the reduction of the external project portfolio.. Total employees as of December 31, 2013 amounted to 251 compared with 256 at the end of 2012 and 267 at the end of 2011. The Company has spent $0.5 million on pre-clinical and clinical studies in 2013 compared with $0.7 million in 2012 and $2.5 million in 2011. This reduction is predominantly due to a reduction in pre-clinical spending on Medusa projects as management has reprioritized project development efforts between the platforms, refocused innovative opportunities to expand the technological platforms, which, in early phases of formulation and prototyping requires, reduced external expenditure. Costs are expected to increase in the future as projects advance into clinical development. In 2013, costs of $7.4 million have been incurred on the Éclat portfolio for contract manufacturing services and regulatory activities, including FDA filing fees. These costs are associated with the development of products with outside contractors and costs for preparation of the FDA filing, including meetings with the agency at key points in the development program and FDA filing and submission fees.

Costs of products and services sold were $4.3 million in 2013, $5.9 million in 2012 and $6.3 million in 2011. These costs relate primarily to the supply of commercial quantities of microparticles of Coreg CR to GSK and the availability of relevant production capacity. In 2013, costs have continued to decline in line with ongoing demand for the product, optimized production scheduling and reduced payroll costs from the release of payroll accruals following changes we implemented in employee compensation, moving to a plan that is performance-based from prior plans that were based on longevity of service.

SG&A expenses, amounted to $13.3 million in 2013, $14.2 million in 2012 and $10.8 million in 2011. SG&A expenses included stock based compensation expense of $1.2 million in 2013, $1.9 million in 2012 and $1.2 million in 2011. SG&A expenses in 2013 include Éclat-related expenses of $4.3 million for 2013 and 2.0 million for 2012. SG&A expenses decreased by $1.2 million over 2012 expenses at comparable currency exchange rates. This decrease is due to legal costs and severance costs incurred as a consequence of the acquisition of Éclat in March 2012 and the change in Chief Executive Officer.

Non-Operating Items

Interest income and realized gains on the sale of monetary SICAVs (*Sociétés d'Investissement à Capital Variable*) were $0.3 million in 2013 compared with of $0.6 million in 2012 and $0.7 million in 2011. Interest income has reduced due to the reduction in cash and marketable securities. Interest expense was $2.6 million in 2013, $118,000 in 2012 and $24,000 in 2010. The increase in interest expense is due to the $15 million debt financing concluded with Deerfield Management in February 2013 and to a lesser extent the $5 million tranche drawn down on the $15 million debt financing concluded with Broadfin Healthcare Master Fund in December 2013.

The characteristics of the debt financing are as follows:

- Deerfield Management: nominal interest rate of 12.5% payable quarterly in arrears on the first day of each quarter. Principal amount of the loan repayable over four years as follows: 10% July 1, 2014 and 20%, 30%, and 40% on the second, third and further anniversary respectively, of the original disbursement date. The total principal amount of the Debt of $15 million and accrued interest was repaid on March 24, 2014. Deerfield Management will also receive a 1.75% royalty on net sales of certain products sold by Éclat Pharmaceuticals, subject to required regulatory approvals and sales of these products, until December 31, 2024.
- Broadfin Healthcare Master Fund: $15 million debt financing divided into three tranches of $5 million each, of which only the initial loan $5 million was drawn. Nominal interest rate of 12.5% payable quarterly in arrears on the first day of each quarter. Principal amount of the loan repayable by January 1, 2017. The total principal amount and outstanding accrued interest was repaid on March 24, 2014. Broadfin will also receive a 0.834% royalty on net sales of certain products sold by Éclat Pharmaceuticals, subject to required regulatory approvals and sales of these products, until December 31, 2024.

The Royalty agreements concluded with Deerfield Management and Broadfin Healthcare Master Fund of respectively 1.75% and 0.834% on net sales of certain products sold by Éclat Pharmaceuticals, subject to required regulatory approvals, generated non-cash expense of $2.0 million in 2013. The fair value option was elected for the measurement of the Royalty liabilities.

Foreign exchange loss was $288,000 in 2013, $180,000 in 2012 and a gain of $273,000 in 2011. These exchange gains and losses are generated by transactions denominated in foreign currency and in particular revenues denominated in USD. The variation in foreign exchange gain/loss results from the volume of operations in foreign currency and the variation in exchange rates over the year.

Other income in 2013 amounted to $0.6 million and consisted of reimbursement of the deductible from a 2007 class action that was dismissed in 2013, compared with $0.1 million in 2012 and 2011.

Income tax benefit in 2013 amounted to $11. million, which reflects tax benefit of statutory net operating losses generated by the operations in the US. In 2012 income tax benefit amounted to 4.7 million of which 4.8 million reflected tax benefits of operations in the US. French business tax calculated on gross profits generated tax expense of $0.1 million in 2013 and 2012, $0.2 million in 2011.

As of December 31, 2013, the Company had $201.6 million in French net operating loss carry-forwards and $36.6 million in US net operating losses carry-forwards. The French carry-forwards can be utilized against future operating income indefinitely, subject to an annual limitation of €1.0 million and 50% of taxable income in excess of this threshold and the US carry-forwards can be utilized against future operating income subject to a limitation of $1.8 million per year on pre-acquisition tax losses of $4.9 million.

Net Income/Loss

For the year ended December 31, 2013, the Company reported a net loss of $42.9 million or $1.69 per share. For the year ended December 31, 2012, Company reported a net loss of $3.2 million or $0.13 per share. For the year ended December 31, 2011, the Company reported a net loss of $8.8 million or $0.36 per share. For the year ended December 31, 2013 adjusted net loss was $16.1 million or $0.63 per share and for the year ended December 31, 2012 adjusted net loss was $17.7 million or $0.70 per share.

Flamel is providing below adjusted net income, which is a non-GAAP financial. Flamel believes that an evaluation of its ongoing operations (and comparison of current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to disclosing its financial results determined in accordance with GAAP, Flamel is disclosing adjusted net income that excludes the net of tax effect of fair value remeasurement on acquisition liabilities and royalty agreements, impairment of intangible assets and includes operating cash flows associated with the commitments to make earnout payments to Deerfield, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. The Company's management uses these non-GAAP measures internally for forecasting, budgeting and measuring its operating performance. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most closely applicable GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP.

	Twelve months ended December 31,			
	2012		**2013**	
GAAP Net income (loss) and diluted earnings (loss) per share	$ (3,228)	$ (0.13)	$ (42,925)	$ (1.69)
Fair value remeasurement of acquisition liabilities	(18,834)		28,135	
Fair value remeasurement of royalty agreements	-		1,990	
Tax effects of the above items	258		(2,416)	
Asset Impairment net of tax effects	4,302			
Earn-out acquisition payment payable	(160)		(840)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share	$ (17,661)	$ (0.70)	$ (16,057)	$ (0.63)

Liquidity and Capital Resources

On December 31, 2013, the Company had $6.6 million in cash and cash equivalents and $0.4 million in marketable securities compared with $2.7 million in cash and cash equivalents and $6.4 million in marketable securities on December 31, 2012 and $3.5 million in cash and cash equivalents and $21.0 million in marketable securities on December 31, 2011. The decrease in the level of cash and cash equivalents and marketable securities results from the funding of ongoing operations and the reduction in revenues due to termination of certain projects.

Net cash used in operating activities was $20.7 million as of December 31, 2013, compared with $23.1 million as of December 31, 2012, and $10.3 million as of December 31, 2011. As of December 31, 2013 net cash used in operating activities reflected a net loss of $42.9 million, offset by non-cash movements of $23.9 million, including $30.1 million of expenses on remeasurement of acquisition liabilities, ($11.3) million tax benefit which will be set off against future taxable income, $3.1 million of depreciation on property and equipment, $2.0 million relative to stock compensation expense, ($0.7) million of grants recognized to the income statement and $0.7 million of calculated interest on amortized method on debt financing. Movement in working capital year on year generated a decrease in cash of ($1.7) million representing cash decrease of ($1.4) million related to the commercial launch of Bloxiverz™ and inventory build, offset by increased accrued liabilities and decreased prepaid expenses on R&D expenditure of $1.5 million, increase in R&D tax credit of $0.7 million, offset by a reduction in current and long-term liabilities following the reversal of payroll accruals following the change in compensation policy for a total of ($2.5) million. Cash used by operating activities decreased year on year due to a reduction in cash operating expenses.

Net cash provided by investing activities was $6.0 million in 2013, compared with $15.4 million in 2012. Investing activities included proceeds from the sale of marketable securities for $7.2 million and purchase of marketable securities for $1.1 million. In 2012 and 2013, the Company has maintained the same investment policy and the sale and purchase of marketable securities are limited to the financing of ongoing operations. In 2013, $1.0 million was spent in the purchase of property and equipment compared with $1.1 million in 2012. In 2013, $1.0 million was received as proceeds from the disposal of property and equipment, including the disposal of the license for commercialization of Hycet. In 2012, $1.8 million of cash was acquired following the acquisition of Éclat in March, 2012.

Net cash provided by financing activities was $18.3 million in 2013 and includes loans of $15 million received subsequent to the debt financing concluded with Deerfield Management in February 2013 and $5 million of the $15 million debt financing concluded with Broadfin Healthcare Master Fund in December 2013, and earn-out payments for the acquisition of Éclat of $0.9 million. Cash provided by financing activities was $7.0 million in 2012 and includes an advance of $5.7 million received in the second quarter of 2012 from Oseo, secured against the research and development tax credit of $6.1 million earned in 2011. Cash provided by financing activities was $6.1 million in 2011 and included an advance of $7.4 million received in the second quarter of 2011 from Oseo, secured against the research and development tax credit of $7.7 million earned in 2010 and reimbursement of an advance from Oseo of ($1.9) million, secured against the 2007 research tax credit.

Since its inception, the Company's operations have consumed substantial amounts of cash and may continue to do so. In March 2014, the Company completed an underwritten public offering of 10,800,000 American Depositary Shares, each representing one ordinary share of Flamel, with an offering price of $9.75 per ADS. Total net proceeds, after deduction of commissions, amounted to $113.6 million. The Company repaid a total of $32 million of principal on outstanding debt on March 24, 2014 relating to the Acquisition liability note with Deerfield of $12 million in principal, the Deerfield Facility Agreement of $15 million in principal and the Broadfin Facility Agreement of $5 million in principal.

The Company believes that ongoing research and product development programs are adequately funded for the next year and believe current working capital to be sufficient for the Company's present requirements, including commercial launch of products from the Éclat pipeline. The Company also believes current financial resources and cash from various grants, royalty payments, licenses and commercialization of products will be sufficient to meet the Company's cash requirements in the near future. We believe we have sufficient funds to finance operations and cash requirements for at least the next twelve months.

As of December 31, 2013, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities totaled $0.4 million at December 31, 2013 and $6.4 million at December 31, 2012.

As of December 31, 2013, the Company had loans of $2.6 million from Oseo, $2.0 million advance from the French Ministry of Industry for a 'Proteozome' research project. These loans do not bear interest and are repayable only in the event that the research is successful technically or commercially. The Company has evaluated the debt due for the purchase of Éclat Pharmaceuticals at $48.4 million as of December 31, 2013. The obligations relative to the acquisition arise from the $12 million senior note issued by our U.S. subsidiary, Flamel US Holdings, Inc., that was guaranteed by us and our subsidiaries and secured by the membership interests and assets of Éclat and the commitment by Flamel US Holdings, to pay 20% of any gross profit generated by certain Éclat launch products and two warrants to purchase a total of 3,300,000 ADSs. The Company has evaluated the debt due on the Facility Agreement and Royalty Agreement concluded with Deerfield management at $12.5 million and $4.6 million respectively and the debt due on the Facility Agreement and Royalty Agreement concluded with Broadfin Healthcare Master Fund at $2.8 million and $2.2 million respectively as of December 31, 2013 See *Item 10. Additional Information – Material Contracts and Note 16 – Long Term Debt* for more information regarding these obligations. Long-term indebtedness associated with the $12 million acquisition note, Deerfield Facility and Broadfin Facility was subsequently repaid in March 2014 as described above.

In 2004, Flamel and GSK entered into a four year supply agreement which included provisions for payments to Flamel of $20.7 million to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. Flamel has immediate title to the building and fixtures and title to production equipment vests with GSK for the duration of the supply agreement.

If the Company breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment.

Upon cessation of the supply agreement, in the normal course, GSK will pass title to all production equipment to Flamel without cost. A total of $8.2 million has been spent on the acquisition of buildings and fixtures and a total of $11.1 million has been spent on behalf of GSK for the purchase of production equipment. The funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $0.3 million and as a long term liability for $3.4 million. The total liability is being amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

In July 2006, the supply agreement was supplemented by an agreement with GSK to partly sponsor the expansion of facilities at Pessac from two lines to three. The provisions of the agreement include payments to Flamel of $8.1 million to partially support the acquisition of equipment, building and fixtures to which Flamel has immediate title. As of December 31, 2013 these funds are classified as a current liability for $0.3 million and as a long term liability for $2.6 million. The liability is being amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. The amortization of the liability is reflected as an offset of the depreciation of the related assets.

In June 2011, the Company obtained an advance from OSEO for $7.4 million secured against the research tax credit due to the Company by the tax authorities for expenditures incurred in 2010, totaling $7.7 million. In June 2012, the Company obtained an advance from OSEO for $5.7 million secured against the research tax credit due to the Company by the tax authorities for expenditures incurred in 2011, totaling $6.1 million. The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.9%. As of December 31, 2013 the total liability amounted to $13.2 million classified as a current liability for $7.1 million and as a long term liability for $6.1 million.

The contractual cash obligations of the Company as of December 31, 2013, are as follows:

	Payments Due by Period				
(in thousands of U.S. dollars)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Long-Term Debt Obligations (see Note 16) [1]	$ 124,053	$ 20,286	$ 52,343	$ 28,647	$ 22,777
Capital Lease Obligations (see Note 17)	$ 194	$ 91	$ 103	-	-
Operating Leases Obligations (see Note 23.2)	$ 1,580	$ 846	$ 716	$ 18	-
Other Long-Term Liabilities reflected on the Registrant's Balance Sheet under GAAP (see Note 21)	$ 997	$ 153	$ 250	$ 260	$ 334
Total Contractual Cash Obligations	$ 126,824	$ 21,376	$ 53,412	$ 28,925	$ 23,111

Future interest payments included in capital lease obligations amount to a total of $6,000.

[1] The Company repaid a total of $32 million of principal on outstanding debt on March 24, 2014 relating to the Acquisition liability note, $12 million in principal, Deerfield Facility Agreement, $15 million in principal and Broadfin Facility Agreement, $5 million in principal.

Off-Balance Sheet Arrangements

As of December 31, 2013, the Company has no off-balance sheet arrangements.

ITEM 6. Directors, Senior Management and Employees

Directors and Senior Management

The following table sets forth the name and position of the directors of the Company as of December 31, 2013. Michael S. Anderson, former Chief Executive Officer of Éclat, was appointed Chief Executive Officer of the Company, effective March 13, 2012.

Name	Position	Year of Initial Appointment
Stephen H. Willard (1) (4)	Non-Executive Chairman of the Board of Directors	2000
Michael S. Anderson	Chief Executive Officer and Director	2012
Catherine Bréchignac (3)	Director	2011
Guillaume Cerutti (1) (2)	Director	2011
Dr. Francis J.T Fildes (1) (2)	Director	2008
Craig Stapleton (1) (2) (3)	Director	2011
Elie Vannier (2) (3)	Director	2005

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Appointed as a Director in 2001

The following table sets forth the name and position of the executive officers and senior management of the Registrant.

Name	Position	Year of Initial Appointment
Michael S. Anderson	Chief Executive Officer	2012
Siân Crouzet	Principal Financial Officer	2005
Christian Kalita	Directeur Général Délégué Pharmacien Responsable (Chief Pharmacist)	2005
Steven A. Lisi	Senior Vice President, Business and Corporate Development	2012
Gregg Stetsko	Vice President, Research and Development	2013
Phillandas T. Thompson	Senior Vice President and General Counsel	2013

The term of office of each of the directors expires at the year 2014 ordinary shareholders meeting. With the exception of Mr. Anderson, all of the directors are independent as defined in NASDAQ Marketplace Rule 5605 (a)(2).

In accordance with French law governing a *société anonyme*, the Company is managed by its Board of Directors and by its *Directeur Général* (Chief Executive Officer), who has full executive authority to manage the affairs of the Company, subject to the prior authorization of the Board of Directors or of the Company's shareholders for certain decisions expressly specified by law. In addition, the *Directeur Général* may submit to the Board of Directors the nomination of one or more, but not more than five *Directeurs Généraux Délégués*.

The Board of Directors reviews and monitors Flamel's business, financial and technical strategies. In addition, under French law, the Board of Directors prepares and presents the year-end French statutory accounts of the Company to the shareholders and convenes shareholders' meetings. French law provides that the Board of Directors be composed of no fewer than three and not more than 18 members. The actual number of directors must be within such limits and may be provided for in the *statuts*, our bylaws, or determined by the shareholders at the annual general meeting of shareholders. The number of directors may be increased or decreased only by decision of the shareholders. No more than a third of directors may be over the age of seventy.

Under French law, a director may be an individual or a legal entity. A legal entity that serves as a director must appoint an individual, as a 'permanent representative,' who represents such legal entity on the Board. There is no limitation, other than applicable age limits, on the number of terms that a director may serve. Directors are elected by the shareholders and serve until the expiration of their respective terms, or until their resignation, death or removal, with or without cause, by the shareholders. Vacancies which exist on the Board of Directors: (i) because of the resignation or death of a director, may be filled by the Board of Directors pending the next shareholders' meeting, if the number of remaining directors after such resignation or death exceeds the minimum number of directors set forth in the Articles of Association; (ii) for whatever reason, must be filled by the Board of Directors within three months of such vacancy, if the number of remaining directors after such vacancy is less than the minimum number of directors set forth in the Articles of Association but exceeds the minimum legal requirement; and (iii) for whatever reason, must be filled immediately at a shareholders' meeting if the number of directors after such vacancy is less than the minimum legal requirement.

The Company's Board of Directors currently consists of seven members, six of whom are outside directors and whom we believe bring broad experience to Flamel:

- Mr. Stephen H. Willard was the Chief Executive Officer through March 12, 2012 and has been Chairman of the Board of Directors of Flamel Technologies SA since June 2012. Prior to being asked to serve as CEO by the Board of Directors in June 2005, Mr. Willard was the Company's Chief Financial Officer and General Counsel;

- Catherine Bréchignac is the Permanent Secretary for the French National Academy of Sciences, former Chairperson of the French National Centre for Scientific Research (CNRS), a member of the American Academy of Arts and Sciences and French Ambassador for Sciences and Technology;

- Guillaume Cerutti is the Chairman and Chief Executive Officer of Sotheby's France, former CEO of the French Directorate General for Competition, Consumer Affairs and Repression of Fraud, (Ministry of Finance and Economy) and currently serves as Chairman of the Board of the 'Institut de Financement du Cinéma et des Industries Culturelles';

- Francis JT Fildes is the former Senior Vice President: Head of Global Development for AstraZeneca, PLC, former Director of ProStrakan Pharmaceuticals PLC and a current Director of Fildes Partners Ltd and a Fellow of the Royal Society of Medicine and the Royal Society of Chemistry;

- The Honorable Craig Stapleton is the former United States Ambassador to France and Director of Carlisle Bank and Lead Director of Abercrombie and Fitch;

- Elie Vannier, is the former Group Managing Director of WALLY, former Chief Operating Officer of GrandVision SA, and a current Director of Ingénico, Famar, New Cities Foundation, GPPH and Pharmacie Principale;

Board Practices

Non-executive Directors of the Company receive fees for their services and are entitled to subscribe for warrants (as described in Note 19.3 to our Consolidated Financial Statements). Directors' fees and warrants are proposed by the Board of Directors and are submitted for the approval of shareholders at the annual general shareholders' meeting. Non-executive directors are reimbursed, upon request, for expenses incurred in attending Board meetings. Upon termination, no benefits are provided to non-executive directors.

All directors are elected by the shareholders at each ordinary shareholders' meeting approving the annual French statutory accounts of the Company. A quorum of the Board consists of one-half of the members of the Board of Directors, and actions are generally approved by a vote of the majority of the members present or represented by other members of the Board of Directors. The Chairman of the Board does not have the ability to cast a deciding vote in the event of a tie vote. A director may give a proxy to another director, but a director cannot represent more than one other director at any particular meeting. Members of the Board of Directors represented by another member at meetings do not count for purposes of determining the existence of a quorum.

Directors are required to comply with applicable law and Flamel's *statuts*. Under French law, directors are liable for violations of French legal or regulatory requirements applicable to '*sociétés anonymes*', violation of the Company's *statuts* or mismanagement. Directors may be held liable for such actions both individually and jointly with the other directors.

French law requires that companies having at least 50 employees for a period of 12 consecutive months has a *Comité d'Entreprise* (Employee Representation Committee) composed of representatives elected from among the personnel. The Employee Representation Committee was formed in 1997. Two of those representatives are entitled to attend all meetings of the Board of Directors of the Company and shareholders' meetings, but they do not have any voting rights.

The Board has a Compensation Committee comprised of solely independent directors, namely Francis J.T. Fildes (Chairman), Guillaume Cerutti, Ambassador Craig Stapleton, and Stephen H. Willard. The Compensation Committee makes recommendations to the Board on the compensation of the executive officers of the Company, including the Chief Executive Officer. The Board makes the final decisions on compensation. The Board has an Audit Committee comprised of solely independent directors, namely Guillaume Cerutti (Chairman), Francis J.T. Fildes, Ambassador Craig Stapleton, and Elie Vannier. The Audit Committee recommends to the Board the selection of Flamel's independent auditors and reviews the findings of the auditors and operates in accordance with the Audit Committee Charter, which is reviewed annually. The Board has a Nominating and Corporate Governance Committee, composed of solely independent directors, namely Ambassador Craig Stapleton (Chairman), Catherine Bréchignac and Elie Vannier. Each of the Compensation Committee, Audit Committee, and Nominating and Corporate Governance Committee has a written charter. The Audit Committee Charter outlines the roles and responsibilities of the Audit Committee which includes appointment, compensation and oversight of the work of any registered public accounting firm employed by the Company and review of all related party transactions. The Audit Committee also assists the Board in oversight of: (1) the integrity of the financial statements of the Company; (2) the adequacy of the Company's system of internal controls; (3) compliance by the Company with legal and regulatory requirements; (4) the qualifications and independence of the Company's independent auditors; and (5) the performance of the Company's independent and internal auditors. The Company also has an informal Scientific Advisory Board.

The Chief Executive Officer of Flamel has full executive authority to manage the affairs of Flamel and has broad powers to act on behalf of Flamel and to represent Flamel in dealings with third parties, subject only to those powers expressly reserved by law or corporate resolutions of the Board of Directors or the shareholders. The Chief Executive Officer determines, and is responsible for the implementation of the goals, strategies and budgets of Flamel, which are reviewed and monitored by the Board of Directors. The Board of Directors has the power to appoint and remove, at any time, the Chief Executive Officer. The Chief Executive Officer is appointed for a term of one year, expiring at the end of the general shareholders' meeting called to approve the financial statements for the prior financial year.

Compensation of Directors and Officers

During 2013, the amount of compensation paid or accrued for the benefit of executive officers of the Company and its subsidiaries for services in all capacities was $531,222 for Michael S. Anderson. In the event that Mr. Anderson's is terminated for any reason, subject to him being in office at least one year, other than for cause, Flamel will pay Mr. Anderson €500,000, subject to his signing a settlement agreement with Flamel. A total of $992,000 has been accrued at December 31, 2013, including applicable social charges.

On June 20, 2013, a shareholders' meeting approved a total amount of annual attendance fees to be allocated to the Board of 225,000 Euros, of which 210,000 Euros was subsequently distributed. For the fiscal year 2013 a total amount of 222,500 Euros ($295,525) was paid or accrued for the benefit of non-executives for their services in that capacity. Executive directors do not receive compensation for their service in that capacity.

Executive Officers

The Company's executive officers and senior management includes the following individuals:

Mr. Michael S. Anderson has been Chief Executive Officer of Flamel Technologies SA since his appointment effective on March 13, 2012. He has also served as Chief Executive Officer of Éclat Pharmaceuticals LLC since its creation in November 2010. Previously Mr. Anderson worked for KV Pharmaceuticals as President and CEO of its generic business, ETHEX Corporation and President and CEO of Ther-Rx Corporation, a leader in women's healthcare. Mr. Anderson also has worked for Schein Pharmaceuticals and started his career at A.H Robins.

Mrs. Sian Crouzet has been Principal Financial Officer of Flamel Technologies SA since March 2008. She previously worked as Financial Controller France for McCormick & Company Inc. Mrs. Crouzet also worked five years as an external auditor with Ernst and Young (France and UK). She is a UK Chartered Accountant and a graduate of Bradford University (UK).

Mr. Christian Kalita has been Responsible Pharmacist, Director of Quality and Regulatory Affairs of Flamel Technologies SA since 2005. He worked previously at Skye Pharma as Director of Quality for Europe. Mr. Kalita also worked at Merck Lipha and Merck generics for 10 years in different roles as Chief Pharmacist, Head of Quality Control Management and Head of Industrial Affairs.

Mr. Steve Lisi was appointed Senior Vice President, Business and Corporate Development in June 2012. Previously, he served as partner at Deerfield Management, a leading global healthcare focused hedge fund, between 2007 and 2012. Prior to that, he was founder and managing member/portfolio manager at Panacea Asset Management LLC (New York) between 2005 and 2007, and healthcare portfolio manager at Millenium Partners (New York) between 2002 and 2005. Between 1994 and 2002, he served as analyst in several companies. Mr. Lisi is a graduate of Pepperdine University (Malibu, California).

Dr. Gregg Stetsko was appointed Vice President, Research and Development in February 2013. Dr. Stetsko has over 30 years of experience in the pharmaceutical business, with roles of increasing responsibility at Sandoz, Sterling Winthrop, Ligand Pharmaceutical, and Amylin, where he was Vice President of Operations and Global Leader for the Amylin-Lilly Exenatide Alliance. More recently, he was Chief Scientific Officer for Eagle Pharmaceuticals and a Principal at Tahoe Consulting. Dr. Stetsko earned a B.S. degree in Pharmacy from the University of Rhode Island and a Ph.D. in Industrial and Physical Pharmacy from Purdue University.

Mr. Phil Thompson was appointed Senior Vice President and General Counsel in November 2013. Previously, he served as Vice President, Legal Affairs at West-Ward Pharmaceutical Corp., Vice President, General Counsel at Paddock Laboratories, Inc., Vice President, Strategic Business Transactions and Assistant General Counsel at KV Pharmaceutical Co, Associate General Counsel at Barr Laboratories, Inc. and a corporate associate at White & Case, LLP. Mr. Thompson earned a B.A. from Washington University and is also a graduate of the University of Michigan Law School and the University of Michigan's Ross School of Business.

Options to Purchase Securities from the Company

On June 20, 2013, the shareholders of the Company authorized the issuance of up to 300,000 warrants reserved to a category of beneficiaries comprising directors and Scientific Advisory Board's members who are neither authorized agents nor employees of the company, but including the Chairman of the Board of Directors of which 200,000 have been subscribed for.

On June 20, 2013, the Board of Directors authorized the Directors of the Company, Mrs. Bréchignac and Mssrs, Cerutti, Fildes, Stapleton,Vannier and Willard, to subscribe for 45,000 warrants each and two members of the Scientific Advisory Board to subscribe for 10,000 warrants each at a subscription price of 0.43 Euros per warrant ($0.58) based on the historical exchange rate on the grant date. Each warrant is exercisable to purchase one share at a price of 4.58 Euros ($6.14) based on the historical exchange rate on the grant date.

On June 20, 2013 the shareholders of the Company authorized the creation of a share option plan (the '2013 Plan'), which authorizes the Board of Directors to issue options to subscribe for up to 600,000 Shares. The 2013 Plan is designed to permit the granting of 'qualifying stock options' under French tax law principles as well as 'incentive stock options' under the Internal Revenue Code of 1986, as amended. Options granted under the 2013 Plan will have an exercise price based on the market price of the share, in the form of ADS, on NASDAQ, on the day preceding the date of the Board meeting, provided however, that such price is not less than 80% of the average market price for the shares on the NASDAQ, in the form of ADSs, during the last twenty trading days preceding said meeting. In this case, the price of the shares should be equal or superior to 80% of the average market price for the share on NASDAQ, in the form of ADS, during the last twenty trading days preceding such meeting. The options granted under the 2013 Plan are exercisable up to ten years from the date of grant.

On June 20, 2013, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards, the shares are definitively owned by the beneficiaries two years following their allocation, and the beneficiaries are required to retain the shares for a further two years.

Free Share Awards Granted and Warrants Subscribed from January 1, 2013 to March 31, 2014

	Stock Options	Exercise Price in Euros	Exercise Price in USD (1)	Expiration	Free Share Awards
Anderson	80,500	3.00	4.07	February 2023	
Bourboulou	-	-	-	-	7,000
Capelle	5,000	3.00	4.07	February 2023	
	6,000	5.35	7.36	December 2023	5,000
Chatellier	7,000	3.00	4.07	February 2023	
	20,000	5.35	7.36	December 2023	10,000
Crouzet	10,000	3.00	4.07	February 2023	
	20,000	5.35	7.36	December 2023	10,000
Kalita	5,000	3.00	4.07	February 2023	
	6,000	5.35	7.36	December 2023	5,000
Lisi	25,000	3.00	4.07	February 2023	
	95,000	5.35	7.36	December 2023	
Macke	7,500	3.00	4.07	February 2023	
	20,000	5.35	7.36	December 2023	10,000
Stetsko	100,000	3.00	4.07	February 2023	
	80,000	5.35	7.36	December 2023	10,000
Thompson	100,000	5.35	7.36	December 2023	

(1) Historical value at date of grant.

Employees

As of December 31, 2013, Flamel had 246 full-time employees and an average of 251 employees over 2013. The following table sets forth the average number of employees for each of the last three years based on their principal geographic locations.

Employees

Year End	**Venissieux (1)**	**Pessac (2)**	**U.S. (3)**	**Total**
2011	141	138	3	282
2012	125	131	8	264
2013	118	124	9	251

(1) Primarily engaged in research activities
(2) Primarily engaged in technical and pharmaceutical development activities and manufacturing
(3) Primarily engaged in administrative, commercial and marketing activities

The Company's future will depend on its ability to attract and retain highly qualified personnel. The Company believes that its employee relations are good. As required by French law, the Company has created an Employee Representation Committee ('Comité d'Entreprise') composed of representatives elected from among the personnel. Two of these representatives are entitled to attend certain meetings of the Board of Directors of the Company, but they do not have any voting rights.

Share Ownership

The following table sets forth the share ownership of directors and executive officers as of the date indicated:

OWNERSHIP OF SHARES AS OF MARCH 31, 2014

Name	Shares Owned	% of Ordinary Shares Outstanding	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD (1) $	Expiration	Free Share Awards	Total	Total %
Willard	449,998	1.18%		150,000	14.81	19.70	December 2014			
				100,000	16.23	19.35	December 2015			
				100,000	25.39	33.46	December 2016			
				75,000	4.03	5.17	December 2018			
				100,000	5.06	7.46	December 2019			
				100,000	5.29	7.01	December 2020			
				100,000	3.28	4.39	December 2021		1,174,998	2.57%
Bréchignac	1	0.00%							1	0.00%
Cerutti	1	0.00%	50,000		3.54	5.04	June 2015			
			45,000		4.58	6.14	June 2017		95,001	0.21%
Fildes	1	0.00%	50,000		5.44	6.68	June 2014			
			50,000		3.54	5.04	June 2015			
			45,000		4.58	6.14	June 2017		145,001	0.32%
Stapleton	303,251	0.79%	50,000		3.54	5.04	June 2015			
			45,000		4.58	6.14	June 2017		398,251	0.87%
Vannier	1	0.00%	45,000		4.58	6.14	June 2017		45,001	0.10%
Anderson	26,000	0.07%		275,000	5.25	6.93	March 2022			
				80,500	3.00	4.07	February 2023	35,250	416,750	0.91%
Crouzet	44,560	0.12%		49,990	12.86	15.83	September 2015			
				5,000	16.23	19.35	December 2015			
				3,750	25.39	33.46	December 2016			
				10,000	5.06	7.46	December 2019			
				5,000	3.28	4.39	December 2021			
				10,000	3.00	4.07	February 2023			
				20,000	5.35	7.36	December 2023	20,000	168,300	0.37%
Kalita	29,500	0.08%		50,000	16.23	19.35	December 2015			
				6,500	25.39	33.46	December 2016			
				5,000	5.06	7.46	December 2019			
				5,000	5.29	7.01	December 2020			
				5,000	3.28	4.39	December 2021			
				5,000	3.00	4.07	February 2023			
				6,000	5.35	7.36	December 2023	10,000	122,000	0.27%
Lisi	117,000			275,000	4.09	5.01	July 2022			
				25,000	3.00	4.07	February 2023			
				95,000	5.35	7.36	December 2023	2,500	514,500	1.13%
Stetsko	20,000	0.05%		100,000	3.00	4.07	February 2023			
				80,000	5.35	7.36	December 2023	10,000	210,000	0.46%
Thompson	-			100,000	5.35	7.36	December 2023		100,000	0.22%

(1) Historical value at date of grant

ITEM 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth as of March 31, 2014, the percentage of Ordinary Shares owned by Deerfield Capital Management L.P. and Broadfin Capital LLC., the persons each known to beneficially own more than 5% of the Company's Ordinary Shares. The table set forth below is based on information contained in Schedule 13/Ds or 13/Gs on file with the SEC as of March 31, 2014. Percentages are calculated based on 38,267,550 total shares, which was the total number of shares outstanding as of March 31, 2014.

Identity of Person or Group	Amount of Ordinary Shares Owned	Percentage of Class
Deerfield Capital L.P	4,333,475(1)	11.32%
Broadfin Capital LLC	3,767,911	9.85%

1) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G filed with the SEC on December 5, 2012 by Deerfield Capital L.P. and its affiliates ("Deerfield"). Deerfield shares beneficial ownership with Deerfield Special Situations Funds LP in respect of 532,712 Ordinary Shares, Deerfield Private Design Fund II LP in respect of 1,432,534 Ordinary Shares, Deerfield Private Design International II in respect of 1,641,574 Ordinary Shares, and Deerfield Management Company L.P. and Deerfield Special Situations Fund International Limited in respect of all 726,655 Ordinary Shares. Such reported amount excludes warrants to purchase ADSs representing 3,300,000 ordinary shares of Flamel held by Breaking Stick Holdings, LLC (formerly Éclat Holdings), the manager of which is Deerfield Management Company, LP and of which Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. are members. The address of Deerfield is 780 Third Avenue, 37th Floor, New York, New York 10017.
2) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G/A filed with the SEC on February 14, 2014 by Broadfin Capital LLC ("Broadfin"). As of the close of business on December 31, 2012, Broadfin beneficially owned 2,491,261 ADRs, (The address of Broadfin is 237 Park Avenue, Suite 900, New York, New York 10017.

The Company's major shareholders do not have different voting rights. To the best of our knowledge, Flamel Technologies is not directly or indirectly owned or controlled by another corporation, by any government, or by any other natural or legal person. We are not aware of any arrangement that may at a subsequent date result in a change of control. As of March 31, 2014, the Company has Ordinary shareholders of record including the Bank of New York. Approximately 97.4% of the Company's outstanding shares are represented by American Depositary Shares (ADS). Approximately 2.07% of the Ordinary Shares are held in France. No record holder resides in France.

Significant changes in the percentage ownership held of record by any of our major shareholders in the last three years, as reported to the SEC, were as follows:

Major Shareholder	Filing Date	Ownership Percentage
BVF, Inc.	February 10, 2010	14.49%
BVF Partners L.P.	February 11, 2011	11.56%
	January 11, 2012	7.84%
	February, 14, 2013	0.85%
Broadfin Capital LLC	September 28, 2012	5.12%
	February 18, 2013	9.80%
	June 13, 2013	7.80%
	February 14, 2014 [1]	9.85%
Deerfield Capital L.P.	August 31, 2011	4.90%
	December 5, 2011	5.01%
	January 4, 2012 [1]	11.32%
O.S.S. Capital Management LP	February 22, 2010	23.52%
Schafer Brothers LLC	March 31, 2010	13.1%
Oscar S. Schafer	February 14, 2011	12.47%
	January 4, 2012	0.0%
Visium Asset Management L.P.	April 9, 2010	7.58%
	February 14, 2011	7.09%
	February 10, 2012	7.74%
	February 14, 2013	0%

[1] Percentages have been adjusted to reflect the capital raise completed in March, 2014.

Related Party Transactions

In March 2012, we acquired, through our wholly owned subsidiary Flamel US, all of the membership interests of Éclat from Éclat Holdings, an affiliate of our largest shareholder Deerfield Capital L.P., for consideration primarily consisting of a $12 million senior, secured six-year note that is guaranteed by us and our subsidiaries and secured by the equity interests and assets of Éclat, two warrants to purchase a total of 3,300,000 ADSs of Flamel and commitments to make earnout payments of 20% of any gross profit generated by certain Éclat launch products and 100% of the gross profit generated by our former product Hycet®, which we sold in 2013, up to a maximum of $1 million. Upon closing of the acquisition, Mr. Anderson, the Chief Executive Officer of Éclat, was appointed Chief Executive Officer of Flamel. Mr. Anderson retains a minority interest in Éclat Holdings, renamed Breaking Stick, and does not have the ability to control this entity by virtue of his minority interest. The senior secured note was repaid in full in March 2014 using the net proceeds from our public sale of ADSs.

On February 4, 2013, we entered into a Facility Agreement (the “Deerfield Facility”), through Flamel US with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (together, the “Deerfield Entities”) providing for debt financing of $15 million by the Deerfield Entities (the “Loan”). The loan was repaid in full in March 2014 using the net proceeds from our public sale of ADSs.

The Deerfield Facility was subject to certain limitations, and allowed us to use the funds for working capital, including continued investment in our research and development projects. Interest accrued at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013, and on the first business day of each July, October, January and April thereafter Pursuant to the Deerfield Facility, we were required to pay the Deerfield Entities a fee of $112,500 for entering into the transaction and to reimburse the Deerfield Entities for legal costs and expenses incurred in effecting the transaction.

The Deerfield Facility agreement is attached hereto as Exhibit 4.7 and incorporated herein by this reference.

In conjunction with our entry in the Deerfield Facility, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, "Deerfield PDF/Horizon"). The Royalty Agreement provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales price of the products sold by us and any of our affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Royalty Agreement requires Éclat to take all commercially reasonable efforts to obtain the necessary regulatory approvals to sell the products in the United States and to market the Products after receiving such approvals.

The Royalty agreement is attached hereto as Exhibit 4.8 and incorporated herein by this reference.

We have also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the intellectual property and regulatory rights related to the products to secure the obligations of Éclat and Flamel US, including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement.

The Security Agreement is is attached hereto as Exhibit 4.8 and incorporated herein by this reference.

We have also entered into two pledge agreements on certain receivables and equipment we own. These agreements are required to be recorded under French law at the request of Deerfield.

As of December 3, 2013, we and certain of our U.S. subsidiaries entered into a Facility Agreement (the "Broadfin Facility") with Broadfin Healthcare Master Fund, Ltd. ("Broadfin") providing for loans by Broadfin in an aggregate amount not to exceed $15.0 million. The loans under the Facility were secured by a first priority security interest in intellectual property associated with our Medusa technology and a junior lien on substantially all of the assets of the borrowers, which were previously pledged in connection with the Deerfield Facility, the Royalty Agreement and the notes issued in connection with the Éclat acquisition. In addition, we have agreed to grant a junior lien on certain equipment located in France, if such equipment is pledged under the Deerfield Facility and/or the Éclat note.

Under the terms of the Broadfin Facility, upon closing Broadfin made an initial loan of $5.0 million and we had the ability to request, at any time prior to August 15, 2014, up to two additional loans in the amount of $5.0 million each, with funding subject to certain specified conditions. Loans under the Facility were scheduled to mature upon the earlier to occur of (i) January 31, 2017 and (ii) the repayment in full of all outstanding amounts under the Deerfield Facility, but in no event prior to November 15, 2015. We had the ability to prepay the outstanding loans under the Broadfin Facility at any time, without prepayment penalty and the full $5.0 million outstanding was subsequently repaid using a portion of the net proceeds from our public sale of ADSs in March 2014. Prior to repayment, interest accrued on the loan under the Broadfin Facility at a rate of 12.5% per annum, payable quarterly in arrears, commencing on January 1, 2014.

In connection with entering into the Broadfin Facility, we also entered into a Royalty Agreement with Broadfin, dated as of December 3, 2013 (the "Broadfin Royalty Agreement"). Pursuant to the Broadfin Royalty Agreement, we are required to pay a royalty of 0.834% on the net sales of certain products sold by Éclat Pharmaceuticals, LLC and any of its affiliates until December 31, 2024.

Concurrent with entering into the Braodfin Facility, we also amended the terms of the Deerfield Facility and the agreement governing the Éclat notes to, among other things, permit the indebtedness and liens under the Braodfin Facility and to grant a junior lien to the respective lenders on the Medusa Technology.

The Broadfin Facility and the Broadfin Royalty Agreement are attached hereto as Exhibits [4.10] and [4.11], respectively

Interests of Experts and Counsel

Not applicable

ITEM 8. Financial Information

Financial Statements

The financial statements contained in this Annual Report begin on page F-1.

Legal Proceedings

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in and we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding that management believes will have a material adverse effect on our consolidated financial position or results of operations.

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled Billhofer v. Flamel Technologies, et al. By Order dated March 8, 2013, the Court granted the Company's motion to dismiss and the action was dismissed with prejudice and costs. The complaint purported to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and seeks the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint that continued to name the Company and two previously named officers as defendants and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. On April 29, 2010, the lead plaintiff moved to withdraw and substitute another individual as lead plaintiff and to amend the Case Management Order. On June 22, 2010, the lead plaintiff voluntarily agreed to dismiss the action against one of the previously named officers. On September 20, 2010, the Court granted the lead plaintiff's withdraw and substitution motion and the parties proceeded to engage in fact discovery. On March 6, 2012, the Court issued its opinion granting the lead plaintiff's motion for class certification, which was originally filed in October 2010 and opposed by the Company. On July 30, 2012, the Court issued an opinion denying the lead plaintiff's motion, filed on December 15, 2011, to further amend his complaint, which motion sought to substantially revise plaintiff's asserted basis for contending that the defendants should be found liable for the statements at issue. In its opinion, the Court held that the proposed amended complaint failed to properly plead a viable claim.

In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is held by the Company and associated with Coreg CR. The lawsuit was dismissed in favor of a lawsuit involving the same parties for infringement of the same patent that was lodged in the U.S. District Court for the District of Maryland in May 2011. GSK is a third party defendant in the Maryland lawsuit. The lawsuit is based on the Abbreviated New Drug Application (ANDA) filed by Lupin seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012.

In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. The lawsuit is based on the ANDA filed by Anchen seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In May 2012, the Company concluded an agreement whereby Anchen agreed to pay the sum of $400,000 in settlement of the claim.

Dividend Policy

The Company has never declared or paid a cash dividend on any of its capital stock and does not anticipate declaring cash dividends in the foreseeable future.

Significant Changes

In March 2012, the Company acquired all of the membership interests of Éclat, a St. Louis-based specialty pharmaceutical company focused on the development, approval and commercialization of niche branded and generic pharmaceutical products. For more information about this transaction, see 'Item 10. *Additional Information – Material Contracts*'. In March the Company closed an offering whereby a total of 12.4 million ADSs, representing Company's ordinary shares, were sold in an underwritten public offering resulting in net proceeds (after commissions) of $113.6 million.

ITEM 9. The Offer and Listing

The principal trading market for the Company's securities in ADSs is the NASDAQ Global Market. Each ADS represents one Share, nominal value 0.122 Euros. Each ADS is evidenced by an ADR. The Bank of New York is the Depositary for the ADRs. As of December 31, 2013, there were 24,499,792 ADSs outstanding in the United States and there were 30 holders of ADSs on record. As of December 31, 2013, there were 25,612,550 Shares outstanding. As a result of the public offering completed in March 2014, the number of ADSs and shares outstanding was significantly increased to 37,259,367 ADSs and 38,267,550 shares as of March 31, 2014.

The following table shows the high and low closing sales prices of the ADSs on the NASDAQ Market for the periods indicated.

	Price Per ADS (U.S.$)	
Year	**High**	**Low**
2009	9.67	3.99
2010	9.60	6.02
2011	6.97	3.85
2012	7.67	2.99
2013	8.21	3.25

	Price Per ADS (U.S.$)	
Quarter Ended	**High**	**Low**
1st Quarter, 2011	6.97	5.82
2nd Quarter, 2011	6.63	5.02
3rd Quarter, 2011	5.44	3.85
4th Quarter, 2011	5.26	4.08
1st Quarter, 2012	7.67	5.11
2nd Quarter, 2012	5.65	4.05
3rd Quarter, 2012	5.50	4.06
4th Quarter, 2012	4.25	2.99
1st Quarter, 2013	4.59	3.25
2nd Quarter, 2013	6.28	4.05
3rd Quarter, 2013	6.66	5.68
4th Quarter, 2013	8.21	5.39
1st Quarter, 2014	14.70	8.15

	Price Per ADS (U.S.$)	
Month Ended	**High**	**Low**
October 31, 2013	7.56	6.18
November 30, 2013	7.34	5.39
December 31, 2013	8.21	7.20
January 31, 2014	11.00	8.15
February 28, 2014	10.80	9.20
March 31, 2014	14.70	10.1

ITEM 10. Additional Information

Memorandum and Articles of Association

For a general description of these documents, see 'Description of Share Capital' in the Company's registration statement on Form F-1, as filed with the U.S. Securities and Exchange Commission on April 19, 1996, registration number 333-03854, which is incorporated by reference. There have been no changes to these documents. No more than a third of the Directors may be over the age of seventy.

Ownership of Shares by Non-European Union Persons

A 'declaration administrative' or administrative declaration is required in The Republic of France to be filed with the French Ministry of the Economy, Finance and the Budget at the time of the acquisition of a controlling interest in Flamel by any non-EU resident or group of non-EU residents acting in concert or by any EU resident controlled by a non-EU resident. With respect to the acquisition (by a EU resident or a non-EU resident) of a controlling interest in a company that could affect 'public health,' the administrative declaration is replaced by a procedure that requires prior declaration of the acquisition to the French Ministry of Economy, Finance and the Budget with the ability for such Ministry to oppose the investment during a one-month period. As it is a pharmaceutical company, the acquisition of a controlling interest in Flamel could be deemed to affect 'public health.'

Under existing administrative rulings, ownership of 20% or more of a listed company's share capital is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (such as when the shareholder has the ability to elect members of the board of directors). No administrative declaration is required where an EU resident or group of EU residents acts in concert to acquire a controlling interest in Flamel provided that the acquiring party or parties satisfy the requirements of EU residency.

Under French law, there is no limitation on the right of non-resident or foreign shareholders to vote securities of a French company.

Material Contracts

We have entered into certain material contracts in connection with the Éclat acquisition and other debt financing. *See 'Item 7: Major Shareholders and Related Party Transactions'*. The following is a summary of the material terms of these contracts that is qualified in its entirety by reference to the actual documents attached as exhibits to this Annual Report on Form 20-F and for those incorporated by reference herein:

Note Agreement and Note

Under the terms of a Note Agreement among Flamel, Flamel US and Éclat Holdings dated March 13, 2012, Flamel US issued a $12 million senior note to Éclat Holdings that was guaranteed by Flamel and its subsidiaries and secured by the membership interests and assets of Éclat. The note was payable over six years only if certain contingencies are satisfied. The note accrued interest at an annual rate of 7.5%, payable in kind, until one Éclat launch product is approved by the FDA. After FDA approval of one Éclat launch product is obtained, any interest previously capitalized was payable in cash no later than nine months following FDA approval, and any future interest was payable in cash when due. The note was repaid in full in March 2014.

Warrants to Purchase ADSs

In addition to the note, Flamel also issued to Éclat Holdings, two six-year warrants to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. In June 2012, shareholder approval was obtained for issuance of the warrants. In connection with the issuance of the warrants, Flamel entered into a registration rights agreement with Éclat Holdings dated March 13, 2012, pursuant to which Flamel filed, on September 18, 2012, a registration statement with the SEC covering the resale of the ADSs issuable upon exercise of the warrants.

Deerfield Facility Agreement

The Deerfield Facility was effective as of December 31, 2012, and allowed Flamel to use the funds for working capital, including continued investment in its research and development projects. The aggregate principal amount of the Loan was required to be repaid over four years as follows: 10% on July 1, 2014, and 20%, 30% and 40% on the second, third, and fourth anniversary, respectively, of the original disbursement date of the Loan. Notwithstanding the foregoing, the entire principal amount of the Loan could be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest accrued at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013, and on the first business day of each July, October, January and April thereafter. All amounts under the Deerfield Facility were repaid in full in March 2014.

Deerfield ***Royalty Agreement***

The Royalty Agreement, dated December 31, 2012, provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales price of the Products sold by Flamel and any of its affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Royalty Agreement requires Éclat to take all commercially reasonable efforts to obtain the necessary regulatory approvals to sell the Products in the United States and to market the Products after receiving such approvals.

Broadfin Facility and Royalty Agreement

The Broadfin Facility was effective as of December 3, 2013 and allowed Flamel to use the funds for working capital, including continued investment in its research and development projects. Under the terms of the Broadfin Facility, upon closing Broadfin made an initial loan of $5.0 million and we had the ability to request, at any time prior to August 15, 2014, up to two additional loans in the amount of $5.0 million each, with funding subject to certain specified conditions. Loans under the Facility were scheduled to mature upon the earlier to occur of (i) January 31, 2017 and (ii) the repayment in full of all outstanding amounts under the Deerfield Facility, but in no event prior to November 15, 2015. We had the ability to prepay the outstanding loans under the Broadfin Facility at any time, without prepayment penalty and the full $5.0 million outstanding was subsequently repaid in March 2014. Prior to repayment, interest accrued on the loan under the Broadfin Facility at a rate of 12.5% per annum, payable quarterly in arrears, commencing on January 1, 2014.

In connection with entering into the Broadfin Facility, we also entered into the Broadfin Royalty Agreement. Pursuant to the Broadfin Royalty Agreement, we are required to pay a royalty of 0.834% on the net sales of certain products sold by Éclat Pharmaceuticals, LLC and any of its affiliates until December 31, 2024.

Exchange Controls

The payment of any dividends to foreign shareholders must be effected through an authorized intermediary bank. All registered banks and credit establishments in the Republic of France are authorized intermediaries. Under current French exchange control regulations, there are no limitations on the amount of cash payments that may be remitted by Flamel to residents of the United States. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an authorized intermediary bank.

Taxation

The following is a discussion of French and U.S. federal income tax consequences of owning and disposing of Flamel Ordinary Shares or Flamel ADSs. This description is only relevant to holders of Flamel Ordinary Shares or Flamel ADSs who are not residents of France and do not hold their shares in connection with a permanent establishment or a fixed base in France through which the holders carry on a business or perform personal services.

This description may not address all aspects of French tax laws that may be relevant in light of the particular circumstances of individual holders of Flamel Ordinary Shares or Flamel ADSs. It is based on the applicable tax laws, regulations and judicial decisions as of the date of this annual report, and on the Convention between the United States of America and the Republic of France for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital dated as of August 31, 1994 entered into force on December 30, 1995, and the 2004 and 2009 Protocols amending the Treaty, all of which are subject to change, possibly *with retroactive* effect, or different interpretations. This discussion refers to the treaty between the United States and France described above, and the two Protocols together as the ‘Treaty’.

The following discussion should be considered only as a summary and does not purport to be a complete analysis of all potential tax effects of the purchase or ownership of the Flamel Ordinary Shares or Flamel ADSs. This summary does not address all potential tax implications that may be relevant as a holder, in light of particular circumstances.

Tax Consequences to Non-U.S. Holders

The following discussion applies to holders of Flamel Ordinary Shares that are not 'U.S. Holders,' as defined below. Holders of Flamel Ordinary Shares should consult their tax advisor concerning the French tax consequences.

Taxation on Sale or Disposal of Flamel Ordinary Shares

Generally, a holder of Flamel Ordinary Shares will not be subject to any French income tax or capital gains tax when the holder sells or disposes of Flamel Ordinary Shares if all of the following cumulative conditions apply:

- the holder is not a French resident for French tax purposes;
- the holder has held not more than 25% of Flamel's dividend rights, known as *droits aux bénéfices sociaux*, at any time during the preceding five years, either directly or indirectly;
- the holder is not a resident of a non-cooperative jurisdiction as defined below; and
- Flamel is not considered as a real estate company.

If a double tax treaty bet*ween France and the country* of residence of a holder of Flamel Ordinary Shares contains more favorable provisions, a holder may not be subject to any French income tax or capital gains tax when the holder sells or disposes of any Flamel Ordinary Shares, even if one or all of the above statements does not apply to the holder.

Subject to various conditions, foreign states, international organizations and a number of foreign public bodies are not considered as French residents for these purposes.

As from January 1, 2012, transfers of a listed company's shares are subject to French registration or transfer taxes when they are documented by a written deed, irrespective of whether that deed is executed in France or outside of France. A tax credit will be available (up to the extent of the transfer taxes triggered in France) in order to shelter the foreign transfer tax liability (if registration is also required under foreign law). From January 1, 2012 to July 31, 2012, the following rates apply to the transfer of listed company shares: (i) 3% for the portion of the value below €200,000; (ii) 0.5% for the portion of the value between €200,000 and €500,000,000 and; (iii) 0.25% for the portion of the value above €500,000,000. As from August 1, 2012, a unique 0.10% tax rate will apply to the transfer of listed company's shares.

Taxation of Dividends

In France, companies may only pay dividends out of income remaining after tax has been paid.

French companies must, in principle, deduct a 30% withholding tax from dividends paid to non-residents. As from January 1, 2008, the rate of this withholding tax has been reduced to 21% for dividends paid to EU, Norway Iceland and Liechtenstein residents individuals.

In addition, anti-avoidance rules regarding transactions concluded with non-cooperative jurisdictionsprovide that dividends distributed to non-cooperative jurisdictions residents as of March 1, 2010, as per the criteria defined by the French tax code, would be subject to a 55% withholding tax.

The following countries were considered by the French tax authorities as non-cooperative jurisdictions in 2012:

Botswana	Guatemala	Montserrat	Niue
Brunei	Marshall Islands	Nauru	Philippines

Under most double tax treaties between France and other countries, the rate of this withholding tax may be reduced or eliminated in some circumstances. Generally, if dividends are subject to a French withholding tax, a holder who is a non-French resident is subsequently entitled to a tax credit in that holder's country of residence for the amount of tax actually withheld.

However, France has entered into tax treaties with various countries under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15% or 5%) or an elimination of the French withholding tax.

If these arrangements apply to a shareholder, Flamel will withhold tax from the dividend at the lower rate, provided that the shareholder has established, before the date of payment of the dividend, that the shareholder is entitled to the lower rate and has complied with the filing formalities. Otherwise, Flamel must withhold tax at the full rate of 30% (for other than European Union, Iceland, Norway or Liechtenstein residents individuals) or 21% (for European Union, Iceland, Liechtenstein or Norway residents individuals), and the shareholder may subsequently claim the excess tax paid.

Estate and Gift Tax

France imposes estate and gift tax on shares of a French company that are acquired by inheritance or gift, this tax applying without regards to the residence of the transferor. However, France has entered into estate and gift tax treaties with certain countries pursuant to which, provided that certain conditions are met, residents of the treaty country may be exempt from such tax or obtain a tax credit.

Non-residents should consult their own tax advisors regarding whether French estate and gift tax would apply to them and whether they might be able to claim an exemption or tax credit pursuant to an applicable tax treaty.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals may be subject to French wealth tax (*impôt de solidarité sur la fortune*) only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real estate companies, are exempt from wealth taxes as long as the individuals own less than 10% of the French company's capital stock, either directly or indirectly, provided that their shares do not enable them to exercise influence on the French company.

Even if these conditions are not satisfied, a non-French resident holder may be exempt from French wealth tax if such holder is entitled to more favourable provisions pursuant to a double tax treaty between France and the holder's country of residence.

Tax Consequences to U.S. Holders

The following is a discussion of the U.S. federal income tax consequences of the ownership and disposition of Flamel Ordinary Shares or Flamel ADSs by a U.S. Holder. For purposes of this discussion a "U.S. Holder" is a beneficial owner of the Flamel Ordinary Shares or Flamel ADSs who is (i) an individual citizen or resident of the United States; (ii) a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof; (iii) an estate whose income is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust whose administration is subject to the primary supervision of a United States court and over which one or more United States persons have the authority to control all substantial decisions of the trust. This discussion does not apply to a U.S. Holder who is also a resident of France for French tax purposes.

If an entity that is treated as a partnership for United States federal income tax purposes holds Flamel Ordinary Shares or Flamel ADSs, the tax treatment of a partner of such partnership will generally depend on the status of the partner and upon the activities and organization of the partnership. If you are a partner of such a partnership you are urged to consult your tax advisor.

This summary is based in part upon the representations of the custodian and the assumption that each obligation in the Depositary Agreement with the Bank of New York relating to our ADSs and any related agreement will be performed in accordance with its terms.

The following is a general summary of the principal tax effects on U.S. Holders for purposes of U.S. federal income tax and French tax, if all of the following four points apply:

- the U.S. Holder owns, directly, indirectly, or constructively, less than 10% of Flamel's share capital;
- the U.S. Holder is entitled to the benefits of the Treaty (including under the 'limitations on benefits article of the Treaty);
- the U.S. Holder holds Flamel Shares as capital assets; and

· the U.S. Holder's functional currency is the U.S. dollar.

For purposes of the Treaty and the U.S. Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), Holders of Flamel ADSs will be treated as the owner of the Flamel Ordinary Shares represented by such ADSs.

Special rules may apply to United States expatriates, insurance companies, pass-through entities and investors in such entities, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, securities broker-dealers, persons who use the mark-to-market method of accounting for their securities holdings, and persons holding their Flamel Ordinary Shares or Flamel ADSs as part of a conversion or other integrated transaction, among others. Special rules relevant to those holders are not discussed in herein.

Holders of Flamel Ordinary Shares or Flamel ADSs should consult their own tax advisers as to the particular tax consequences to them of owning Flamel Ordinary Shares or Flamel ADSs, including their eligibility for benefits under the Treaty, the applicability and effect of U.S. federal, state, local, non-U.S. and other tax laws and any possible changes in tax law.

Taxation of Dividends

Withholding Tax

Dividends paid to non-residents by French companies are subject to a 30% French withholding tax. Under the Treaty, this withholding tax is reduced to 15% if a U.S. Holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France.

Dividends paid to a U.S. Holder by French companies are immediately subject to a reduced rate of 15%, provided that such U.S. Holder establishes before the date of payment that he is a U.S. resident under the Treaty by completing and providing the depositary with a simplified certificate (the "*Certificate*") in accordance with the French tax guidelines (4 J–1-05 released on February 25, 2005). In order to establish U.S. residency for this Certificate, the U.S. resident should submit a Form 8802 (Application for United States Residency Certification) for certification from the U.S. Internal Revenue Service ("*IRS*"). The Form 8802 is used to request Form 6166, a letter of U.S. residency certification for purposes of claiming benefits under an income tax treaty. The application for the Form 8802 requires a non-refundable user fee of $85 USD and should be submitted by mail with the application at least 45 days prior to the date the certification is needed.

Dividends paid to a U.S. Holder that has not filed the Certificate before the dividend payment date will be subject to French withholding tax at the rate of 30%. The tax withheld in excess of 15% can be reclaimed, provided that such U.S. Holder duly completes and provides the French tax authorities with the relevant form described in the tax guidelines mentioned above (the "*Form*") before December 31 of the second calendar year following the year during which the dividend is paid. U.S. Pension Funds (as defined by Sections 401(a), 401(b), 403(b) and 457 of the Internal Revenue Code) and other Tax-Exempt Entities (as defined by Section 501(c) 3) of the Internal Revenue Code) are subject to the same general filing requirements as other U.S. Holders except that they may be required to supply additional documentation evidencing their entitlement to these benefits.

The Certificate and the Form, together with instructions, will be provided by the depositary to all U.S. Holders registered with the depositary. The depositary will arrange for the filing with the French Tax authorities of all Certificates properly completed and executed by U.S. Holders of Shares and returned to the depositary in sufficient time that they may be filed with French Tax authorities before the distribution so as to obtain an immediate reduced withholding tax rate.

U.S. Federal Income Tax

For U.S. federal income tax purposes, subject to the rules discussed below under the section titled "PFIC Status," the gross amount of a dividend paid by Flamel, including any French tax withheld, will be included in each U.S. Holder's gross income as dividend income when payment is received by them (or the custodian, if the U.S. Holder owns Flamel ADSs), to the extent they are paid or deemed paid out of Flamel's current or accumulated earnings and profits as calculated for U.S. federal income tax purposes.

Dividends paid by Flamel will not give rise to any dividends received deduction. They will generally constitute foreign source "passive" income for "foreign tax credit" purposes. For certain recipients, dividends will constitute foreign source "general" income for foreign tax credit purposes

Under current U.S. federal tax law, as a general matter, amounts distributed as dividends by Flamel with respect to Flamel Ordinary Shares or Flamel ADSs paid in taxable years beginning before January 1, 2013 will be eligible to be treated as "qualified dividend income" that is subject to a U.S. federal income tax at a maximum rate of 15% provided both that certain minimum holding period and other requirements are met (i.e. Flamel meets the requirements of a "qualified foreign corporation" under the US federal income tax rules)and that Flamel is not treated as a PFIC (as defined below under the section titled "*PFIC Status*").

For U.S. federal income tax purposes, the amount of any dividend paid in Euros, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A U.S. Holder will generally be required to recognize foreign currency gain or loss when the U.S. Holder sells or disposes of the Euros. A U.S. Holder may also be required to recognize foreign currency gain or loss if that U.S. Holder receives a refund under the Treaty of tax withheld in excess of the Treaty rate. This foreign currency gain or loss will generally be U.S. source ordinary income or loss.

To the extent that any dividends paid exceed Flamel's current and accumulated earnings and profits as calculated for U.S. federal income tax purposes, the distribution generally will be treated as follows:

- First, as a tax-free return of capital, to be applied against and reduce in the adjusted basis of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs. Accordingly, this adjustment will increase the amount of gain, or decrease the amount of loss, which a U.S. Holder will recognize if such U.S. Holder later disposes of those Flamel Ordinary Shares or Flamel ADSs, as the case may be.
- Second, the balance of the dividend in excess of the adjusted basis will be taxed as capital gain recognized on a sale or exchange.

French withholding tax (which, as described above), is imposed on at a rate of 15% under the Treaty generally is treated for U.S. federal income tax purposes as payment of a foreign income tax. A U.S. Holder may take this amount as a credit or deduction against the U.S. Holder's U.S. federal income tax liability. The foreign tax credit is subject to various conditions and limitations, including minimum holding period requirements. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the maximum 15% tax rate applicable to qualified dividend income.

To the extent a refund of French tax withheld with respect to dividends is available under the Treaty or otherwise under French law, the amount of tax withheld that is refundable will not be eligible for credit against your U.S. federal income tax liability.

Taxation of Capital Gains

French Tax. A U.S. Holder who is a resident of the United States for purposes of the Treaty will not be subject to French tax on any capital gain if such U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs, unless the U.S. Holder has a permanent establishment or fixed base in France and the Flamel Ordinary Shares or Flamel ADSs the U.S. Holder sold or exchanged were attributable to that permanent establishment or fixed base. Special rules apply to individuals who are residents of more than one country.

U.S. Income Tax. In general, for U.S. federal income tax purposes, a U.S. Holder will recognize capital gain or loss if the U.S. Holder sells or exchanges its Flamel Ordinary Shares or Flamel ADSs. Any such gain or loss generally will be U.S. source gain or loss. If a U.S. Holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the U.S. Holder meets applicable minimum holding period requirements.

PFIC Status. Flamel believes that it will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, for the current taxable year or for future taxable years. However, an actual determination of PFIC status is factual and cannot be made until the close of the applicable taxable year. Flamel will be a PFIC for any taxable year in which either:

- 75% or more of its gross income is passive income; or
- its assets which produce passive income or which are held for the production of passive income amount to at least 50% of the value of its total assets on average.

If Flamel were to be treated as a PFIC, the tax consequences applicable to distributions on Flamel Ordinary Shares and Flamel ADSs, and any gains a U.S. Holder realizes when the U.S. Holder disposes of such Flamel Ordinary Shares or Flamel ADSs, may be less favorable to the U.S. Holder. In addition, a U.S. Holder would be required to file Form 8621 with respect to its interest in Flamel. Each U.S. Holder should consult its own tax advisors regarding the PFIC rules and their effect on the U.S. Holder if they purchase Flamel Ordinary Shares or Flamel ADSs.

French Estate and Gift Taxes

Under 'The Convention Between the United States of America and the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritance and Gifts of November 24, 1978,' if a U.S. Holder transfers their Flamel Shares by gift, or if they are transferred by reason of the U.S. Holder's death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

- the U.S. Holder is domiciled in France at the time of making the gift, or at the time of the U.S. Holder's death; or
- the U.S. Holder used the Flamel Ordinary Shares or Flamel ADSs in conducting a business through a permanent establishment or fixed base in France, or the U.S. Holder held the Flamel Ordinary Shares or Flamel ADSs for that use.

French Wealth Tax

The French wealth tax does not generally apply to Flamel Ordinary Shares or Flamel ADSs if the U.S. Holder is treated as a 'resident' of the United States for purposes of the Treaty. and if the U.S. Holder does not own a substantial interest (*participation substantielle) in Flamel*. Pursuant to article 23 §2 of the Treaty, "an individual is considered to have a substantial interest if he or she owns, alone or with related persons, directly or indirectly, shares, rights, or interests the total of which gives right to at least 25% of the corporate earnings".

Expansion of U.S. Medicare Tax

The U.S. Health Care and Reconciliation Act of 2010 requires that, in certain circumstances, certain U.S. Shareholders that are individuals, estates, and trusts pay a 3.8% tax on "net investment income," which includes, among other things, dividends on and gains from the sale or other disposition of stock, effective for taxable years beginning after December 31, 2012. Prospective investors should consult their own tax advisors regarding this new legislation.

United States Information Reporting and Backup Withholding

Dividend payments made by us (Flamel) to a U.S. Holder in respect of Flamel Ordinary Shares or Flamel ADSs and proceeds from the sale or disposal of a U.S. Holder's Flamel Ordinary Shares or Flamel ADSs may be subject to information reporting to the Internal Revenue Service.

U.S. federal backup withholding generally is a withholding tax (currently imposed at a rate of 28%) on some payments to persons that fail to furnish required information. Backup withholding will not apply to a U.S. Holder who furnishes a correct taxpayer identification number or certificate of foreign status and makes any other required certification, or who is otherwise exempt from backup withholding. Any U.S. persons required to establish their exempt status generally must file Internal Revenue Service Form W-9, entitled Request for Taxpayer Identification Number and Certification. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability. A U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information within the appropriate amount of time.

Recently Enacted Legislation Related to Disclosure of Information with Respect to Foreign Financial Assets

Recently enacted legislation in the U.S. requires a U.S. Holder that holds an interest in "specified foreign financial assets" to disclose information to the IRS related to these holdings. These new disclosure requirements are effective for taxable years beginning after March 18, 2010, and apply for any year in which the aggregate value of all such holdings is greater than $50,000. For these purposes, "specified foreign financial assets" may include (i) depository or custodial account maintained by foreign financial institutions and foreign investment vehicles, (ii) interests in, or securities issued by, non-U.S. persons, and (iii) other financial instruments or contracts held for investment where the issuer or counterparty is a non-U.S. person. In addition, a U.S. Holder may be required to furnish information to avoid a presumption that the aggregate value of the U.S. Holder's holdings of specified foreign financial assets is in excess of $50,000. A U.S. Holder who fails to comply with these requirements may be subject to penalties. Investors should consult their own tax advisors regarding the effect of this legislation in their particular circumstances.

Documents on Display

Flamel is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with those requirements, files reports and other information with the U.S. Securities and Exchange Commission. Copies of reports and other information, when so filed, may be inspected free of charge and may be obtained at prescribed rates at the public reference facility maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. You may also access documents filed with the SEC at its website www.sec.gov. Certain of the reports that the Company files with the Commission may be available from time to time on the Company's internet website, at www.flamel.com. Flamel is not incorporating the contents of its or the SEC's websites or the website of any other person into this document.

ITEM 11. Quantitative and Qualitative Disclosures About Market Risk

The Company conducts a portion of its business transactions in U.S. dollars. For the year ended December 31, 2013 revenues denominated in U.S. dollars represented 46% of total revenues. As a result, the Company's financial results could be significantly affected by the fluctuation of the Euro relative to the U.S. dollar. Specifically, 34.6% of the Company's cash and cash equivalents, totalling $2.3 million as of December 31, 2013, and all of the Company's marketable securities, totalling $0.4 million, as of December 31, 2013, are denominated in Euros, as are the vast majority of the Company's expenses. If the dollar were to strengthen by 10% versus the Euro, there would be a corresponding negative effect on these items of $0.2 million in our balance sheet. Conversely, if the dollar were to weaken by 10% versus the Euro, there would be a positive effect on these items of $0.3 million in our balance sheet. See 'Item 5. Operating and Financial Review and Prospects - Overview.'

We believe the Company is not exposed to interest rate risk.

ITEM 12. Description of Securities Other Than Equity Securities

ITEM 12.A Debt Securities

Not applicable.

ITEM 12.B Warrants and Rights

Not applicable.

ITEM 12.C Other Securities

Not applicable.

ITEM 12.D American Depositary Shares

Charges of Depositary

The Company will pay fees, reasonable expenses and out-of-pocket charges of the depositary and those of any registrar only in accordance with agreements in writing entered into between the Depositary and the Company from time to time. The following charges may be incurred by holders depositing or withdrawing shares or by any party surrendering receipts or to whom receipts are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the receipts or deposited securities or a distribution of receipts pursuant to the terms of the deposit agreement):

	Amount:	**For:**
1.	$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADRs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADRs for the purpose of withdrawal, including if the Deposit Agreement terminates
2.	$0.05 (or less) per ADS	Any cash distribution to you
3.	A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities which are distributed by the Depositary to ADR holders
4.	$1.50 or less per certificate	Registration or transfer of ADRs
5.	$0.05 (or less) per ADS per calendar year	Depositary services
6.	Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the Depositary or its agent when you deposit or withdraw shares
7.	Expenses of the Depositary	Cable, telex and facsimile transmissions (when expressly provided in the Deposit Agreement)
8.	Taxes and other governmental charges the Depositary or the Custodian has to pay on any ADR or share underlying an ADR, for example, stock transfer taxes, stamp duty or withholding taxes	As necessary
9.	Expenses of the Depositary in converting foreign currency to U.S. dollars	As necessary
10.	Any charges incurred by the Depositary or its agents for servicing the deposited securities.	As necessary

PART II

ITEM 13. Defaults, Dividend Arrearages and Delinquencies

There has not been any material default with respect to any indebtedness of the Company.

ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

ITEM 15. Controls and Procedures

Disclosure Controls and Procedures

The Company's Chief Executive Officer and Principal Financial Officer have evaluated the effectiveness of 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) as of December 31, 2013. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer of the Company concluded that the Company's disclosure controls and procedures were effective as of December 31, 2013.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fiscal year ended December 31, 2012 that has materially affected, or is reasonable likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) of the Company.

The internal control over financial reporting at the Company was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America;
- provide reasonable assurance that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2013. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control – Integrated Framework (1992)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management determined that, as of December 31, 2013, the Company maintained effective internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee of the Board of Directors.

Attestation report of registered public accounting firm

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit, an independent registered public accounting firm, as stated in their report on the Company's internal control over reporting as of December 31, 2013, which is included herein.

See report of PricewaterhouseCoopers Audit, an independent registered public accounting firm, included within the financial statements on page F-2.

ITEM 16. [Reserved]

ITEM 16A. Audit Committee Financial Expert

The Board has determined that Elie Vannier and Guillaume Cerutti are 'audit committee financial experts,' as defined by the rules of the SEC. Messrs Vannier and Cerutti are 'independent' as defined by the NASDAQ Marketplace Rules.

ITEM 16B. Code of Ethics

The Board adopted a written Code of Ethics that applies to the Chief Executive Officer, Chief Operating Officer and senior financial officers. The principles set forth in our Code of Ethics are intended to promote the honest and ethical conduct of our principal executive officer, the principal financial officer, the principal accounting officer or controller, or persons performing similar functions. The Code of Ethics was filed as Exhibit 11.1 to our annual report on Form 20-F for the year ended December 31, 2003, on April 26, 2004.

ITEM 16C. Principal Accountant Fees and Services

The following is a summary of the fees billed to Flamel by PricewaterhouseCoopers Audit for professional services rendered for the fiscal years ended December 31, 2013 and 2012:

Fee Category	Fiscal 2013 Fees (Euros)	Fiscal 2012 Fees (Euros)
Audit Fees	263,000	297,000
Audit-Related Fees	8,500	7,900
Tax Fees		
All Other Fees		
Total Fees	**271,500**	**304,900**

All fees were billed in Euros. Using the average exchange rate of 1.3282 U.S dollars per Euro for 2013, and 1.2856 U.S dollars per Euro for 2012 audit fees equaled $360,606 for Fiscal 2013 and $391,979 for Fiscal 2012.

Audit Fees. Consists of fees billed for professional services rendered for the audit of the Company's consolidated financial statements, review of the interim consolidated financial statements included in quarterly reports and review of internal controls over Financial Reporting.

Audit-Related Fees. Consists of fees billed for assurance and related services by the principal accountant that are reasonably related to the performance of the audit or review of Flamel's consolidated financial statements.

Tax Fees. Consists of fees billed for professional services for tax compliance, tax advice and tax planning.

All Other Fees. There were no fees billed for professional services in fiscal years 2013 and 2012 that are not included in one of the above categories.

Audit Committee's Pre-Approval Policies and Procedures

Our Audit Committee nominates and engages our independent auditors to audit our financial statements. See also 'Item 6. Directors, Senior Management and Employees – Board Practices – Committees of the Board of Directors.' In 2005, our Audit Committee adopted a revised policy requiring management to obtain the Committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. Pursuant to this policy, which is designed to assure that such engagements do not impair the independence of our auditors, the Audit Committee annually pre-approves, in accordance with an audit plan, specific audit and non-audit services in the categories Audit Service, Audit-Related Services, Tax Consulting Services, and Other Services that may be performed by our auditors. All of the fees to the principal accountants were approved by the Audit Committee pursuant to paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X in 2005. Our Principal Financial Officer reviews all individual management requests to engage our auditors as a service provider in accordance with this policy and, if the requested services are permitted pursuant to the audit plan approved by the Audit Committee and are less than €10,000, approves the request accordingly. In the event of a request for services pursuant to the audit plan in excess of €10,000 and less than €20,000, the Chairman of the Audit Committee approves the request. Any services in excess of €20,000 are to be pre-approved by the Audit Committee. We inform the Audit Committee about all approvals made by the Principal Financial Officer or Chairman of the Audit Committee at the following Audit Committee meeting. The chairman of our Audit Committee is not permitted to approve any engagement of our auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

ITEM 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable**.**

ITEM 16F. Change in Registrant's Certifying Accountant

Not applicable**.**

ITEM 16G. Corporate Governance

Flamel was incorporated under the laws of France with securities listed on the Nasdaq Global Market, a regulated public market in the U.S. Our corporate governance framework reflects the mandatory provisions of French law and may differ in certain respects described below from the practices followed by U.S. companies listed on the Nasdaq Global Market.

The Company is exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the Shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting.

The Company also has been granted an exemption from NASDAQ Marketplace Rule 5620(b). The French Commercial Code does not require that we solicit or provide proxy statements for meetings of shareholders. In accordance with the French Commercial Code and our statuts, we inform shareholders of all meetings in a public notice, which notice states the requirements for admission to the meeting. Meeting the Nasdaq requirement to solicit proxies and provide proxy statements for shareholder meetings would be contrary to accepted business practice in France.

French corporate law provides that the Board of Directors must vote to authorize certain related party transactions that could create conflicts of interest between Flamel on the one hand and its directors, chief executive officer or shareholders owning more than 10% of the voting rights on the other hand for such transactions to be legally binding and must have such transactions documented, audited and approved by the shareholders at each ordinary shareholders' meeting approving the annual French statutory accounts of the Company. If the shareholders do not approve such related party transactions, the transactions remain legally binding, provided that they are not fraudulent and consequently declared null and void by competent courts.

Under French law, the committees of our Board of Directors are advisory only, and where the Nasdaq requirements would vest certain decision-making powers with specific committees by delegation (e.g., nominating or audit committees), our Board of Directors remains under French law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of the Company that is competent to appoint our auditors upon the proposal of our Board of Directors.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option plans or other share capital increases, whether for the benefit of top management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As a 'foreign private issuer' under the U.S. securities laws, our Chief Executive Officer and our Principal Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on Form 10-Q.

ITEM 16H. Mine Safety Disclosure

Not applicable

PART III

ITEM 17. Financial Statements

Not applicable. See 'Item 18. Financial Statements.'

ITEM 18. Financial Statements

The following financial statements, together with the reports of Independent registered public accounting firm thereon, are filed as part of this Annual Report:

See pages F-1 through F-41.

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

ITEM 19. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Amended and Restated Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (2)
4.1*	Note Agreement among Flamel Technologies S.A., Flamel US Holdings, Inc. and Éclat Holdings, LLC, dated March 13, 2012 (3)
4.2	Guaranty of Note made by Flamel Technologies S.A. in favor of Éclat Holdings, LLC, dated March 13, 2012 (3)
4.3	Warrant to purchase 2,200,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (3)
4.4	Warrant to purchase 1,100,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (3)
4.5	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC, dated March 13, 2012 (3)
4.6	Facility Agreement among Flamel US Holdings, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P dated December 31, 2012 (1)
4.7*	Royalty Agreement among Eclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P dated December 31, 2012 (1)
4.8*	Security Agreement between Éclat Pharamaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl, dated February 4, 2013 (1)
4.9	Broadfin Facility Agreement, effective as of December 3, 2013 (filed herewith)
4.10*	Broadfin Royalty Agreement, dated as of December 3, 2013 (filed herewith)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (*Directeur Généra*l), Delegated Managing Directors (*Directeurs Généraux Délégués*) and Senior Financial Officers (4)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)

12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)

(1) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013.
(2) Incorporated by reference to the Company's registration statement on Form F-6 filed February 12, 2014, as amended (No. 333-193892).
(3) Incorporated by reference to the Company's Current Report on Form 6-K, filed March 21, 2012.
(4) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.

*Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
Flamel Technologies SA
Vénissieux

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive income, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Flamel Technologies SA and its subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control - Integrated Framework 1992* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting, appearing on page 75 of the 2013 Annual Report to Shareholders. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Lyon, France, April 30, 2014

PricewaterhouseCoopers Audit

/s/ Nicolas Brunetaud
Represented by
Nicolas Brunetaud

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of dollars except share data)

	Note	December 31, 2012	December 31, 2013
ASSETS			
Current assets:			
Cash and cash equivalents	7	$ 2,742	$ 6,636
Marketable securities	8	6,413	401
Accounts receivable (net of allowance of $137, $139 and $ 144 at December 31, 2011, 2012 and 2013 respectively)		5,464	6,204
Inventory	9	1,520	3,762
Research and development tax credit receivable current portion	20	6,632	14,139
Prepaid expenses and other current assets	10	2,314	2,481
Total current assets		25,085	33,623
Goodwill	12	18,491	18,491
Property and equipment, net	11	18,238	17,435
Intangible assets, net	12	41,589	40,139
Other assets:			
Research and development tax credit receivable less current portion	20	13,725	6,410
Other long-term assets		183	154
Total assets		$ 117,311	$ 116,252
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Current portion of long-term debt	16 - 25	3,351	19,194
Current portion of capital lease obligations	17	77	85
Accounts payable		3,596	5,099
Current portion of deferred revenue	15	614	1,264
Advances from customers		575	116
Accrued expenses	13	5,013	6,527
Other current liabilities	14	1,133	8,310
Total current liabilities		14,359	40,595
Long-term debt, less current portion	16 - 25	33,278	66,320
Capital lease obligations, less current portion	17	179	103
Deferred revenue, less current portion	15	181	
Deferred tax liabilities	20	14,130	2,806
Other long-term liabilities	14 - 21	24,680	15,940
Total long-term liabilities		72,448	85,169
Commitments and contingencies:		-	-
Shareholders' equity :			
Ordinary shares: 25,415,400 issued and outstanding at December 31, 2012 and 25,612,550 at December 31, 2013 (shares authorised 34,379,690) at nominal value of 0.122 euro	19	3,714	3,746
Additional paid-in capital		209,158	211,473
Accumulated deficit		(192,621)	(235,546)
Accumulated other comprehensive income		10,253	10,815
Total shareholders' equity		30,504	(9,512)
Total liabilities and shareholders' equity		$ 117,311	$ 116,252

The accompanying notes are an integral part of the consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of dollars except share data)

		Year ended December 31,		
	Note	**2011**	**2012**	**2013**
Revenue:				
License and research revenue	4	$ 10,566	$ 9,324	$ 6,549
Product sales and services	3	13,395	9,657	8,952
Other revenues		8,639	7,120	6,942
Total revenue		32,600	26,101	22,443
Costs and expenses:				
Cost of products and services sold		(6,284)	(5,860)	(4,349)
Research and development	5	(25,089)	(26,115)	(26,686)
Selling, general and administrative		(10,810)	(14,153)	(13,307)
Remeasurement of acquisition liabilities	2 - 16 - 25	-	18,834	(28,135)
Impairment of assets	2	-	(7,170)	-
Total		(42,183)	(34,464)	(72,477)
Income (loss) from operations		(9,583)	(8,363)	(50,034)
Interest expense	16 - 25	(73)	(118)	(2,610)
Interest expense on the debt related to the royalty agreement	16 - 25	-	-	(1,990)
Interest income		667	629	254
Foreign exchange gain (loss)		273	(180)	(288)
Other income		134	102	573
Income (loss) before income taxes		(8,582)	(7,930)	(54,095)
Income tax	20	(192)	4,702	11,170
Net income (loss)		$ (8,774)	$ (3,228)	$ (42,925)
Earnings (loss) per share				
Basic earnings (loss) per share	18	$ (0.36)	$ (0.13)	$ (1.69)
Diluted earnings (loss) per share		$ (0.36)	$ (0.13)	$ (1.69)
Weighted average number of shares outstanding (in thousands) :				
Basic		24,669	25,135	25,450
Diluted		24,669	25,135	25,450

The accompanying notes are an integral part of the consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Amounts in thousands of dollars except share data)

	Year Ended December 31,		
	2011	**2012**	**2013**
	(In thousands)		
Net loss	$ (8,774)	$ (3,228)	$ (42,925)
Other comprehensive income (loss):			
Net foreign currency translation gain (loss)	(816)	196	561
Other comprehensive income (loss), net of tax	(816)	196	561
Comprehensive loss	$ (9,590)	$ (3,032)	$ (42,364)

The accompanying notes are an integral part of the consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
(Amounts in thousands of dollars except share data)

	Ordinary Shares		Additional Paid-in	Accumulated	Accumulated Other Comprehen-sive Income	Shareholders'
	Shares	Amount	Capital	Deficit	(Loss)	Equity
Balance at January 1, 2011	24,645,650	$ 3,589	$ 202,462	$ (180,619)	$ 10,873	$ 36,305
Subscription of warrants			200			200
Issuance of ordinary shares on exercise of stock - options	44,200	8	88			96
Issuance of ordinary shares on vesting of free shares	272,400	44	(44)			-
Stock-based compensation expense			2,783			2,783
Net loss				(8,774)		(8,774)
Other comprehensive income (loss)					(816)	(816)
Balance at December 31, 2011	24,962,250	$ 3,641	$ 205,489	$ (189,393)	$ 10,057	$ 29,794
Subscription of warrants			5			5
Issuance of ordinary shares on exercise of stock - options	195,000	31	570			601
Issuance of ordinary shares on vesting of free shares	258,150	42	(42)			-
Stock-based compensation expense			3,136			3,136
Net loss				(3,228)		(3,228)
Other comprehensive income (loss)					196	196
Comprehensive loss						$ (3,032)
Balance at December 31, 2012	25,415,400	$ 3,714	$ 209,158	$ (192,621)	$ 10,253	$ 30,504
Subscription of warrants			(27)			(27)
Issuance of ordinary shares on exercise of stock - options or warrants	50,000	8	391			399
Issuance of ordinary shares on vesting of free shares	147,150	24	(24)			-
Stock-based compensation expense			1,975			1,975
Net loss				(42,925)		(42,925)
Other comprehensive income (loss)					562	562
Comprehensive loss						$ (42,363)
Balance at December 31, 2013	25,612,550	$ 3,746	$ 211,473	$ (235,546)	$ 10,815	$ (9,512)

The accompanying notes are an integral part of the consolidated financial statements

FLAMEL TECHNOLOGIES S.A.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of dollars except share data)

	Year ended December 31,		
	2011	**2012**	**2013**
Cash flows from operating activities:			
Net income (loss)	$ (8,774)	$ (3,228)	$ (42,925)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment	3,346	3,183	3,062
Loss (gain) on disposal of property and equipment	(11)	(37)	14
Gains on sales of marketable securities	(41)	(6)	-
Grants recognized in other income and income from operations	(3,227)	(975)	(676)
Remeasurement of acquisition liabilities (Note 25)	-	(18,834)	28,135
Interest expense on debt related to the royalty agreements (Note 25)			1,990
Impairment of assets	-	7,170	-
Calculated interest on amortized method (Note 25)			712
Change in deferred tax	-	(4,758)	(11,320)
Stock compensation expense	2,779	3,040	2,029
Increase (decrease) in cash from:			
Accounts receivable	(464)	2,610	(512)
Inventory	(917)	176	(2,186)
Prepaid expenses and other current assets	856	800	315
Research and development tax credit receivable	(3,938)	(6,642)	665
Accounts payable	(825)	(613)	1,318
Deferred revenue	856	(4,984)	(14)
Accrued expenses	(491)	(742)	1,211
Other current liabilities	399	(682)	(517)
Other long-term assets and liabilities	129	1,383	(1,977)
Net cash used in operating activities	(10,323)	(23,139)	(20,676)
Cash flows from investing activities:			
Purchases of property and equipment	(1,903)	(1,069)	(1,029)
Proceeds from disposal of property and equipment	185	67	1,006
Proceeds from sales of marketable securities	26,382	18,246	7,152
Purchase of marketable securities	(25,015)	(3,567)	(1,085)
Cash transferred on acquisition		1,771	-
Net cash provided by (used in) investing activities	(351)	15,448	6,044
Cash flows from financing activities:			
Reimbursment of loans or conditional grants	(1,910)	(223)	(475)
Proceeds from loans or conditional grants (Note 25)	7,855	6,668	19,333
Principal payments on capital lease obligations	(96)	(97)	(77)
Earn-out payment for acquisition (Note 25)	-	-	(907)
Cash proceeds from issuance of ordinary shares and warrants	296	607	400
Net cash provided by financing activities	6,145	6,955	18,274
Effect of exchange rate changes on cash and cash equivalents	(199)	22	252
Net increase (decrease) in cash and cash equivalents	(4,728)	(714)	3,894
Cash and cash equivalents, beginning of year	8,184	3,456	2,742
Cash and cash equivalents, end of year	$ 3,456	$ 2,742	$ 6,636
Supplemental disclosures of cash flow information:			
Income tax paid	-	56	153
Interest paid	73	118	1,701
The supplemental schedule of non cash investing and financing activities is as follows			
Capital lease obligations incurred	220	-	-
Fair value of assets acquired at acquisition date:	-	50,927	-
Liabilities assumed at acquisition date:	-	50,927	-

The accompanying notes are an integral part of the consolidated financial statements

1. Nature of business and summary of significant accounting policies:

1.1. Nature of business:

Flamel Technologies, S.A. (the "Company") is organized as a *société anonyme*, a form of corporation under the laws of The Republic of France. The Company was founded in 1990. The Company is a specialty pharmaceutical company with a long history of drug delivery expertise. The Company operates primarily in France and has commercial and marketing capabilities in the US.

1.2. Management estimates

The accompanying consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates reflected in the consolidated financial statements include, but are not limited to, purchase price allocation of its acquisitions, remeasurement of liabilities accounted at fair value, the recoverability of the carrying amount and estimated useful lives of long-lived assets, in progress R&D and goodwill, share-based compensation expenses, evaluation of long term personnel compensation, calculation of R&D tax credit, and valuation allowance of deferred tax assets. Management makes these estimates using the best information available at the time the estimates are made; however, actual results could differ from those estimates.

1.3. Going concern

Management believes that the equity financing that generated $113.6 million in net proceeds in March 2014, is sufficient for the company to continue as a going concern for at least the next twelve months.

1.4. Principles of consolidation

The accompanying consolidated financial statements include the Company and its wholly-owned subsidiaries in the United States. All inter-company accounts and transactions have been eliminated. The list of the subsidiaries is detailed in Exhibit 8.1.

1.5. Translation of financial statements of foreign entities and foreign currency transactions:

The reporting currency of the Company and its wholly-owned subsidiary is the U.S. dollar as permitted by the SEC for a foreign private issuer (S-X Rule 3-20(a)). All assets and liabilities in the balance sheets of the Company, whose functional currency is the Euro, except those of the U.S. subsidiaries whose functional currency is the U.S. dollar, are translated into U.S. dollar equivalents at exchange rates as follows: (1) asset and liability accounts at year-end rates, (2) income statement accounts at weighted average exchange rates for the year, and (3) shareholders' equity accounts at historical rates. Corresponding translation gains or losses are recorded in shareholders' equity.

Transaction gains and losses are reflected in the statement of operations.

The Company has not undertaken hedging transactions to cover its currency translation exposure.

1.6. Revenue recognition

Revenue includes upfront licensing fees, milestone payments for R&D achievements, compensation for the execution of research & development activities and product sales.

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

The Company uses a multiple attribution model, referred to as the milestone-based method:

- As milestones relate to discrete development steps (i.e. can be used by the co-development partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.
- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.
- Research and development work is compensated at a non-refundable hourly rate for a projected number of hours. Revenue on such agreements is recognized proportionally to the actual number of hours worked compared to the latest estimated total hours.. Costs incurred under these contracts are considered costs in the period incurred. Payments received in advance of performance are recorded as deferred revenue and recognized in revenue as services are rendered.

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. As is customary in the pharmaceutical industry, the Company’s gross product sales are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of its products, an estimate of provision for sales return and allowances is recorded which reduces product sales. These adjustments include estimates for product returns, chargebacks, payment discounts and other sales allowances and rebates. The return allowance, when estimable, is based on an analysis of the historical returns of the product or similar products.

For new product launches the Company recognizes revenue based on net product sales of wholesalers to their customers, until sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, renowned wholesaler inventory tracking service. Net sales of wholesalers to their customers are calculated by deducting estimates for returns for wholesaler customers, chargebacks, payment discounts and other sales or discounts offered from the applicable gross sales value. When the Company has the ability to estimate product returns from wholesalers, product sales are recognized upon shipment, net of discounts, returns and allowances. Estimates for product returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors.

The Company launched Bloxiverz® in July of 2013 and determined that market acceptance of the product had not occurred given the absence of wholesaler reorders and insufficient data to determine product returns. For the twelve months ended December 31, 2013, the criteria for recognizing the revenue were not met and the Company deferred $1.1M of revenue as of December 31, 2013.

The Company receives royalty revenues under a license agreement with a third party that sells products based on technology developed by the Company. There are no future performance obligations on the part of the Company under this license agreement. The license agreements provide for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period and classified these revenues in ‘Other Revenues’.

The Company signs feasibility study agreements. Revenue is recognized over the term of the agreement as services are performed.

1.7. Governmental Grants:

The Company receives financial support for various research or investment projects from governmental agencies.

The Company recognizes conditional grants related to specific development projects conditioned on completion of investment program and ongoing employment at the facilities as an offset to operating expenses once all conditions stated in the grant have been met.

The Company recognizes unconditional grants for research and development (R&D) projects requiring the collaboration of both private and public research partners as an offset to R&D expense on a pro-rata basis over the duration of the program.

The Company receives funds to finance R&D projects. These funds are repayable on commercial success of the project. In the absence of commercial success, the Company is released of its obligation to repay the funds and as such the funds are recognized in the Income Statement as 'Other Income'. The absence of commercial success must be formally confirmed by the granting authority. Should the Company wish to discontinue the research and development to which the funding is associated, the granting authorities must be informed.

1.8. Research and development costs:

Research and development (R&D) expenses comprise the following types of costs incurred in performing R&D activities: salaries, allocated overhead and occupancy costs, clinical trial and related clinical or development manufacturing costs, contract and other outside service fees, filing fees and regulatory support. Research and development expenditures are charged to operations as incurred.

The Company does not disclose research development costs per partner funded contract and does not believe such disclosure would be material to investors.

1.9. Concentration of credit risk:

The Company's cash and cash equivalents are mainly deposited with HSBC, Crédit Agricole, Commerce Bank and Citibank.

The marketable securities issued by Crédit Agricole have strong credit ratings (rated "A" by Standard and Poor).

The Company's revenues are derived mainly from product sales and services, collaborative research and development contracts and supply agreements with pharmaceutical companies based in Europe and the United States. All significant customers are discussed in Note 4.

The Company performs ongoing credit evaluations of its customers and maintains provisions for potential credit losses as considered necessary. The Company generally does not require collateral. Historically, the Company has not experienced significant credit losses on its customer accounts. The allowance for doubtful accounts was $137,000, $139,000 and $145,000 at December 31, 2011, 2012 and 2013, respectively.

1.10.Earnings per share:

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period. Such securities are not considered in computing diluted loss per share as their effects would be anti-dilutive.

1.11. Cash and cash equivalents:

Cash and cash equivalents consist of cash on hand, cash on deposit and fixed term deposit being highly liquid investments with a maturity of three months or less at the date of purchase.

1.12.Marketable securities:

Marketable securities consist of highly liquid investments in money market mutual funds. Marketable securities are classified as available-for-sale securities in accordance with ASC 320-10, "Accounting for Certain Investments in Debt and Equity Securities" These investments are recorded at fair value, which is based on quoted market prices. Accordingly, unrealized gains and losses are included in accumulated other comprehensive income until realized.

1.13.Accounts Receivable:

Accounts receivable are stated at amounts invoiced net of allowances for doubtful accounts**.** The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables deemed uncollectible. Provision is made based upon a specific review of all significant outstanding invoices.

1.14.Inventories:

Inventories consist of raw materials and finished products, which are stated at cost determined under the first-in, first-out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as research and development costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

1.15.Property and equipment:

Property and equipment is stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Land and buildings	20 years
Laboratory equipment	4 - 8 years
Office and computer equipment	3 years
Furniture, fixtures and fittings	5-10 years

Assets under capital leases are amortized over the economic lives of the assets. Amortization of the carrying value of assets under capital leases is included in depreciation expense.

1.16.Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized, but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, “Goodwill and other intangible assets”, the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company’s tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit’s goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased licenses and in progress R&D recognized as part of the Eclat acquisition purchase price allocation. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset. If the related project is not completed in a timely manner or the project is terminated or abandoned, we may have an impairment related to the IPR&D, calculated as the excess of the asset’s carrying value over its fair value.

Our policy defines IPR&D as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires us to make significant estimates. The amount of the purchase price allocated to IPR&D is determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rate used is determined at the time of measurement in accordance with accepted valuation methods. These methodologies include consideration of the risk of the project not achieving commercial feasibility.

At the time of acquisition, we expect that all acquired IPR&D will reach technological feasibility, but there can be no assurance that the commercial viability of these products will actually be achieved. The risks associated with achieving commercialization include, but are not limited to, delay or failure to obtain required market clearances.

1.17.Impairment of Long-Lived Assets:

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the asset (or the group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted future cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the asset, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on management assumptions and are subject to risk and uncertainty.

1.18.Income taxes:

The Company accounts for income taxes in accordance with ASC 740. Under ASC 740, deferred tax assets are determined based on the difference between the financial reporting and tax basis of assets and liabilities, applying enacted statutory tax rates in effect for the year in which the tax differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in the tax laws and rates on the date of enactment.

1.19.Research credit tax

The Company is eligible to receive a French research tax credit that is calculated based on a percentage of eligible research and development costs. The tax credit can be refundable in cash and is not contingent on future taxable income. As such, the Company considers the research credit tax as a grant, offsetting operating expenses.

1.20.Employee stock options and warrants:

The Company accounts for Stock based compensation based on grant-date fair value estimated in accordance with ASC 718.

The Company estimated the fair value of stock options and warrants using a Black-Scholes option-pricing valuation model (“Black-Scholes model”).

The Company uses a simplified method to estimate the maturity. The Company considered historical data was insufficient and irrelevant relative to the grant of stock-options and warrants to a limited population and the simplified method was used to determine the expected term for stock-options and warrants granted.

The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

1.21 Long-Term Debt

The Long Term debt associated with the acquisition liabilities arising from the acquisition of Eclat Pharmaceuticals are accounted at fair-value (*see note 2 – Business Combinations and note 16 Long-Term Debt*). Changes in fair value are recorded in the income statement in operating expenses as remeasurement of acquisition liabilities.

The long-term debt associated with the Deerfied Facility and Broadfin Facility agreements are accounted for at amortized cost. The Company elected the fair value option for the measurement of the long-term liability associated with the Deerfield and Broadfin Royalty agreements (*see note 16 Long-Term Debt*). Changes in fair value are recorded in the income statement in interest expense on the debt related to the royalty agreement.

1.22 Recent Accounting Pronouncements

In February 2013, the FASB issued ASU No. 2013-02, “Comprehensive Income” (“ASU 2013-02”). ASU 2013-02 requires new disclosures related to amounts reclassified out of accumulated other comprehensive income (“AOCI”) by component, as well as disclosures related to reclassifications from AOCI to net income. These disclosures may be presented on the face of the consolidated financial statements or in the notes thereto. ASU 2013-02 is effective for reporting periods beginning after December 15, 2012. The adoption of ASU 2013-02 had no effect on the consolidated financial position, results of operations or cash flows of the Company.

In July 2013, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists" ("ASU 2013-11"). ASU No. 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. ASU 2013-11 is effective for fiscal years and interim periods within those years, beginning after December 15, 2013. The Company does not expect the provisions of ASU 2013-11 to have a material effect on the consolidated financial position, results of operations or cash flows of the Company.

2. Business combinations

Effective March 13, 2012, Flamel acquired, through its wholly owned subsidiary Flamel US Holdings, Inc., or Flamel US, all of the membership interests of Éclat Pharmaceuticals, LLC, or Éclat Pharmaceuticals, from Éclat Holdings, LLC, or Éclat Holdings, an affiliate of Flamel's largest shareholder Deerfield Capital L.P. Éclat Pharmaceuticals is a specialty pharmaceuticals business focused on the development, approval and commercialization of niche brands and generic pharmaceutical products. In exchange for all of the issued and outstanding membership interests of Éclat Pharmaceuticals, Flamel US provided consideration consisting of:

- a $12 million senior, secured six-year note that is guaranteed by the Company and its subsidiaries and secured by the equity interests and assets of Éclat;
- two warrants to purchase a total of 3,300,000 American Depositary Shares, each representing one ordinary share of Flamel ("ADSs"); and
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat Pharmaceuticals launch products
- a commitment to pay 100% of any gross profit generated by Hycet® up to a maximum of $1 million.

The Purchase Agreement also contains certain representations and warranties, covenants, indemnification and other customary provisions.

Flamel US issued the note pursuant to a Note Agreement among Flamel, Flamel US and Éclat Holdings dated March 13, 2012. The note is payable over six years only if certain contingencies are satisfied, namely that: (a) two or more Éclat Pharmaceuticals launch products are approved by the FDA, or (b) one Éclat Pharmaceuticals launch product is approved by the FDA and has generated $40 million or more in cumulative net sales. These contingencies are referred to as thresholds. If either Threshold is satisfied, Flamel US will pay 25% of the original principal amount due under the note on each of the third, fourth, fifth and sixth anniversaries of the date of the note. The note accrues interest at an annual rate of 7.5% (calculated on the basis of the actual number of days elapsed in each month) and is payable quarterly in arrears commencing on July 2, 2012 and on the first business day of each October, January, April and July thereafter; provided, however, that if on any such interest payment date, at least one Éclat Pharmaceuticals launch product has not been approved by the FDA, the interest payable on such date will not be payable, but will be added on such date to the outstanding principal amount of the note. Flamel must pay any interest so accrued no later than nine months after such FDA approval and, upon such payment; such outstanding principal amount of the note will be reduced by the amount thereof.

In addition to the note, two six year warrants were issued to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. The warrants provide that they may only be exercised for six years following the approval, for the purposes of French law, by the holders of a majority of Flamel's ordinary shares, of the authorization and issuance of the warrants and the ordinary shares underlying the warrants and the waiver of all preferential subscription rights of holders of ordinary shares (and ADSs) with respect to the warrant and the underlying shares. On June 22, 2012, the authorization and issuance and waiver were approved by the holders of the requisite number of ordinary shares

The acquisition-date fair value of the consideration transferred totaled $50,927,000 which consisted of the following:

(Amounts in thousands of USD)		
Note	$	5,625
Warrants		12,065
Deferred consideration		33,237
Total acquisition liabilities	$	50,927

The fair value of the note was estimated using a probability-weighted discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The key assumptions are as follows: 20% discount rate, 72% probability of success.

The fair value of the warrants was determined by using a Black-Scholes option pricing model with the following assumptions:

Share price	$	7.29
Risk-free interest rate		2.00%
Dividend yield		-
Expected volatility		56.26%
Expected term		6.0 years

The deferred consideration fair value was estimated by using a discounted cash flow model based on probability adjusted annual gross profit of each of the Éclat Pharmaceuticals products. A discount rate of 20% has been used, except for Hycet for which a discount rate of 13% has been retained.

The transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible assets and identifiable intangible assets acquired and liabilities assumed were recorded at fair value, with the remaining purchase price recorded as goodwill.

The following table summarizes the final fair values of the assets acquired and liabilities assumed at the acquisition date.

At March 13, 2012 (amounts in thousands of USD)

Cash and cash equivalent	$	1,771
Account receivables		210
Inventories		38
Prepaid expenses and other current assets		430
Property and equipment, net		57
Intangible assets		49,282
Goodwill		18,491
Total identifiable assets acquired		70,279
Current liabilities		(459)
Deferred Tax Liabilities		(18,887)
Long term liabilities		(6)
Total liabilities assumed		(19,352)
Net identifiable assets acquired	$	70,279
Net assets acquired	$	50,927

Of the $49,282,000 of acquired intangible assets, $47,309,000 was allocated to in-process research and development (IPR&D) assets that were recognized at fair value on the acquisition date. The fair value was determined using an income approach, including a discount rate of 20%, applied to probability adjusted after-tax cash flows. The estimated costs to complete the IPR&D projects represents management's best estimate of expected costs, but are subject to change based on additional information received as development activities advance. The remaining useful life has been estimated to be four years once the products in question have been approved. The remaining $1,973,000 was allocated to the acquired product license for Hycet® (3-year useful economic life). In November 2013, the Company disposed of the product license for Hycet generating a gain on sale of $0.1 million.

The deferred tax liability of $18.9 million relates to temporary differences associated primarily with the IPR&D, which are not deductible for tax purposes. Deferred taxes have been calculated at the statutory rate of 40%.

The difference between the purchase price and the fair value of the assets acquired and liabilities assumed of $18.5 million was allocated to goodwill. This goodwill is attributable to the remaining product opportunities identified by the acquired entity at the date of acquisition, but for which limited development had occurred and the regulatory approval process had not commenced. None of the goodwill is expected to be deductible for income tax purposes.

The Company recognized $635,000 of acquisition related costs that were expensed and included in SG&A expenses.

The amounts of revenues and earnings of Éclat Pharmaceuticals included in the Company's consolidated income statement from the acquisition date to the period ending December 31, 2012 (in thousands) are as follows:

	Revenue and earnings included in the consolidated income statement from March 13, 2012 to December 31, 2012
Revenues	$ 560
Net Income/(Loss)	$ (5,301)

The following supplemental pro forma information presents Flamel's financial results for the twelve month period as if the acquisition of Éclat Pharmaceuticals had occurred on January 1, 2011 (in thousands):

	Twelve months ended December 31,	
	2011	2012
	(unaudited)	
Revenues	$ 33,209	$ 26,314
Net Income/(Loss)	$ (13,624)	$ (3,754)

The above unaudited pro forma information was determined based on the historical US GAAP results of Flamel and Éclat Pharmaceuticals. The unaudited pro forma consolidated results are not necessarily indicative of what the Company's consolidated results of operations actually would have been if the acquisition was completed on January 1, 2011. The unaudited pro forma consolidated net income primarily reflects adjustment of:

i. Elimination of $0.6 million of transaction costs, which are directly attributable to the transaction, for Flamel for the period ended December 31, 2012, and integration of these costs as if they were expensed in the period ended December 31, 2011.
ii. Adjustment to record the estimated amortization expense for intangible asset. The amortization expense was calculated using estimated useful life of three years for the Hycet product license acquired by Éclat Pharmaceuticals in July 2011, with an estimated value of $2.0 million, considering the acquisition would have been completed on January 1, 2011. The amortization for period ended December 31, 2011 amounts to $660,000.

iii. An adjustment to record the estimated increase in amortization expense for intangible assets for the period prior to the acquisition (from January 1, 2012 to March 13, 2012). The incremental expense for the three months was $25,000.

Net loss for the twelve month period ended December 31, 2012 includes income of $14.4 million of which $18.8 million represents remeasurement of the fair value of the acquisition liabilities and $4.3 million of expenses net of tax in connection with the impairment of certain assets acquired. Net loss for the twelve month period ended December 31, 2013 includes expenses of $28.1 million related to the remeasurement of the fair value of the acquisition liabilities. The Company's result of operations in future periods will be affected by the movements in the fair value of the acquisition liabilities which are remeasured at each balance sheet date. Changes in fair value will be recognized in operating income. Changes in assumptions or other variants used to calculate the fair value of acquisition liabilities, such as, but not limited to, the Company's share price, volatility of the share price, discount rates, probability assessment of success in completing development and commercializing acquired products, market share, market size and selling prices negotiated for each product will have an effect on the fair value of the acquisition liabilities. Future non-discounted probability adjusted deferred consideration payments, as of December 31, 2013, are expected to amount to $57.9 million.

As of December 31, 2012 and 2013, the Company conducted impairment tests of the IPR&D and recognized an expense of $7,170,000 in the year ended December 31, 2012, based on the management's best estimates of the present value of future cash flows compiled on a project by project and product by product basis (*see note 12 Goodwill and intangible assets*). The impairment of these assets resulted from new facts and circumstances that occurred post acquisition regarding the potential competitive landscape of one of the products in the portfolio.

3. Subcontracting agreement:

In October, 2011, the Company signed a new supply agreement with GSK for the production of Coreg CR microparticles. Under the agreement, the Company is entitled to guaranteed minimum payments to supply Coreg CR microparticles over a period of five years. No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. Pursuant to the agreement, the Company received a payment of € 1,300,000 ($1,835,000) during the third quarter of 2011 and a further €1,300,000 ($1,752,000) payment in the fourth quarter of 2011, as well as a higher margin on all product produced by Flamel for GSK since January 1, 2011. For the year 2011, the Company recognized as revenues from product sales a total amount of $13,395,000 of which $2,711,000 relates to the €2,600,000 received in the third quarter and the fourth quarter 2011. For 2012, the Company recognized as revenues from product sales a total amount of $9,097,000 of which $852,000 relates to the €2,600,000 received in 2011. For 2013, the Company recognized as revenues from product sales a total amount of $7,969,000.

4. License, research and consulting agreements:

GlaxoSmithKline (GSK)

In March 2003, Flamel Technologies and SB Pharma Puerto Rico Inc, an affiliate of GSK entered into a license agreement whereby the Company agreed to license its controlled-release Micropump® in order to develop a new formulation for carvedilol, which is marketed by GSK as Coreg.

In 2011, the Company recognized $8,210,000 of royalties on Coreg sales.

In 2012, the Company recognized $6,870,000 of royalties on Coreg sales.

In 2013, the company recognized $6,807,000 of royalties on Coreg sales

In December 2004, Flamel and GSK (GSK) entered into a four year supply agreement whereby Flamel agreed to supply GSK with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20,717,000 to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditures consist of both buildings and fixtures, and production equipment. Flamel will have immediate title to buildings and fixtures; however title to production equipment remains with GSK for the duration of the supply agreement.

If the Company breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. The likely occurrence of this event is deemed remote given the Company's ability to perform under supply arrangements based on its historical experience. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment.

Upon cessation of the supply agreement, in the normal course of business, GSK will pass title to all production equipment to Flamel without cost of any kind.

A total of $8,188,000 has been incurred on the acquisition of buildings and fixtures and a total of $11,138,000 has been incurred on behalf of GSK for the purchase of production equipment and associated costs. As of December 31, 2013, the funds received from GSK to finance the acquisition of assets owned by Flamel are classified in other current liabilities for $331,000 and in other long term liabilities for $3,357,000. The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets.

In July 2006, Flamel and GSK entered into a further agreement as a supplement to the original supply agreement whereby GSK partly sponsored the extension of the then existing facilities at Pessac from two lines to three. GSK has exclusive use of part of this equipment, in for the production of Coreg CR microparticles. The total funding provided by GSK amounted to $8.1 million to finance the acquisition of equipments, buildings and fixtures. The Company received all installments due under the agreement by December 31, 2007. As of December 31, 2013 the funds received from GSK to finance the extension were classified in other current liabilities for $348,000 and long term liabilities for $2,596,000. The liability is amortized on a pro-rata basis over the expected life of the assets and proportionally based on funding received compared with the total value of the related assets. This amortization is reflected as an offset of the depreciation of the related assets (see Note 13).

In October, 2011, the Company signed a new supply agreement with GSK for the production of Coreg CR microparticles; the Company is the sole supplier of Coreg CR microparticles for GSK. Under the agreement, the Company will receive guaranteed minimum payments to supply Coreg CR microparticles over a period of over a minimum period of five years.

No earlier than January 1, 2013, GSK may terminate the agreement at their sole discretion by giving six months written notice. *See Note 3. Subcontracting Agreement.*

Wyeth Pharmaceuticals

On September 12, 2007 the Company entered into a development and license agreement with Wyeth Pharmaceuticals, ('Wyeth') now part of Pfizer Inc., whereby the Company agreed to license its Medusa technology for the development and licensing of a marketed protein. The Company received an upfront fee and may receive development fees, milestones and royalties on the product. On September 2, 2008 Wyeth confirmed their intention to pursue the development and license agreement triggering a $500,000 payment. On November 4, 2009 Wyeth exercised the option for the licensing of Flamel technology and paid $1,000,000.

In 2011, the Company recognized research and development revenues of $75,000. The Company also recognized $665,000 of amortization of up-front payment and option payment, of which $425,000 relates to accelerated amortization due to termination.

In March 2012 the Company announced that the arrangement with Wyeth Pharmaceuticals was discontinued.

Merck Serono, a division of Merck KGaA

On December 20, 2007 Flamel Technologies entered into a relationship with Merck Serono, a division of Merck KGaA, to investigate the applicability of Flamel's Medusa technology for the extended release of a therapeutic protein of Merck Serono's portfolio.

In consideration of the agreement signed in 2007, Merck Serono made an upfront payment of $2.7 million for investigating the therapeutic protein, which has been amortized over the initial feasibility period. In February 2009 Merck Serono exercised the option to license our technology triggering a payment of $ 6,500,000 (€5,000,000). Under the terms of the agreement, the Company is eligible to receive up to €41 million ($53 million) in milestone payments upon certain agreed-upon development events.

In 2011, the Company recognized research and development revenues of $2,398,000. The Company also recognized $1,391,000 of amortization of the initial up-front and option payments.

On November 2, 2012, Flamel received notice from Merck Serono to terminate for convenience the development and license agreement, effective January 31, 2013. For the year 2012, the Company recognized $2,745,000 of amortization of the initial up-front and option payments, of which $1,426,000 relates to accelerated amortization due to termination.

Baxter Healthcare Inc.

On June 19, 2009 the Company entered into agreement with Baxter Healthcare Inc., to formulate controlled release applications of blood clotting factor replacement therapies using Flamel's Medusa® technology. In consideration of this agreement the Company received an access fee of $3,600,000 (€2,500,000).

In 2011, the Company recognized license revenues of $871,000 as amortization of the initial up-front fee. In October 2011 the Company announced that the agreement had been terminated.

Eagle Pharmaceuticals Inc

On October 12, 2011 the Company entered into a license and development agreement with Eagle Pharmaceuticals for the development of a Medusa-based hydrogel depot formulation of the small molecule antibiotic, tigecycline. In consideration of this agreement, the Company recognized research and development revenues of $345,000. Milestone payments amounting to $1.2 million (€0.9 million) will be received upon achievement of certain development and commercial events.

In 2012, the Company recognized research and development revenues of $659,000. The Company also recognized $43,000 of amortization of the initial up-front fee.

In 2013, the Company recognized research and development revenues of $31,600 as amortization of the initial up-front fee

Pfizer Inc

The company entered into research collaboration with Pfizer Inc. to assess the applicability of the Medusa platform to certain molecules in development. Under this collaboration, the Company recognized research and development revenues of $18,000 in 2011. In March 2012 the Company announced that the collaboration with Pfizer had been discontinued.

Corning

In December 1998, the Company signed a long-term research and product development agreement with Corning France and Corning Incorporated. Pursuant to the terms of this agreement, Flamel receives royalties on the sales of Corning products that utilize Flamel's innovations.

The Company recognized royalties on Corning's sales of $372,000 in 2011, $152,000 in 2012 and $111,000 in 2013. On February 12, 2014 the Company signed an amendment effectively terminating the research and product development agreement and received a payment of $280,000 excluding sales taxes.

Others

The Company recognized license and research and development revenues with undisclosed partners for an amount of $4,808,000 in 2011,$5,877,000 in 2012 and $6,525,000 in 2013.

5. Research and Development expenses

Total research and development expenditures can be disaggregated in the following significant type of expenses ($USD in millions):

	2011	2012	2013
Research and Development Expenses	33.7	32.7	32.5
R&D Tax Credit	(6.0)	(6.5)	(5.8)
Grants	(1.7)	(0.1)	-
Total	25.1	26.1	26.7

As of December 31, 2012 the Company recognized to the income statement unconditional grants for a total of $103,000. No unconditional grants have been recognized to the income statement in 2013.

6. Stock based compensation:

6.1 ASC 718

The Company applies the provisions of ASC 718 in accounting for its stock based compensation. The fair value of each option and warrant granted during the year is estimated on the date of grant using the Black-Scholes option pricing model. Option valuation models require the input of subjective assumptions and these assumptions can vary over time. The weighted-average assumptions on grants made in each of the following years were:

	Year Ended December 31		
	2011	**2012**	**2013**
Weighted-average expected life (years)	$ 4.00	$ 5.70	$ 5.43
Expected volatility rate	63.60%	62.50%	61.00%
Expected dividend yield	-	-	-
Risk-free interest rate	0.83%	0.95%	1.40%
Forfeiture rate	-	-	-

We base our determination of expected volatility predominantly on the implied volatility of our traded options with consideration of our historical volatilities. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Stock based compensation expense recognized was as follows:

As of December 31, 2013, the projected compensation expense related to non vested options or warrants amounted to $4,090,000 and are expected to be recognized over a weighted average period of 2.13 years.

(In thousands of U.S dollars except per share data)	**Options**			**Free of charge share awards**			**Warrants**			**Total**		
	2011	**2012**	**2013**	**2011**	**2012**	**2013**	**2011**	**2012**	**2013**	**2011**	**2012**	**2013**
Research and development	332	419	398	897	649	320	-	-	61	1,229	1,068	779
Cost of goods sold	3	2	1	89	46	19	-	-	-	91	49	20
Selling, general and administrative	461	1,280	903	671	464	211	327	179	116	1,459	1,923	1,230
Total stock-based compensation expense	796	1,701	1,302	1,657	1,160	550	327	179	177	2,779	3,040	2,029
Effect on earnings per share												
Basic	0.03	0.07	0.05	0.07	0.05	0.02	0.01	0.01	0.01	0.11	0.12	0.08
Diluted	0.03	0.07	0.05	0.07	0.05	0.02	0.01	0.01	0.01	0.11	0.12	0.08

6.2 Warrants

The summary of warrants activity is as follows:

	Warrants Outstanding	Weighted Average Exercise Price in U.S dollars [1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2011	750,000	$ 7.82	€ 5.50
Warrants granted	300,000	$ 5.03	€ 3.54
Warrants cancelled	150,000	$ 6.94	€ 4.98
Balance at December 31, 2011	900,000	$ 6.89	€ 4.85
Warrants granted	3,300,000	$ 8.63	€ 6.61
Warrants reintegrated	100,000	$ 6.65	€ 4.97
Warrants cancelled	200,000	$ 10.20	€ 6.57
Balance at December 31, 2012	4,100,000	$ 8.12	€ 6.18
Warrants granted	200,000	$ 6.14	€ 4.58
Warrants exercised	50,000	$ 6.29	€ 4.50
Warrants cancelled	200,000	$ 6.29	€ 4.50
Balance at December 31, 2013	4,050,000	$ 8.14	€ 6.21

[1] Historical exchange rate at date of grant

50,000 warrants were exercised in 2013 and no warrants were exercised in 2011 and 2012.

Exercise prices and intrinsic value for warrants outstanding as of December 31, 2013 were as follows:

	Warrants Outstanding				Warrants Exercisable		
Range of exercise prices in euros	Number of shares	Weighted average remaining contractual life	Weighted average exercise price in euros	Weighted average intrinsic value in euros	Number of shares	Weighted average exercise price in euros	Weighted average intrinsic value in euros
0 to 4.58	500,000	0.89	3.96	1.88	320,000	3.61	2.23
5.44 to to 6.57	2,450,000	3.82	5.67	0.16	2,450,000	5.67	0.16
6.58 to 8.52	1,100,000	4.20	8.42	-	1,100,000	8.42	-
	4,050,000	**3.56**	**6.21**	**0.33**	**3,870,000**	**6.28**	**0.40**

The total fair value of warrants vested during 2011 amounted to €257,000or $358,000 (average exchange rate of the year).

The total fair value of warrants vested during 2012 amounted to €271,000or $348,000 (average exchange rate of the year).

No warrants were vested during 2013.

Intrinsic value represents the variance between the share price and the exercise price. As of December 31, 2013 the aggregate intrinsic value of warrants outstanding amounted to €1,342,000 or $1,867,000 (historical exchange rate at date of grant).

6.3 Stock Options

The activity under the option plans is as follows:

	Shares Available for Grant	Options Granted and Outstanding	Weighted Average Exercise Price in U.S dollars[1]	Weighted Average Exercise Price in Euros
Balance at January 1, 2011	475,000	3,098,490	$ 14.69	€ 11.71
Options authorized		-	-	-
Granted	(200,000)	200,000	$ 4.39	€ 3.28
Exercised	-	(44,200)	$ 1.48	€ 1.63
Forfeited	-	(113,300)	$ 8.93	€ 7.49
Balance at December 31, 2011	275,000	3,140,990	$ 14.65	€ 11.66
Options authorized	1,000,000	-	-	-
Granted	(550,000)	550,000	$ 5.97	€ 4.67
Exercised	-	(195,000)	$ 2.04	€ 2.33
Forfeited	10,000	(223,500)	$ 16.88	€ 13.69
Balance at December 31, 2012	735,000	3,272,490	$ 13.79	€ 10.90
Options authorized	600,000	-	-	-
Cancelled	(10,000)	-	-	-
Granted	(710,000)	710,000	$ 5.97	€ 4.36
Forfeited	13,000	(647,500)	$ 15.29	€ 12.63
Balance at December 31, 2013	628,000	3,334,990	$ 11.84	€ 9.17

[1] Historical exchange rate at date of grant

The total intrinsic value of options exercised during 2011 amounted to €111,000 or $149,000 (historical exchange rate at date of exercise).

The total intrinsic value of options exercised during 2012 amounted to €735,000 or $973,000 (historical exchange rate at date of exercise).

No options were exercised during 2013.

Stock options outstanding at December 31, 2013, which expire from 2014 to 2023, had exercise prices ranging from €3.00 to € 25.39. The weighted average remaining contractual life of all options is 3.80 years. As of December 31, 2013, there were 3,334,990 outstanding options at a weighted average exercise price of €9.17, of which 2,217,990 were exercisable at a weighted average price of €11.59. Exercise prices and intrinsic value for options outstanding as of December 31, 2013 were as follows:

	Stock Options Outstanding				Stock Options Exercisable		
Range of exercise prices in euros	**Number of shares**	**Weighted average remaining contractual life**	**Weighted average exercise price in euros**	**Weighted average intrinsic value in euros**	**Number of shares**	**Weighted average exercise price in euros**	**Weighted average intrinsic value in euros**
0 to 3.28	482,000	8.43	3.12	2.72	97,500	3.28	2.56
4.03 to 5.44	1,585,000	6.43	4.94	0.89	852,500	4.87	0.96
6.40 to 12.02	63,500	1.18	11.43	-	63,500	11.43	-
12.86 to 16.23	898,990	1.58	14.64	-	898,990	14.64	-
19.2 to 25.39	305,500	2.61	24.09	-	305,500	24.09	-
	3,334,990	**3.80**	**9.17**	**1.32**	**2,217,990**	**11.59**	**1.13**

The total fair value of options vested during 2011 amounted to €473,000 or $659,000 (average exchange rate of the year).

The total fair value of options vested during 2012 amounted to €846,000 or $1,088,000 (average exchange rate of the year).

The total fair value of options vested during 2013 amounted to €999,000 or $1,327,000 (average exchange rate of the year).

The aggregate intrinsic value of options outstanding amounted to €2,729,000 or $3,531,000 (historical exchange rate at date of grant). The aggregate intrinsic value of options exercisable amounted to €1,070,000 or $1,385,000 (historical exchange rate at date of grant).

6.4 Free share award

The activity under the free share award plans is as follows:

	Free of Charge Share Award Available for Grant	Free of Charge Share Award Granted and Outstanding	Weighted Average Fair Value at grant date in U.S dollars[1]	Weighted Average Fair Value at grant date in Euros
Balance at January 1, 2011	18,150	522,500	$ 7.25	€ 5.16
Options authorized	200,000	-	-	-
Granted	(200,000)	200,000	$ 4.39	€ 3.28
Exercised	-	(272,400)	$ 7.47	€ 5.07
Forfeited	8,450	(8,450)	$ 7.22	€ 5.18
Cancelled	1,000	(1,000)	$ 7.45	€ 5.06
Balance at December 31, 2011	26,600	440,650	$ 5.81	€ 4.36
Options authorized	200,000	-	-	-
Granted	(189,700)	189,700	$ 3.07	€ 2.38
Exercised	-	(258,150)	$ 6.52	€ 4.92
Forfeited	21,550	(21,550)	$ 5.79	€ 4.35
Balance at December 31, 2012	58,450	350,650	$ 3.81	€ 2.88
Options authorized	200,000	-	-	-
Granted	(192,500)	192,500	$ 7.36	€ 5.35
Exercised	-	(137,150)	$ 4.39	€ 3.28
Forfeited	20,600	(38,400)	$ 5.10	€ 3.72
Balance at December 31, 2013	86,550	367,600	$ 5.32	€ 3.93

[1] Historical exchange rate at date of grant

As of December 31, 2011 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,774,000 or $2,296,000 (historical exchange rate at date of grant).

As of December 31, 2012 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,009,000 or $1,336,000 (historical exchange rate at date of grant).

As of December 31, 2013 the total fair value (or intrinsic value) of Free Share Award outstanding amounted to €1,446,000 or $1,954,000 (historical exchange rate at date of grant).

7. Cash and Cash Equivalents:

Cash consists of cash on deposit and fixed term investments held in several major banks, and cash on hand. The components of cash and cash equivalents were as follows:

(In thousands of U.S. dollars)	December 31, 2012	December 31, 2013
HSBC	$ 880	$ 3,657
Credit Agricole	641	48
Commerce Bank	1,057	2,898
Citibank	159	28
Other	5	5
Total cash and cash equivalents	$ 2,742	$ 6,636

8. Marketable securities:

Marketable securities are classified as available-for-sale securities and are recorded at fair market value. Unrealized gains and losses are recorded as other comprehensive income in shareholder's equity, net of income tax effects.

For the year ended December 31, 2011, 2012 and 2013 marketable securities amounted respectively to $21,036,000, $6,413,000 and $401,000.

As of December 31, 2011, 2012 and December 31, 2013 there were no unrealized gains or losses.

(in thousands of U.S dollars)	Fair value		Value at cost		Unrealized Gains	
	2012	2013	2012	2013	2012	2013
Credit Agricole securities	6,413	401	6,413	401	-	-
HSBC securities	-	-	-	-	-	-
Total	6,413	401	6,413	401	-	-

Gross realized gains on sales of these available-for-sale securities amounted to $41,000, $6,000 and $0 for the years ended December 31, 2011, 2012 and 2013 respectively.

(in thousands of U.S dollars)	Proceeds from sales		Purchase of securities		Gross gains (Losses)	
	2012	2013	2012	2013	2012	2013
Credit Agricole securities	15,143	7,152	3,573	1,085	3	-
HSBC securities	3,216	-	-	-	3	-
Total	18,359	7,152	3,573	1,085	6	-

9. Inventory:

The components of inventories were as follows:

(In thousands of U.S. dollars)	December 31, 2012	December 31, 2013
Raw materials	894	1,715
Finished goods	626	2,047
Inventories, net	1,520	3,762

10. Prepaid expenses and other current assets:

The components of prepaid expenses and other current assets were as follows:

(In thousands of U.S. dollars)	December 31, 2012	2013
Valued-added tax recoverable	1,013	689
Prepaid expenses	906	1,478
Advance to suppliers	324	219
Other currents assets	-	95
Grants recoverable	71	-
Total Prepaid expenses and other current assets	2,314	2,481

11. Property and Equipment:

The components of property and equipment were as follows:

(In thousands of U.S. dollars)	December 31, 2012	2013
Land and buildings	10,332	10,799
Laboratory equipment	29,314	30,053
Office and computer equipment	5,135	5,800
Furniture, fixtures and fittings	20,697	21,078
Construction in progress	-	-
Total property and equipment	65,478	67,730
Less accumulated depreciation and amortization	(47,240)	(50,295)
Property and equipment, net	18,238	17,435

Depreciation expense related to property and equipment amounted to $3,346,000, $3,183,000 and $3,062,000 for the years ended December 31, 2011, 2012 and 2013, respectively.

Property and Equipment include costs of $509,000, $507,000 and $391,000 at December 31, 2011, 2012 and 2013 respectively that are related to capitalized lease assets. Accumulated amortization of these leased assets was approximately $173,000, $211,000 and $142,000 at December 31, 2011, 2012 and 2013 respectively. Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2011, 2012 and 2013 and amounted to $56,000, $44,000 and $49,000 respectively.

12. Goodwill and intangible assets

	December 31,							
	2012				2013			
(In thousands of U.S. dollars)	Gross carrying amount	Accumulated amortization	Impairment	Intangible assets, net	Gross carrying amount	Accumulated amortization	Impairment	Intangible assets, net
Goodwill	$ 544	(544)	-	-	$ 544	(544)	-	-
Goodwill Eclat acquisition	18,491	-	-	18,491	18,491	-	-	18,491
Total Goodwill	$ 19,035	$ (544)	$ -	$ 18,491	$ 19,035	$ (544)	$ -	$ 18,491
In-progess R&D	47,309	-	(7,170)	40,139	47,309	-	(7,170)	40,139
License	1,973	(523)		1,450	-	-		-
Total Intangible assets	$ 49,282	$ (523)	$ (7,170)	$ 41,589	$ 47,309	$ -	$ (7,170)	$ 40,139

See note 2 – Business combinations.

13. Accrued Expenses

Accrued expenses consist mainly of expenses related to paid vacations, compensatory leaves with related social charges.

Accrued expenses comprises of the following:

(In thousands of U.S. dollars)	December 31, 2012	2013
Accrued compensation	1,671	2,440
Accrued social charges	3,193	3,566
Accrued Interest	-	521
Other	149	-
Total accrued expenses	5,013	6,527

14. Other current and Long Term liabilities:

14.1. Other current liabilities:

Other current liabilities comprise the following:

(In thousands of U.S. dollars)	December 31, 2012	2013
R&D credit tax financing short term	-	7,121
Funding from partner GSK short term	669	679
Employee service award provision short term	263	285
Provision for retirement indemnity short term	-	153
Other	-	71
Valued-added tax payable	201	1
Total Other current liabilities	1,133	8,310

In 2011, the Company obtained an advance from OSEO, a governmental agency supporting innovation, for $6,813,000 (€5,164,000) secured against the research tax credits due to the company by the tax authorities for expenditure incurred in 2010. The interest rate applied is the monthly average of the Euro Interbank Offered Rate (EURIBOR) plus 0.9%. In 2012 the operation was renewed with the same conditions and secured against the research credit tax from 2011. The Company received an amount of $5,848,000 (€4,432,000). As of December 31, 2012 the total funding was classified as a long term liability for an amount of $12,661,000. As of December 31, 2013 the total funding amounted to $13,234,000 of which $7,121,000 was classified as short term liability and $6,113,000 was classified as a long term liability (see note 14.2).

In connection with the 2004 supply agreement with GSK (see Note 4), the Company received funds to finance facilities related assets. A total of $8,188,000 has been spent on the acquisition of buildings and fixtures and a total of $11,138,000 has been spent on behalf of GSK for the purchase of production equipment. As of December 31, 2013 the funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $331,000 and as a long term liability for $3,357,000. In July 2006, Flamel and GSK entered into a side agreement to the original agreement whereby GSK partially sponsored the extension of the Micropump development facility (see Note 4). This facility was completed in March 2008. As of December 31, 2007, the Company had received all installments from GSK for financing of this project. The total installments amounted to $8,097,000. As of December 31, 2013, the funds received from GSK are classified as a current liability for $348,000 and as a long term liability for $2,596,000 (see Note 14.2).

The liability is amortized on a pro-rata basis over the expected life of the related assets and reflected as an offset of the depreciation of the related assets (see Note 4).

The Service award provision is accrued over the respective service period (5, 10, 15 and 20 years) using actuarial assumptions and calculations as for the lump sum retirement indemnity (see Note 21). In October 2013, the Company terminated payment of the service award with an effective date of June 30, 2014 and as such, reversed the long term provision in operating expenses.

For the year ended December 31, 2012 the provision amounted to $3,031,000 of which $263,000 is short term. For the year ended December 31, 2013 the total provision amounted to $285,000 and is classified as short term.

14.2. Other long term liabilities

Other long term liabilities are composed of the following:

(In thousands of U.S. dollars)	December 31, 2012	2013
Funding from partner GSK long term	6,345	5,953
R&D credit tax financing long term	12,661	6,113
Provision for retirement indemnity (see note 21)	2,875	3,834
Employee service award provision long term	2,768	-
Other	31	40
Total Other long term liabilities	24,680	15,940

Funding from GSK long term amounted to $3,357,000 in connection with the supply agreement signed in December 2004 and relates to the acquisition of buildings and fixtures and $2,596,000 in connection with the side agreement to the original agreement, signed in July 2006 (see Note 14.1).

As of December 31, 2013 the total financing of the R&D tax credit amounted to $13,234,000 of which $6,113,000 was classified as a long term liability (see Note 14.1).

15. Deferred Revenue:

Current portion of deferred revenue comprises of upfront licensing fees which are recognized over the development period of the contract and revenue on shipments of Bloxiverz.

For the year ended December 31, 2012 deferred revenues amounted to $795,000 and $1,264,000 for the year ended December 31, 2013.

In 2012, these deferred revenues result from the upfront license fees received from undisclosed partners. In 2013, these deferred revenues result from the upfront license fees received from undisclosed partners for $189,000 and the deferral of revenue on shipments of Bloxiverz® for $1,075,000, a product which was launched in July 2013. As of December 31, 2013, the criteria for recognizing the revenue have not been met, accordingly all revenues on shipments of the product in 2013 have been deferred.

16. Long-term Debt:

Long-term debt comprises:

(In thousands of U.S. dollars)	December 31, 2012	2013
Oseo ANVAR loans (a)	2,751	2,553
French Ministry of Research (b)	1,945	2,033
Acquisition liability contingent consideration (c)	24,063	37,991
Acquisition liability note (c)	5,713	10,405
Acquisition liability warrant consideration (c)	2,157	10,497
Deerfield Facility agreement (d)	-	12,492
Deerfield Royalty agreement (d)	-	4,590
Broadfin Facility agreement (e)		2,767
Broadfin Royalty agreement (e)	-	2,187
Total	36,629	85,515
Current portion	3,351	19,195
Long-term portion	33,278	66,320

(a) OSEO Anvar is an agency of the French government that provides financing to French companies for research and development. At December 31, 2012 and 2013, the Company had outstanding loans from Anvar of $2,751,000and $2,553,000, respectively for various programs. These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. Repayment is scheduled to occur from 2013 through 2019.

(b) In 2002, the Company received a loan of $464,000 from the French Ministry of Research on a research project (the “Proteozome” project) related to the development of new Medusa applications. Pursuant to the agreement, the Company is granted a loan equal to 50% of the total expenses incurred on this project over a three-year period beginning on January 2, 2002. The remainder of the advance of $1,707,000 was received in 2005. This loan is due for repayment in 2014. The loan is non-interest bearing and is repayable only in the event the research project is technically or commercially successful.

(c) The Acquisition liability relates to the acquisition by the Company through its wholly owned subsidiary Flamel US Holdings, Inc., or Flamel US, all of the membership interests of Éclat Pharmaceuticals, LLC (*see note 2 Business combinations*). In exchange for all of the issued and outstanding membership interests of Éclat Pharmaceuticals, Flamel US provided consideration consisting of:

- a $12 million senior, secured six-year note that is guaranteed by the Company and its subsidiaries and secured by the equity interests and assets of Éclat;
- two warrants to purchase a total of 3,300,000 American Depositary Shares, each representing one ordinary share of Flamel (“ADSs”); and
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat Pharmaceuticals launch products and to pay 100% of any gross profit generated by Hycet® up to a maximum of $1 million. The Purchase Agreement also contains certain representations and warranties, covenants, indemnification and other customary provisions.

As of December 31, 2013, the fair value of the note was estimated using a probability-weighted discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The key assumptions are as follows: 20% discount rate, 100% probability of success. The note has no early redemption premium.

The fair value of the warrants was determined by using a Black-Scholes option pricing model with the following assumptions for each of the years indicated:

	2012	2013
Share price	$ 3.03	$ 8.05
Risk-free interest rate	0.77%	1.27%
Dividend yield	-	-
Expected volatility	53.75%	50.0%
Expected term	5.2 years	4.3 years

Pursuant to guidance of ASC 815-40-15-7(i), the Company determined that the Warrants issued in March 2012 as consideration for the acquisition of Éclat could 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 is the Euro. The Company determined that these warrants should be accounted as a debt instrument.

As of December 31, 2013, the deferred consideration fair value was estimated by using a discounted cash flow model based on probability adjusted annual gross profit of each of the Éclat Pharmaceuticals products. A discount rate of 20% has been used.

See also Note 22 – Fair Value of Financial Instruments.

(d) On February 4, 2013 the Company concluded a $15 million debt financing transaction (Facility Agreement) with Deerfield Management, a current shareholder. Subject to certain limitations, the Company may use the funds for working capital, including continued investment in its research and development projects.

Consideration received was as follows:

- $12.4 million for a Facility agreement of a nominal value of $15 million, including a premium on reimbursement of $2.6 million. The principal amount of the Loan must be repaid over four years as follows: 10% on July 1, 2014, and 20%, 30% and 40% on the second, third, and fourth anniversary, respectively, of the original disbursement date of the Loan. Notwithstanding the foregoing, the entire principal amount of the Loan may be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest is payable quarterly, on the first business day of each January, April, July and October.
- $2.6 million for a Royalty agreement whereby, the Company's wholly owned subsidiary Éclat subject to required regulatory approvals and launch of product, is to pay a 1.75% Royalty of the net sales of certain products sold by Éclat and any of its affiliates until December 31, 2024.

The facility agreement is accounted for at amortized cost using an effective rate of 23%. The Company elected the fair value option for the measurement of the royalty liability.

The facility and royalty agreements are secured by the intellectual property and regulatory rights related to certain 'Éclat' Products and certain receivables and the Company has agreed to pledge certain physical assets.

As of December 31, 2013, the fair value of the Royalty was estimated using a probability-weighted discounted cash flow model based on probability adjusted projected annual net sales of each of the products which may be approved and sold by Éclat Pharmaceuticals. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The discount rate used is 20%.

See also Note 22 – Fair Value of Financial Instruments.

(e) On December 3, 2013 the Company concluded with Broadfin Healthcare Master Fund, a current shareholder, a $15 million debt financing transaction (Facility Agreement) divided in 3 tranche of $5 million each, Under the terms of the Facility, upon closing Broadfin made an initial loan of $5.0 million and the Borrowers may request, at any time prior to August 15, 2014, up to two additional loans in the amount of $5.0 million each, with funding subject to certain specified conditions. Subject to certain limitations, the Company may use the funds for working capital, including continued investment in its research and development projects

Consideration received was as follows:

- $2.8 million for a Facility agreement of a nominal value of $5 million, The principal amount of the Loan must be repaid over three years as follows: 100% on January 1, 2017. Notwithstanding the foregoing, the entire principal amount of the Loan may be repaid in whole or in part on any interest payment date occurring after December 31, 2013. Interest is payable quarterly, on the first business day of each January, April, July and October.
- $2.2 million for a Royalty agreement whereby, the Company's wholly owned subsidiary Éclat subject to required regulatory approvals and launch of product, is to pay a 0.834% Royalty of the net sales of certain products sold by Éclat and any of its affiliates until December 31, 2024. The amount of the royalty payable under the Royalty Agreement will increase by 0.583% for each additional loan made under the Facility, if any, up to a maximum royalty amount of 2.0%.

The facility agreement is accounted for at amortized cost using an effective rate of 41%. The Company elected the fair value option for the measurement of the royalty liability.

The facility and royalty agreements are secured by intellectual property associated with the Company's Medusa technology and a junior lien on substantially all of the assets of the Borrowers, which were previously pledged in connection with the Deerfield facility, royalty and acquisition liabilities.

Concurrent with entering into the Facility, the Acquisition liability note was amended to eliminate, effective as of December 31, 2014, the thresholds that must be reached before repayment of the note is required.

As of December 31, 2013, the fair value of the Royalty was estimated using a probability-weighted discounted cash flow model based on probability adjusted projected annual net sales of each of the products which may be approved and sold by Éclat Pharmaceuticals. This fair value measurement is based on significant inputs not observable in the market and thus represents a level 3 measurement as defined in ASC 820. The discount rate used is 20%.

Total future payments on long-term debt for the next five years ending December 31 (assuming the underlying projects are commercially or technically successful for governmental research loans) are as follows:

(In thousands of U.S. dollars)	**December 31,**
2014	20,286
2015	27,802
2016	24,541
2017	21,340
2018	7,307
	101,276

17. Capital lease obligations:

The Company leases certain of its equipment under capital leases. Each lease contract generally has a term of four years with a purchase option. No specific restrictions or guarantee provisions are included in the arrangement.

Future payments on capital leases for the years ending December 31 are as follows:

(In thousands of U.S. dollars)	December 31,
2014	91
2015	89
2016	14
Total	194
Less amounts representing interest	(6)
Future payments on capital leases	188
Less current portion	85
Long term portion	103

Interest paid in the years ended December 31, 2011, 2012 and 2013 was approximately $20,000, $14,000 and $9,700 respectively.

18. Earnings Per Share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations:

(In thousands, except per share amounts)	Year ended December 31, 2011	2012	2013
Numerator:			
Net income (loss)	$ (8,774)	$ (3,228)	$ (42,924)
Denominator:			
Weighted average shares outstanding used for basic earnings (loss) per share .	24,668,579	25,135,416	25,450,175
Effect of dilutive securities:			
Stock-options and warrants	-	-	-
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	24,668,579	25,135,416	25,450,175
Basic earnings (loss) per share	$ (0.36)	$ (0.13)	$ (1.69)
Diluted earnings (loss) per share	$ (0.36)	$ (0.13)	$ (1.69)

For the years ended December 31, 2011, 2012 and 2013, the effects of dilutive securities were excluded from the calculation of earnings per share as a net loss was reported in these periods.

Options to purchase 7,384,990 shares of common stock at an average of €7.55 per share were outstanding during 2013. The options, which expire in December 2023, were still outstanding at the end of year 2013.

19. Shareholders' Equity:

191. Preemptive subscription rights:

Shareholders have preemptive rights to subscribe for additional shares issued by the Company for cash on a pro rata basis when the Company makes a share offering. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

19.2. Dividends:

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception, as the result of an accumulated statutory deficit of approximately $168.5 million at December 31, 2013. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

19.3. Warrants:

The effects of applying the fair value method provided in accordance with ASC 718 are shown in Note 6.

On June 24, 2009 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.74 per warrant ($1.03). Each warrant is exercisable to purchase one Share at a price of €4.50 ($6.29). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in July 2009. As of December 31, 2013, 50,000 warrants were exercised and 200,000 warrants were cancelled.

On June 25, 2010 the Company authorized the Directors of the Company, to subscribe to 250,000 warrants for a subscription price of €0.70 per warrant ($0.90). Each warrant is exercisable to purchase one Share at a price of €5.44 ($6.68). These warrants are issued for a four-year period and will vest over one year from the date of issuance. These warrants were subscribed in July 2010.

On June 24, 2011 the Company authorized the Directors of the Company, to subscribe to 350,000 warrants for a subscription price of €0.47 per warrant ($0.67). Each warrant is exercisable to purchase one Share at a price of €3.54 ($5.03). These warrants are issued for a four-year period and will vest over one year from the date of issuance. 300,000 warrants were subscribed in July 2011.

On March 13, 2012, in connection with the acquisition of Éclat Pharmaceutical, Flamel issued to Breaking Stick LLC (formerly Éclat Holdings LLC), two six-year warrants to purchase an aggregate of 3,300,000 ADSs, each representing one ordinary share, of Flamel. One warrant is exercisable for 2,200,000 ADSs at an exercise price of $7.44 per ADS, and the other warrant is exercisable for 1,100,000 ADSs at an exercise price of $11.00 per ADS. Pursuant to the guidance of ASC 815-40-15-7 the Company determined that the warrants should be accounted for as a liability (*see note 16 Long Term Debt*).

On June 20, 2013, the Company authorized the Directors of the Company, to subscribe to 270,000 warrants for a subscription price of €0.43 per warrant ($0.57). These warrants are issued for a four-year period and will vest over one year from the date of issuance. Each warrant is exercisable to purchase one Share at a price of €4.58 ($6.14). These warrants are issued for a four-year period and will vest over one year from the date of issuance. 180,000 warrants were subscribed in July 2013.

On June 20, 2013, the Company authorized the scientific advisory board members, excluding directors, to subscribe to 20,000 warrants for a subscription price of €0.43 per warrant ($0.57) as an offset to receivables for services provided by members of the scientific advisory board. These warrants are issued for a four-year period and will vest immediately. 20,000 warrants were subscribed in August 2013.

On exercise of warrants by beneficiaries, the Company issues new shares.

19.4. Stock options:

The Company issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000, 2001, 2003, 2004, 2005, 2007, 2010, 2012 and 2013. The option terms provide for exercise within a maximum 10-year term as from the date of grant. Generally, each option vests no more than four years from the date of grant.

In January 1997, the French parliament adopted a law that requires French companies and beneficiaries to pay social contributions, which generally represent 45% of the taxable salary, on the difference between the exercise price of a stock option and the fair market value of the underlying shares on the exercise date if the beneficiary sells the stock before a four-year period following the grant of the option (five years for options granted before 2000). This law is consistent with personal income tax law that requires individuals to pay income tax on the difference between the option exercise price and the fair value of the shares at the sale date if the shares are sold within four years of the option grant. The law applies to all options exercised after January 1, 1997. The Company has instituted an internal rule whereby, whilst remaining an employee of the Company, an individual may not sell the underlying share within four years of the option being granted.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social security contribution of 10% for each option granted, based on either the fair value of the option or 25% of share price at date of grant. This is applicable on all options granted since October 16, 2007. In December 2010, the French parliament introduced a contribution rate of 14% depending on the value of the grant. In July 2012 this rate was increased to 30%.

On exercise of stock options by beneficiaries, the Company issues new shares.

19.5. Free Share Awards

On June 24, 2011, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 22, 2012, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by the beneficiaries two years following their allocation and the Company issues new shares. The beneficiaries are required to retain the shares for two additional years.

On June 20, 2013, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue free of charge to officers and employees of the Company as compensation for services rendered. Under the terms of the awards the shares are definitively owned by French tax resident beneficiaries two years and for US tax resident beneficiaries four years after grant and the Company issues new shares. French tax resident beneficiaries are required to retain the shares for two additional years after definitive acquisition.

In December 2007, the French parliament adopted a law that requires French companies to pay an additional social contribution of 10% for each share granted, based on the share price at date of grant. In December 2010, the French parliament introduced a contribution rate of 14% depending of the value of the grant. In July 2012 the contribution rate was raised to 30%.

On December 10, 2008 the Company granted 210,000 free share awards to officers and employees. On December 10, 2010 the Company issued 200,050 new shares related to this grant. On December 10, 2012 the Company issued 5,000 new shares related to this grant.

On December 11, 2009 the Company granted 295,000 free share awards to officers and employees. On December 11, 2011 the Company issued 267,400 new shares related to this grant. On December 11, 2013, the Company issued 10 000 new shares related to this grant.

On December 6, 2010 the Company granted 230,000 free shares awards to officers and employees. On December 6, 2012 the Company issued 208,150 new shares related to this grant.

On December 7, 2011 the Company granted 200,000 free shares to officers and employees. On December 31, 2012 the Company issued 45,000 new shares related to this grant. On December 7, 2013 the Company issued 137,150 new shares related to this grant.

On December 10, 2012 the Company granted 189,700 free shares to officers and employees.

On December 12, 2013 the company granted 192,500 free shares to officers and employees.

19.6 Restricted Shares

On June 20, 2013, the shareholders of the Company authorized the issuance of 200,000 new shares that the Board of Directors was authorized to award and issue to any person or company who may sold or transfer to the Company asset(s), including any shares, representing immediately or overtime, their ownership or voting rights in any commercial enterprise. No shares have been issued as a result of this authorization.

19.7. Accumulated other comprehensive income:

The components of accumulated other comprehensive income is as follows:

(In thousands of U.S. dollars)	December 31, 2012	December 31, 2013
Foreign currency translation	10,253	10,815
Total	10,253	10,815

20. Income taxes:

Income (loss) before income taxes comprises the following:

(in thousands of U.S. dollars)	Year ended December 31, 2011	Year ended December 31, 2012	Year ended December 31, 2013
France	(8,582)	(14,216)	(231)
United States	-	6,286	(53,864)
Total	$ (8,582)	$ (7,930)	$ (54,095)

A reconciliation of income tax benefit (provision) computed at the French statutory rate (33.33%) and the US statutory rate (40%) to the income tax benefit is as follows:

(in thousands of U.S. dollars)	Year ended December 31, 2011	Year ended December 31, 2012	Year ended December 31, 2013
Income tax benefit (provision) computed at the statutory rate (US & France)	2,860	2,224	21,623
Deferred Tax Allowance	(2,860)	(4,738)	(711)
Business Tax	(192)	(56)	(150)
Non Taxable remeasurement of fair value accounting	-	7,303	(9,592)
Temporary differences	-	(31)	-
Total	$ (192)	$ 4,702	$ 11,170

License fees, milestone and royalties payments may be subject to a withholding tax depending on the tax rules of the country in which the licensee is located. In December 2009, with effect from January 1, 2010 the French authorities abolished the previous business tax and introduced the "Contribution Economique Territoriale" comprised of two components. One of these components is based upon a measure of income and therefore results in income tax accounting. For the year ended December 31, 2011, 2012 and December 31, 2013 the amount of this component was $192,000, $56,000 and $150,000 respectively.

Significant components of the Company's deferred taxes consist of the following:

(In thousands of U.S. dollars)	December 31, 2011	2012	2013
Deferred income tax assets:			
Net taxable operating loss carry-forwards (not utilized)	53,230	65,657	81,769
Other deferred income tax assets	4,133	3,656	1,898
Valuation allowance for french activities	(57,105)	(64,356)	(69,939)
Net deferred income tax assets	258	4,957	13,728
Deferred income tax liabilities	(258)	(19,087)	(16,534)
Deferred income taxes, net	-	(14,130)	2,806

The Company has provided valuation allowances covering 100% of net deferred tax assets generated from its activities in France due to the Company's history of losses. The US operations have been in a loss position since its acquisition and deferred tax assets have been recognized on these losses to the extent of the deferred tax liabilities.

As of December 31, 2013, the Company had $201,565,000 in French net operating losses carry-forwards which have no expiration date, but for which annual utilization is limited to €1,000,000 plus 50% of any taxable income in excess of this threshold and $36,609,000 in US net operating losses carry-forwards which expire from 2030 to 2032, for which utilization of pre-acquisition tax losses of $4,900,000 million is limited to $1,800,000 per year.

The increase in available net operating losses carry-forwards in 2013 is due to a tax loss $35,222,000. The French government provides tax credits to companies for spending on innovative research and development. These credits are recorded as an offset of research and development expenses (see note 5) and are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash. As of December 31, 2013, Flamel had total research tax credits receivable of $20,550,000. In 2011, the Company obtained an advance from OSEO, a governmental agency supporting innovation, secured against the Research tax credit generated in fiscal year 2010. The Company renewed this financing operation in 2012 secured against the research tax credit generated for fiscal year 2011 (see Note 14.1). Generally, if these credits are not applied against future income taxes, they will be received as cash payments in the fourth year after the credit is earned. Since January 1, 2013 the Company meets the criteria for a small-medium sized enterprise under French tax legislation, which allows the Company to receive immediate reimbursement of the Research tax credit in the subsequent fiscal period.

The scheduled payments are shown in the following table

(In thousands of U.S. dollars)	**December 31,**
2014	14,139
Total current portion	**14,139**
2015	6,411
2016	-
Total long term portion	**6,411**
Total	**20,550**

21. Employee Retirement plans:

In accordance with French law, post-retirement benefits for most of the Company’s employees are sponsored by the relevant government agencies in France. The Company’s liability with respect to these plans is generally limited to specific monthly payroll deductions. Consequently, there is no additional liability in connection with these plans. Expenses recognized for these plans were $1,432,000 in 2011, $1,372,000 in 2012, and $1,120,000 in 2013.

French law requires the Company to provide for the payment of a lump sum retirement indemnity to French employees based upon years of service and compensation at retirement. Benefits do not vest prior to retirement. The Company’s benefit obligation was $2,106,000, $2,819,000 and $3,988,000 as of December 31, 2011, 2012 and 2013, respectively. Any actuarial gains or losses are recognized in the income statement in the period when they occur.

In 2008, 2010 and 2013, the French Government reinforced legislation regarding an employer's ability to make employees retire and the final age for retirement. As such the retirement indemnity has been calculated on the assumption of voluntary retirement and the impact on the benefit obligation was recognized as an actuarial loss.

The benefit obligation is calculated as the present value of estimated future benefits to be paid, using the following assumptions:

	2011	2012	2013
Average increase of salaries	3%	3%	3%
Discounted interest rate	4.5%	3%	3.25%
Turn over	actuarial standard and average of the last 5 years	actuarial standard and average of the last 5 years	actuarial standard and average of the last 5 years
Age of retirement	60 to 65 years	60 to 65 years	60 to 65 years
	actuarial standard based on age and professional status	actuarial standard based on age and professional status	actuarial standard based on age and professional status

Changes in the funded status of the benefit plans were as follows:

	December 31,	
In thousands of U.S. dollars	**2012**	**2013**
Benefit obligations at beginning of year	2,106	2,819
Service cost	162	247
Interest cost	91	87
Plan amendments	-	-
Benefits paids	(267)	(133)
Actuarial loss (gain)	723	(218)
Exchange rate changes	4	187
Benefit obligations at end of year	2,819	2,989

The Company does not have a funded benefit plan and the lump sum retirement indemnity is accrued on the balance sheet as a liability.

The future expected benefits to be paid over the next five years and for the five years thereafter is as follows:

Future expected payment of benefits:	Year Ending:		
In thousands of U.S. dollars			
	12/31/2014	61	153
	12/31/2015	202	161
	12/31/2016	234	89
	12/31/2017	-	-
	12/31/2018		260
	Next 5 Years	530	334

In the United States, the Company previously sponsored a defined contribution retirement plan for certain employees located in the United States. The contribution is the lesser of 25% of an employee's wages or $49,000 in 2011 and 2012. The Company made and accrued contributions of approximately $140,000 in 2012 and $55,000 in 2011.

22. Fair value of financial instruments:

At December 31, 2012 and 2013, the carrying values of financial instruments such as cash and cash equivalents, trade receivables and payables, other receivables and accrued liabilities and the current portion of long-term debt approximated their market values, based on the short-term maturities of these instruments.

As noted in Note 8, the company calculates fair value for its marketable securities based on quoted market prices for identical assets and liabilities which represents Level 1 of ASC 820-10 fair value hierarchy.

At December 31, 2012 and 2013 the fair value of long-term debt and long term receivables was comparable with their carrying values.

The following table presents information about the Company securities based on quoted market prices for identical assets and liabilities for 2013 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

(in thousands)	Net Carrying Value as of December 31, 2013	Fair Value Measured and Recorded Using Level 1	Level 2	Level 3	Operational Gain (losses) recognized in earnings	Financial Gain (losses) recognized in earnings	Total
Assets							
Cash and cash equivalent	6,636	6,636	-	-	-	-	-
Marketable securities	401	401	-	-	-	-	-
Liabilities							
Acquisition liability contingent consideration (a)	37,991	-	-	37,991	(14,768)	-	(14,768)
Acquisition liability note (b)	10,405	-	-	10,405	(5,027)	-	(5,027)
Acquisition liability warrant consideration (c)	10,497	-	-	10,497	(8,340)	-	(8,340)
Deerfield Royalty Agreement (d)	4,590			4,590		(1,991)	(1,991)
Broadfin Royalty Agreement (e)	2,187			2,187	-		-
Total					**(28,135)**	**(1,991)**	

The following table presents information about the Company securities based on quoted market prices for identical assets and liabilities for 2012 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

	Net Carrying Value as of December 31, 2012	Fair Value Measured and Recorded Using Level 1	Level 2	Level 3	Operational Gain (losses) recognized in earnings
Assets					
Cash and cash equivalent	2,742	2,742	-	-	-
Marketable securities	6,413	6,413	-	-	-
Liabilities					
Acquisition liability contingent consideration (a)	24,063	-	-	24,063	9,012
Acquisition liability note (b)	5,713	-	-	5,713	(86)
Acquisition liability warrant consideration (c)	2,157	-	-	2,157	9,908
Total					**18,384**

The fair value of the financial instruments in connection with the acquisition of Éclat (*see note 2 Business Combinations*) are estimated as follows:

(a) Acquisition liability deferred consideration: the fair value is estimated using a discounted cash flow model based on probability adjusted projected annual gross profit of each of the products which formed the project portfolio at the time of acquisition of Éclat Pharmaceuticals (*Note 16* Long Term Debt).

The fair value of the deferred consideration will change over time in accordance with the changes in market conditions and thus business plan projections as the relate to market size, market share, product pricing, competitive landscape, gross profit margins expected for each of the products.

(b) Acquisition liability Note: the Company uses a probability-weighted discounted cash flow model (*see note 16 Long Term Debt*).

(c) Acquisition liability warrant consideration: the Company uses a Black-Scholes option pricing model. The fair value of the warrant consideration will change over time depending on the volatility and share price at balance sheet date (*see note 16 Long Term Debt*).

(d) Deerfield Royalty agreement: the fair value is estimated using a discounted cash flow model based on probability adjusted projected annual net sales of each of the products which may be approved and sold by Éclat Pharmaceuticals (*see Note 16 Long Term Debt*).

(e) Broadfin Royalty agreement: the fair value is estimated using a discounted cash flow model based on probability adjusted projected annual net sales of each of the products which may be approved and sold by Éclat Pharmaceuticals (*see Note 16 Long Term Debt*).

The following tables provide a reconciliation of fair value for which the Company used Level 3 inputs:

	Acquisition Liabilities
Liability recorded upon acquisition	$ (50,927)
Operational gain (loss) recognized in earnings for fiscal year 2012	$ 18,993
Net carrying value at January 1, 2013	$ (31,934)
Operational gain (loss) recognized in earnings for fiscal year 2013	$ (28,135)
Payment deferred consideration (Hycet)	$ 841
Payment interest on acquisition liability note	$ 335
Net carrying value at December 31, 2013	$ (58,893)

	Deerfield Royalty Agreement	Broadfin Royalty Agreement
Liability recorded upon execution of Agreeement	$ (2,600)	$ (2,187)
Interest expense recognized in earnings for fiscal year 2013	$ (1,990)	
Net carrying value at December 31, 2013	$ (4,590)	$ (2,187)

The acquisition liabilities, consisting of the note, warrants and deferred consideration, and the Deerfield and Broadfin Royalty agreements all of which are classified as long-term debt, are measured at fair value and the income or expense may change significantly as assumptions regarding the valuations and probability of successful development and approval of products in development vary.

23. Commitments and Contingencies:

23.1. Capital leases

The Company currently has commitments regarding capital leases as described in Note 16.

23.2. Operating leases

The Company leases its facilities and certain equipment under non-cancelable operating leases, which expire through 2017. Future minimum lease payments under operating leases due for the fiscal years ending December 31, 2013 are as follows:

(In thousands of U.S. dollars)	December 31,
2014	846
2015	596
2016	120
2017	18
TOTAL	1,580

Rental expense for the years ended December 31, 2011, 2012 and 2013 was approximately $1,124,000, $1,081,000 and $1,032,000, respectively.

23.3. Litigation

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in and we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding that management believes will have a material adverse effect on our consolidated financial position or results of operations.

On November 9, 2007 a putative class action was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers entitled Billhofer v. Flamel Technologies, et al. The complaint purports to allege claims arising under the Securities Exchange Act of 1934 based on certain public statements by the Company concerning, among other things, a clinical trial involving Coreg CR and seeks the award of damages in an unspecified amount. By Order dated February 11, 2008, the Court appointed a lead plaintiff and lead counsel in the action. On March 27, 2008, the lead plaintiff filed an amended complaint that continued to name the Company and two previously named officers as defendants and asserted the same claims based on the same events as alleged in the initial complaint. On May 12, 2008, the Company filed a motion to dismiss the action, which the Court denied by Order dated October 1, 2009. On April 29, 2010, the lead plaintiff moved to withdraw and substitute another individual as lead plaintiff and to amend the Case Management Order. On June 22, 2010, the lead plaintiff voluntarily agreed to dismiss the action against one of the previously named officers. On September 20, 2010, the Court granted the lead plaintiff's withdraw and substitution motion and the parties proceeded to engage in fact discovery. On March 6, 2012, the Court issued its opinion granting the lead plaintiff's motion for class certification, which was originally filed in October 2010 and opposed by the Company. On July 30, 2012, the Court issued an opinion denying the lead plaintiff's motion, filed on December 15, 2011, to further amend his complaint, which motion sought to substantially revise plaintiff's asserted basis for contending that the defendants should be found liable for the statements at issue. In its opinion, the Court held that the proposed amended complaint failed to properly plead a viable claim. By Order dated March 8, 2013, the Court granted the Company's motion to dismiss and the action was dismissed with prejudice and costs.

In May 2011, we announced the filing of a lawsuit in the U.S. District Court for the District of Columbia against Lupin for infringement of our US Patent No. 6,022,562, which is held by the Company and associated with Coreg CR. The lawsuit was dismissed in favor of a lawsuit involving the same parties for infringement of the same patent that was lodged in the U.S. District Court for the District of Maryland in May 2011. GSK is a third party defendant in the Maryland lawsuit. The lawsuit is based on the Abbreviated New Drug Application (ANDA) filed by Lupin seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In August 2012, the Company concluded a settlement agreement with Lupin and the parties filed a joint stipulation of dismissal on September 11, 2012.

In September 2011, Flamel filed a lawsuit in the U.S. District Court for the District of Maryland against Anchen Pharmaceuticals, Inc., for infringement of the same patent. The lawsuit is based on the ANDA filed by Anchen seeking permission to manufacture and market a generic version of Coreg CR before the expiration of the patent. In May 2012, the Company concluded an agreement whereby Anchen agrees to pay the sum of $400,000 in settlement of the claim.

24. Industry and geographic information:

The Company operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology.

Revenues from GSK represented 67% of total revenues in 2011, 63% in 2012 and 66% in 2013.

Operations outside of France consist principally of the operations of Éclat pharmaceuticals acquired in March 2012 which had sales amounting to $560,000 in 2012 and $983,000 in 2013.

Revenues by geographic location of customers are as follows:

(in thousands of U.S. dollars)	As of December 31,		
	2011	2012	2013
Revenues			
United Kingdom & Ireland	17,619	15,967	14,743
USA	3,694	3,890	3,444
France	1,763	2,930	3,675
Europe	9,524	3,313	581
Total Revenues	32,600	26,100	22,443

The following is a summary of long-lived assets by geographic location:

(in thousands of U.S. dollars)	As of December 31,	
	2012	2013
Long-lived assets:		
USA	$ 60,260	$ 58,868
France	$ 31,966	$ 23,988
Total long-lived assets	$ 92,226	$ 82,856

25. Related Party Transactions

In March 2012, we acquired, through our wholly owned subsidiary Flamel US Holdings, all of the membership interests of Éclat from Éclat Holdings, an affiliate of Flamel's largest shareholder Deerfield Capital L.P., see "note 2 - Business Combinations". The consideration consisted of a $12 million senior, secured six-year note that is guaranteed by us and our subsidiaries and secured by the equity interests and assets of Éclat, two warrants to purchase a total of 3,300,000 ADSs of Flamel and commitments to make earnout payments of 20% of any gross profit generated by certain Éclat launch products and 100% of the gross profit generated by our former product Hycet®, up to a maximum of $1 million, which we have sold in 2013. The $12 million senior note was repaid in full in March 2014 using the net proceeds from our public sale of ADSs. Upon closing of the acquisition, Mr. Anderson, the Chief Executive Officer of Éclat, was appointed Chief Executive Officer of Flamel. Mr. Anderson retains a minority interest in Éclat Holdings, (now renamed Breaking Stick Holdings, LLC), and does not have the ability to control this entity by virtue of his minority interest.

On February 4, 2013, we entered into a Facility Agreement (the "Deerfield Facility"), through Flamel US with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (together, the "Deerfield Entities") providing for debt financing of $15 million by the Deerfield Entities (the "Loan"). The loan was repaid in full in March 2014 using the net proceeds from our public sale of ADSs. The Deerfield Facility was subject to certain limitations, and allowed us to use the funds for working capital, including continued investment in our research and development projects. In conjunction with our entry in the Deerfield Facility, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, "Deerfield PDF/Horizon"). The Royalty Agreement provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales price of the products sold by us and any of our affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. See also note 16 Long Term Debt.

We have also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the intellectual property and regulatory rights related to the products to secure the obligations of Éclat and Flamel US, including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement.

We have also entered into two pledge agreements on certain receivables and equipment we own. These agreements are required to be recorded under French law at the request of Deerfield.

On December 3, 2013, we and certain of our U.S. subsidiaries entered into a Facility Agreement (the "Broadfin Facility") with Broadfin Healthcare Master Fund, Ltd. ("Broadfin") providing for loans by Broadfin in an aggregate amount not to exceed $15.0 million. Under the terms of the Broadfin Facility, upon closing Broadfin made an initial loan of $5.0 million and we had the ability to request, at any time prior to August 15, 2014, up to two additional loans in the amount of $5.0 million each, with funding subject to certain specified conditions. The full $5.0 million outstanding was subsequently repaid using a portion of the net proceeds from our public sale of ADSs in March 2014. In connection with entering into the Broadfin Facility, we also entered into a Royalty Agreement with Broadfin, dated as of December 3, 2013 (the "Broadfin Royalty Agreement"). Pursuant to the Broadfin Royalty Agreement, we are required to pay a royalty of 0.834% on the net sales of certain products sold by Éclat Pharmaceuticals, LLC and any of its affiliates until December 31, 2024. See also note 16 Long-Term Debt.

The loans under the Broadfin Facility were secured by a first priority security interest in intellectual property associated with our Medusa technology and a junior lien on substantially all of the assets of the borrowers, which were previously pledged in connection with the Deerfield Facility, the Royalty Agreement and the notes issued in connection with the Éclat acquisition. In addition, we have agreed to grant a junior lien on certain equipment located in France, if such equipment is pledged under the Deerfield Facility and/or the Éclat note.

Concurrent with entering into the Broadfin Facility, we also amended the terms of the Deerfield Facility and the agreement governing the Éclat notes to, among other things, permit the indebtedness and liens under the Braodfin Facility and to grant a junior lien to the respective lenders on the Medusa Technology.

26. Post Balance Sheet Events

In March 2014, the Company entered into an underwriting agreement with JMP Securities LLC, relating to an underwritten public offering of 10,800,000 American Depositary Shares (the "ADSs"). The offering price to the public was $9.75 per ADS, and the Underwriting Agreement included the payment of a commission of $0.585 per ADS. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 1,600,000 ADSs at the same purchase price. The underwriters executed the option on March 18, 2014 for all of the additional ADSs. Total net proceeds amounted to $113,646,000.

The Company repaid a total of $32,000,000 of principal on outstanding debt on March 24, 2014 relating to the following (*see note 16 Long Term Debt and note 25 Related Party Transactions*):

- Acquisition liability note, $12 million in principal,
- Deerfield Facility Agreement, $15 million in principal
- Broadfin Facility Agreement, $5 million in principal

The non-cash expense that will be recognized related to the early reimbursement of the outstanding debt amounts to $3.0 million in operating expenses and $4.7 million in interest expense.

Remaining proceeds will be used to continue the development of the Company's product pipeline, including possible clinical trials, and for general corporate purposes.

On April 29, 2014 the Company announced the receipt of a complete response letter (CRL) from the FDA for its second NDA application from the Éclat portfolio. A CRL is issued by the FDA when the review of the file is completed and questions remain that precludes the approval of the NDA in its current form. In the CRL, the FDA noted that during a recent inspection of the manufacturing facility of the active pharmaceutical ingredient's (API) supplier, deficiencies were found. Satisfactory resolution of these facility deficiencies is required before this application may be approved. There were no other deficiencies in the CRL. Final agreement on the draft product labeling is also pending.

INCORPORATION BY REFERENCE

As provided by in the Company's Registration Statements on Form F-3, as filed with the Securities and Exchanges Commission on September 18, 2012 and February 12, 2014, each as subsequently amended, this report is being incorporated by reference into such registration statement.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

FLAMEL TECHNOLOGIES S.A.
(Registrant)

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer

Date: April 30, 2014

EXHIBIT INDEX

Exhibit Number	Description
1.1	Revised *Statuts* or bylaws of the Company (Filed herewith)
2.1	Amended and Restated Deposit Agreement among Flamel, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (2)
4.1*	Note Agreement among Flamel Technologies S.A., Flamel US Holdings, Inc. and Éclat Holdings, LLC, dated March 13, 2012 (3)
4.2	Guaranty of Note made by Flamel Technologies S.A. in favor of Éclat Holdings, LLC, dated March 13, 2012 (3)
4.3	Warrant to purchase 2,200,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (3)
4.4	Warrant to purchase 1,100,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. (3)
4.5	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC, dated March 13, 2012 (3)
4.6	Facility Agreement among Flamel US Holdings, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P dated December 31, 2012 (1)
4.7*	Royalty Agreement among Eclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P dated December 31, 2012 (1)
4.8*	Security Agreement between Éclat Pharamaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl, dated February 4, 2013 (1)
4.9	Broadfin Facility Agreement, effective as of December 3, 2013 (filed herewith)
4.10*	Broadfin Royalty Agreement, dated as of December 3, 2013 (filed herewith)
8.1	List of Subsidiaries (Filed herewith)
11.1	Code of Ethics for CEO (*Directeur Général*), Delegated Managing Directors (*Directeurs Généraux Délégués*) and Senior Financial Officers (4)
12.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
12.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith)
13.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
13.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)

(1) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013.
(2) Incorporated by reference to the Company's registration statement on Form F-6 filed February 12, 2014, as amended (No. 333-193892).
(3) Incorporated by reference to the Company's Current Report on Form 6-K, filed March 21, 2012.
(4) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.

*Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission

The registrant undertakes to provide to each shareholder requesting the same a copy of each exhibit referred to herein upon payment of a reasonable fee limited to the registrant's reasonable expenses in furnishing such exhibit.

FLAMEL TECHNOLOGIES

A joint stock company with a share capital of € 4,636,011
Registered office located at VENISSIEUX (Rhône) Parc Club du Moulin à Vent
33, avenue du Docteur Georges Lévy

R.C.S. LYON B 379.001.530

BY LAWS

Updated as of March 21, 2014

ARTICLE 1 – FORM

The Company is a joint stock company governed by applicable laws and regulations and by these by-laws.

ARTICLE 2 – CORPORATE NAME

The corporate name is **FLAMEL TECHNOLOGIES.**

All the decisions and documents of the Company addressed to third parties, including but not limited to, letters, invoices, announcements and releases must indicate the name of the Company, immediately preceded or followed by, in legible form, the words « société anonyme » or of the initials "S.A.", the indication of the amount of the share capital and the SIREN number followed by the mention "R.C.S.", followed by the name of the city where is located the court with which the Company is registered.

ARTICLE 3 – COMPANY PURPOSE

The purpose of the Company is, in France or abroad:

- on the one hand :

- design, realization of new materials for the chemical industry as well as for other industries, specifically in the field of pharmacy, health (biomaterials), cars, aerospace, telecommunications, motorists (turbines), packing and conditioning (specifically in the field of bio-destruction) ;

- research and development of polymer and ceramic materials corresponding to identified needs ;

- filing, study, acquisition, operation and concession of patents, licenses, processes, trademarks and specialized knowledge linked with, or relating to, in any way, to the above mentioned technological fields ;

- production and sale of designed materials ;

- on the other hand:

- design, development, manufacture, distribution, import, export of drugs, pharmaceutical specialities and other health products, as well as the exploitation of pharmaceutical specialities, drugs and other health products,

- and generally, all operations, of any kind, economic or legal, financial, civil or commercial that can be directly or indirectly linked, on its own behalf of on the behalf of third parties, either alone or with third parties, with this corporate purpose or with any similar, related or complementary purpose, as well as the direct or indirect participation of the Company to all activities or industrial operations on any kind, if such activities or operation can be directly or indirectly linked to the company purpose or to any similar, related or complementary purpose.

ARTICLE 4 – REGISTERED OFFICE

The registered office is at VENISSIEUX (Rhône) 33, avenue du Docteur G. Lévy - Parc Club du Moulin à vent.

Notwithstanding the power granted to the shareholders by law and these by-laws in this respect, the registered office may be transferred to any other site in the same *département* or an adjoining *département* upon a decision of the board of directors, subject to ratification at the subsequent ordinary general shareholders meeting, or any other locality by virtue of a decision of an extraordinary general shareholders meeting.

ARTICLE 5 - DURATION

The duration of the Company has started to run as of August 10, 1999 and shall expire on August 9, 2099, except in cases of early dissolution or extension.

ARTICLE 6 – SHARE CAPITAL

The share capital is set at an amount of four million six hundred thirty six thousand and eleven Euros (4.636.011€), divided into 38,012,550 shares each with a value of €0.12196."

ARTICLE 7 – FISCAL YEAR

Each fiscal year shall last one year starting January first of each year and ending on December 31 of the same year.

By exception, the first fiscal year shall end on December 31, 1991.

ARTICLE 8 - ALLOCATION OF THE PROFITS

If the results of the fiscal year, as approved by the general shareholders meeting, show the existence of a distributable profit, the general shareholders meeting shall decide to allocate such profit to one or several reserve accounts of which the general shareholders meeting decides the attribution or use, to carry it forward or to distribute it.

After acknowledging the existence of reserves, the general shareholders meeting may decide the distribution of the amounts taken from the reserves. In this case, the decision expressly mentions the reserve accounts from which the amounts are taken. The general shareholders meeting may also grant to each shareholder, an option between the payment in cash or in shares of all or part of the paid dividend.

ARTICLE 9 - TYPE OF THE SHARES

The shares are registered.

They shall be registered on an account opened by the Company in the name of the shareholder under the conditions set forth in applicable law and regulations. An affidavit of inscription on the account can be granted to the shareholder on shareholder's request.

ARTICLE 10 – SALE AND ASSIGNMENT OF SHARES

Shares are freely negotiable under the conditions and limitations set forth by applicable law and regulations.

Any transfer of shares takes place, as far as both the Company and third parties are concerned, by way of transfer order signed by the assignor or its representative and the assignee if the shares have not yet been paid-up. The transfer order is registered on the day of its receipt on a numbered and initialized register called "registre des mouvements" (share transfer ledger).

The Company may require that the signatures on the transfer orders be certified by a public officer or a mayor, without prejudice to any legal rules to the contrary.

Shares transfer fees are borne by the assignee, except agreement to the contrary between the parties.

Transfer orders concerning shares not paid up to amounts due and payable shall be rejected.

The Company updates, at least on a six-month basis, the list of shareholders with the indication of the domicile declared by the shareholders.

Title to the shares results from their inscription in the name of the holder(s) on the registers or accounts held to that end by the Company or its representative.

ARTICLE 11 – RIGHTS AND DUTIES ATTACHED TO THE SHARES

Each share gives the right to title in the Company’s assets, a share in profit and in the liquidation surplus, proportional to the value of the existing shares.

The same treatment shall be applied to all the shares that make up or that shall re make up the share capital, as far as the fiscal expenses are concerned.

As a consequence, all taxes that, for any reason, due to the repayment of the capital of these shares, could become due with respect to certain of them only, either during the life of the Company or upon liquidation thereof, shall be allocated among all the shares composing the capital at the moment of this repayment or these repayments, such that all existing or future shares grant to their holder, for the paid-up but not redeemed amount, the same real benefits and give them the right to receive the same net proceeds.

Each time it is necessary to hold several shares to exercise any right, the isolated shares or shares in an number less than the one required number, shall give no right to their holders against the Company; the shareholders shall, in this case, be personally responsible for the gathering of the necessary number of shares.

ARTICLE 12 – PAYMENT OF THE SHARE CAPITAL

The amounts that remain to be paid on the shares to be paid in cash are requested by the board of directors.

The shareholders are informed of the amounts requested and of the date when the corresponding amounts must be paid, either by a newspapers notice inserted fifteen days in advance in a journal authorized to publish legal notices in the département where the registered office is located, or by registered letter sent to each of the shareholders within the same time period.

A shareholder that does not proceed on time with the requested payments on the shares he holds, shall automatically and without prior notice owe a late payment interest calculated day by day, as of the date the amount was due, at the legal rate applicable in commercial matters plus tree points and without prejudice to enforcement measures set forth by law.

ARTICLE 13 – BOARD OF DIRECTORS

The Company is managed by a Board of Directors composed of at least three members and a maximum of eighteen members.

Subject to the decisions for which French law requires the physical presence of the Directors, the Board of Directors may provide for in its internal regulation that Directors who participate in the board meeting via videoconferencing or telecommunications means allowing for their identification and guaranteeing their effective participation in the Board meeting, in accordance with the provisions of a Conseil d'Etat decree, are deemed present for calculation of the quorum and the majority.

During the term of the Company, the members of the Board of Directors are appointed and removed, in the conditions provided by applicable laws and regulations.

Each member of the Board of Directors must own at least one share during the whole term of his/her office.

The term of office of the members of the Board of Directors is one year. It expires at the end of the shareholders' meeting called on to rule on the financial statements for the last financial year.

The number of Directors being over the age of 70 years may not, at any time, exceed one third of the total number of Directors in office.

ARTICLE 14 - DELIBERATIONS OF THE BOARD OF DIRECTORS

Board Meetings are convened by the Chairman, as frequently as the interests of the Company so require, either at the registered office, or in any other place indicated in the convening notice.

The members of the Board are convened to meetings by any means, even verbally.

When the Board of Directors has not met for more than two months, at least one third of the members of the Board may request the Chairman to convene a meeting for a defined agenda.
The Managing Director may also request the Chairman to convene a meeting for a defined agenda.
The Chairman is bound by the requests that are addressed to him pursuant to these last two paragraphs.
For sake of validity of deliberations, the effective attendance of at least half of the members in office is required.

Decisions are made with the majority of members present or duly represented: each member holds one vote, and each member may only hold one proxy. The Chairman has no tie-breaking vote.

Deliberations of the Board are recorded in minutes drawn-up, signed and recorded in accordance with applicable laws and regulations.

Copies and excerpts of the minutes for producing in court or elsewhere shall be validly certified either in accordance with applicable laws and regulations.

ARTICLE 15 – POWERS OF THE BOARD OF DIRECTORS

The Board determines the orientation of the Company's activity and ensures that they are implemented. Subject to the powers expressly granted to the Shareholders Meetings and within the corporate purpose, the Board may address any issue relating to the good operation of the Company and settles Company business through its deliberations.

In its relations to third parties, the Company is bound even by the actions of the Board of Directors that are unrelated to the corporate purpose, unless it can prove that the third party knew that the action exceeded the purpose or could not ignore it under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The Board of Directors undertakes the checks and verifications that it considers to be appropriate. Each Director receives all the information necessary to accomplish his mission and has access to all documents that he considers useful.

ARTICLE 16 – CHAIRMAN OF THE BOARD OF DIRECTORS

The Board of Directors elects from amongst its members a Chairman, who must be an individual. The Board determines the Chairman's term of office, which may not exceed his term of office as a Director.

The Chairman of the Board of Directors represents the Board vis-à-vis shareholders and third parties. He organizes and manages the work of the Board and reports thereon to the meeting of the shareholders. He oversees the good operation of the Company bodies, in accordance with applicable laws and regulations.

The Chairman of the Board may simultaneously hold offices of managing directors, member of a Board of Directors, of sole managing director, or member of a supervisory Board of stock corporations (sociétés anonymes) having their registered office in the French territory, only to the extent permitted by applicable laws and regulations

The Chairman of the Board is re-eligible. The Board of Directors may remove him/her at any time.

ARTICLE 17 – GENERAL MANAGEMENT

The general management of the Company is carried out, under his responsibility, either by the Chairman of the Board of Directors or by any other individual appointed by the Board, whether or not chosen from amongst its members, and having the title of Managing Director (Directeur Général).

The Board of Directors chooses between these two ways of exercising the General Management by a simple majority vote. Absent a vote to that effect, general management is undertaken by the Chairman of the Board of Directors, until a contrary decision is adopted by the Board of Directors.

When the general management of the Company is undertaken by the Chairman of the Board of Directors, the provisions of these by-laws relating to the Managing Director apply to the Chairman of the Board.

The Managing Director is appointed for a term of one year, expiring at the end of the general shareholders' meeting called on to rule on the approval of the financial statements for the last financial year.

The Managing Director has the most extensive powers to act under all circumstances in the name of the Company. He exercises these powers within the limit of the corporate purpose and subject to the powers expressly granted by law to Board and Shareholder meetings.

He represents the Company in its relations with third parties. The Company is even bound by the actions of the Managing Director that are not within the scope of the corporate purpose, unless it can prove that the third party knew that the action exceeded this purpose or could not ignore this fact under the circumstances, it being excluded that the publication of the by-laws alone is sufficient to constitute such proof.

The provisions of these by-laws and the decisions of the Board of Directors limiting the powers of the Managing Director may not be invoked against third parties.

Upon a proposal by the Managing Director, the Board of Directors may appoint one or several individuals with the title of Executive Managing Director, responsible for assisting the Managing Director. The Board of Directors may not appoint more than five Executive Managing Directors.

Executive Managing Directors have the same powers as the Managing Director in respect of third parties. With the Managing Director's approval, the Board of Directors determines the extent and duration of the powers assigned to the Executive Managing Directors.

The Board of Directors may remove the Managing Director at any time. The Executive Managing Directors may also be removed, upon a proposal of the Managing Director. If the removal is without just cause, it may give rise to damages, unless the Managing Director also assumes the functions of the Chairman of the Board of Directors.

Whenever the Managing Director ceases to carry or is prevented from carrying out his duties, the Executive Managing Directors retain their duties and attributions, subject to a contrary decision by the Board, until a new Managing Director is appointed.

An individual may not hold more than one office of Managing Director of stock corporations (sociétés anonymes) having their registered office on the French territory.

The remuneration of the Chairman, and that of the Managing Director and Executive Managing Directors, is determined by the Board of Directors; it may be fixed or proportional or both.

ARTICLE 18 – STATUTORY AUDITORS

The control of the Company's financial statements is carried out by one or several statutory auditors, appointed and exercising their duties, in the conditions provided by law.

The statutory auditor(s) may be assisted with one or several controllers appointed by the Board of Directors and chosen either from amongst its members, or from outside them. The controllers may be invited by the Chairman to attend to meetings of the Board of Directors. In this case, they have a consultative vote.

ARTICLE 19 – GENERAL MEETINGS OF SHAREHOLDERS

Shareholders' meetings are called in the conditions provided by applicable laws and regulations.

Meetings take place at the registered office or at any other place indicated in the calling notice.

The right to participate in shareholders' meetings is subject to:

- the registration of the shareholder in the Company's share accounts for owners of registered shares,

- the deposit, at the place indicated in the calling notice, of a certificate of account registration issued by the bank, the financial establishment or the stockbroker, depositary of the shares, as the case may be, for the owners of bearer shares.

The time period during which these formalities must be completed expires a day before the date of the meeting.

General meetings of shareholders are chaired by the Chairman of the Board of Directors, or, in his/her absence, by a director specially delegated to this end by the Board, failing which the shareholders' meeting elects its chairman.

The duties of scrutineers are fulfilled by two members of the meeting present and accepting, who hold the higher number of shares.

The meeting officials appoint the secretary of the meeting, who may choose from outside the shareholders.

An attendance sheet is drawn up in the conditions provided by applicable laws and regulations.

Are deemed to be present for purposes of calculating the quorum and majority, the shareholders who participate in the meeting by videoconference or by means of telecommunication, the nature and conditions of which are determined by a Decree issued by the Conseil d'Etat .

The copies and excerpts of the minutes of the shareholders' meeting are validly certified in accordance with the conditions provided by applicable laws and regulations.

ARTICLE 20 – POWERS AND RESOLUTIONS OF THE SHAREHOLDERS' MEETINGS

The ordinary and extraordinary shareholders' meetings, ruling under the conditions of quorum and majority prescribed by provisions respectively governing them, exercise the powers granted to them by applicable laws and regulations.

ARTICLE 21 - DISSOLUTION - LIQUIDATION

Upon expiration of the term of the Company or in the event of earlier dissolution, the shareholders' meeting determines the method of liquidation and appoints one or several liquidators, of whom it determines their powers, and who exercise their duties in accordance with applicable laws and regulations.

ARTICLE 22 - DISPUTES

Any dispute that may arise during the existence or liquidation of the Company, either between the shareholders or between the Company and the shareholders, regarding the interpretation or the enforceability of these by-laws or regarding, generally, any corporate matter, will be submitted to the relevant courts having jurisdiction where the registered office is located.

To that effect, in the event of a dispute, every shareholder must elect domicile in a place where the courts have jurisdiction over the registered office and all summons or services of process are validly delivered to this domicile.

CERTIFIED TRUE COPY

FACILITY AGREEMENT

FACILITY AGREEMENT (this "Agreement"), dated as of December 3, 2013, by and among Flamel US Holdings, Inc., a Delaware corporation ("Flamel US Holdings"), Éclat Pharmaceuticals, LLC, a Delaware limited liability company ("Éclat"), Talec Pharma, LLC, a Delaware limited liability company, and Flamel Technologies, Inc., a Virginia corporation (each a "Borrower" and collectively, the "Borrowers"), and Broadfin Healthcare Master Fund, Ltd. (the "Lender" and, together with the Borrowers, the "Parties").

WITNESSETH:

WHEREAS, the Borrowers wish to borrow from the Lender up to fifteen million Dollars ($15,000,000) for the purpose described in Section 2.1; and

WHEREAS, the Lender desires to make loans to the Borrowers for such purpose;

NOW, THEREFORE, in consideration of the mutual agreements set forth herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

Section 1.1 General Definitions. Wherever used in this Agreement, the Exhibits or the Schedules attached hereto, unless the context otherwise requires, the following terms have the following meanings:

"Affiliate" means, with respect to any Person, any other Person:

(a) that owns, directly or indirectly, in the aggregate more than 10% of the beneficial ownership interest of such Person;

(b) that directly or indirectly through one or more intermediaries controls, or is controlled by, or is under common control with, such Person; or

(c) that directly or indirectly is a general partner, controlling shareholder, or managing member of such Person.

"Applicable Laws" means all statutes, rules and regulations of the FDA and of other Governmental Authorities in the United States or elsewhere exercising regulatory authority similar to that of the FDA applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by or on behalf of any Borrower or its Subsidiaries.

"Authorizations" has the meaning set forth in Section 3.1(p).

"Breaking Stick" means Breaking Stick Holdings, LLC, a Delaware limited liability company formerly known as Éclat Holdings, LLC.

"Breaking Stick Indebtedness" means Indebtedness in an aggregate amount of $12,000,000 incurred pursuant to that certain Installment Sale Note dated March 12, 2012 from the Borrowers to Breaking Stick.

"Business Day" means a day on which banks are open for business in The City of New York.

"Closing Date" means the first date all the conditions precedent in Article IV are satisfied or waived by Lender.

"Code" means the Internal Revenue Code of 1986, as amended, and any Treasury Regulations promulgated thereunder.

"Deerfield" means collectively, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.

"Deerfield Credit Facility" means the secured credit facility in the original principal amount of $15,000,000 established by Deerfield in favor of the Flamel US Holdings, Inc. pursuant to the terms of the Deerfield Facility Agreement.

"Deerfield Facility Agreement" means that certain Facility Agreement dated as of December 31, 2012 between Flamel US Holdings, Inc. and Deerfield, as amended, restated, supplemented or otherwise modified from time to time.

"Deerfield Intercreditor Agreement" means the Intercreditor Agreement by and among Lender, Deerfield, Breaking Stick, Borrowers and SA.

"Default" means any event which, at the giving of notice, lapse of time or fulfillment of any other applicable condition (or any combination of the foregoing), would constitute an Event of Default.

"Default Rate" means 18.0% simple interest per annum.

"Dollars" and the "$" sign mean the lawful currency of the United States of America.

"Eligible Market" means the over the counter Bulletin Board, the New York Stock Exchange, Inc., the NYSE Area, the NASDAQ Capital Market, the NASDAQ Global Market, the NASDAQ Global Select Market or the NYSE Alternext U.S.

"Event of Default" has the meaning given to it in Section 5.4.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, including the rules and regulations promulgated thereunder.

"Excluded Taxes" means with respect to Lender, (a) income or franchise Taxes imposed on (or measured by) Lender's net income by the United States of America, or by the jurisdiction (or any political subdivision thereof) under the laws of which Lender is organized or incorporated or in which the applicable lending office of Lender is located, (b) any branch profits Taxes imposed by the United States of America, or (c) any withholding Tax that is imposed on amounts payable to Lender at the time Lender becomes a party to this Agreement (or designates a new lending office) or is directly attributable to Lender's failure or inability to comply with Section 2.5(d), except to the extent that Lender (or its assignor, if any) was entitled, at the time of designation of a new lending office (or assignment), to receive additional amounts from the Borrowers with respect to such withholding Tax pursuant to Section 2.5(a) or is legally unable to comply with Section 2.5(d) as a result of any change in the laws of the United States of America, the British Virgin Islands or France occurring subsequent to the date Lender becomes a party to this Agreement (or designates a new lending office).

"FDA" means the U.S. Food and Drug Administration.

"Final Payment" means such amount as may be necessary to repay the outstanding principal amount of the Note and any other amounts owing by the Borrowers to the Lender pursuant to the Transaction Documents.

"Final Payment Date" means the earlier of (i) the date on which the Borrowers voluntarily prepay the Note and any other outstanding Obligations under the Transaction Documents and (ii) the earlier of (x) January 31, 2017, and (y) the date that Borrowers have repaid in full the obligations owed to Deerfield under the Deerfield Credit Facility, provided that in no event shall such date be earlier than November 15, 2015.

"GAAP" means generally accepted accounting principles consistently applied as set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board (or agencies with similar functions of comparable stature and authority within the accounting profession).

"Government Authority" means any government, governmental department, ministry, cabinet, commission, board, bureau, agency, tribunal, regulatory authority, instrumentality, judicial, legislative, fiscal, or administrative body or entity, whether domestic or foreign, federal, state or local, having jurisdiction over the matter or matters and Person or Persons in question.

"Hedging Obligations" means all liabilities under take-or-pay or similar arrangements or under any interest rate swaps, caps, floors, collars and other interest hedge or protection agreements, treasury locks, equity forward contracts, currency agreements or commodity purchase or option agreements or other interest or exchange rate or commodity price hedging agreements and any other derivative instruments, in each case, whether any Borrower and its Subsidiaries is liable contingently or otherwise, as obligor, guarantor or otherwise, or in respect of which liabilities any Borrower or its Subsidiaries otherwise assures a creditor against loss.

"Indebtedness" means the following:

(i) all indebtedness for borrowed money;

(ii) the deferred purchase price of assets or services (other than payables) which in accordance with GAAP would be shown to be a liability (or on the liability side of a balance sheet);

(iii) all guarantees of Indebtedness;

(iv) the maximum amount of all letters of credit issued or acceptance facilities established for the account of Borrowers and any of their Subsidiaries, including without duplication, all drafts drawn thereunder;

(v) all capitalized lease obligations;

(vi) all indebtedness of another Person secured by any Lien on any property of the Borrowers or their Subsidiaries, whether or not such indebtedness has been assumed or is recourse (with the amount thereof, in the case of any such indebtedness that has not been assumed by the Borrowers or their Subsidiaries, being measured as the lower of (x) fair market value of such property and (y) the amount of the indebtedness secured);

(vii) all Hedging Obligations; and

(viii) indebtedness created or arising under any conditional sale or title retention agreement.

"Indemnified Person" has the meaning given to it in Section 6.11.

"Indemnified Taxes" means all Taxes including Other Taxes, other than Excluded Taxes.

"Indemnity" has the meaning given to it in Section 6.11.

"Intellectual Property" means (i) all patents, patent applications, patent disclosures and inventions (whether patentable or unpatentable and whether or not reduced to practice), (ii) all trademarks, service marks, trade dress, trade names, slogans, logos, and corporate names and Internet domain names, together with all of the goodwill associated with each of the foregoing, (iii) copyrights, copyrightable works, and licenses, (iv) registrations and applications for registration for any of the foregoing, (v) computer software (including but not limited to source code and object code), data, databases, and documentation thereof, (vi) trade secrets and other confidential information, (vii) other intellectual property, including the Product Regulatory Rights and (viii) copies and tangible embodiments of the foregoing (in whatever form and medium).

"Interest Payment Date" has the meaning given to it in Section 2.7.

"Interest Rate" means 12.5% simple interest per annum.

"IP" has the meaning given to it in Section 3.1(l).

"IP Asset Disposition" shall mean any sale, assignment, or transfer of all or substantially all of Borrower's Product Regulatory Rights in any Product.

"Lien" means any lien, pledge, preferential arrangement, mortgage, security interest, deed of trust, charge, assignment, hypothecation, title retention, privilege or other encumbrance on or with respect to property or interest in property.

"Loan(s)" has the meaning given to it in Section 2.2(a).

"Loss" has the meaning given to it in Section 6.11.

"Major Transaction" means any of the following:

(i) a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or other similar event, following which the holders of the Ordinary Shares of SA (including holders of American Depository Shares attributable to underlying Ordinary Shares) immediately preceding such consolidation, merger, exchange, recapitalization, reorganization, combination or event either (a) no longer hold a majority of the Ordinary Shares (including American Depository Shares attributable to such Ordinary Shares) of SA or the shares of the Successor Entity (or the Parent Entity of a Successor Entity) or (b) no longer have the ability to elect a majority of the board of directors of SA or the Successor Entity (collectively, a "Change of Control Transaction");

(ii) a sale or transfer of all or substantially all of the SA's assets;

(iii) a purchase, tender or exchange offer, made to the holders of outstanding Ordinary Shares or American Depository Shares, such that following the consummation of such purchase, tender or exchange offer a Change of Control Transaction shall have occurred;

(iv) the liquidation bankruptcy, insolvency, dissolution or winding-up (or the occurrence of any analogous proceeding) affecting SA;

(vi) SA fails at any time to own, directly or indirectly, one-hundred percent (100%) of the equity interest in each Borrower free and clear of all Liens (other than Permitted Liens), except where such failure is as a result of a transaction permitted by the Facility Agreement or

(vii) either of Michael S. Anderson or Steven A. Lisi shall for any reason cease to hold the office of Chief Executive Officer and Senior Vice President, Business and Corporate Development of SA, respectively, or be actively engaged in the day-to-day management of SA and Borrowers, unless within sixty (60) days of such cessation, a successor to the office of the effected individual is appointed by Borrowers, which successor is acceptable to Lender; provided that this clause (vii) shall cease to be in effect from and after November 1, 2015 if Michael S. Anderson and Steven A. Lisi (or an acceptable successor) continue to hold the office of Chief Executive Officer and Senior Vice President, Business and Corporate Development of SA, respectively on November 1, 2015.

"Material Adverse Effect" means a material adverse effect on the business, operations, condition (financial or otherwise) or assets of the Borrowers and their Subsidiaries, taken as a whole.

"Medusa Technology" means the Intellectual Property for the polymer-based sustained release technology for protein and peptide drugs known as the "Medusa Technology", including the regulatory history and submissions, clinical data, manufacturing know-how, copyrights and trademarks, licenses, partnerships, manufacturing, supply and distribution agreements related thereto.

"Membership Interest Purchase Agreement" means that certain Membership Interest Purchase Agreement, dated as of March 13, 2012, by and among Breaking Stick, Éclat, SA and Flamel US Holdings, as amended, restated, supplemented or otherwise modified from time to time.

"Note" means has the meaning given to it in Section 2.2(c).

"Obligations" means all obligations (monetary or otherwise) of the Borrowers arising under or in connection with the Transaction Documents.

"Organizational Documents" means the documents under which any Borrower was organized, each as amended to date, of this Agreement.

"Other Taxes" means any and all present or future stamp or documentary taxes or any other excise or property taxes, duties, other charges or similar levies, and all liabilities with respect thereto, together with any interest, fees, additions to tax or penalties applicable thereto (including by reason of any delay in payment) arising from any payment made hereunder or from the execution, delivery, registration or enforcement of, or otherwise with respect to, any Transaction Document.

"Parent Entity" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of a Major Transaction.

"Permitted Affiliate Transactions" means

(i) The Royalty Agreement dated as of February 4, 2013 and entered into by Éclat Pharmaceuticals, LLC, Deerfield Private Design Fund II, L.P., and Horizon Sante FLML, SARL;

(i) The transactions pursuant to or in connection with the Membership Interest Purchase Agreement, including without limitation the Breaking Stick Indebtedness and the warrants issued pursuant to such Membership Interest Purchase Agreement;

(ii) The Deerfield Credit Facility;

(iii) Transactions with the Lender and its Affiliates; and

(iv) Transactions between and among SA, the Borrowers and their subsidiaries.

" Permitted Indebtedness" means:

(i) The Obligations;

(ii) Indebtedness of the Borrowers under the Deerfield Credit Facility;

(iii) Item (ii) under the definition of Indebtedness (including any earnout and other similar obligations incurred to a seller in an acquisition);

(iv) Item (v) under the definition of Indebtedness;

(v) Indebtedness to purchase equipment and other assets, including Indebtedness secured by purchase money Liens; provided that such Indebtedness when incurred by any Borrower or any of its Subsidiaries shall not exceed the purchase price of the asset(s) financed;

(vi) Indebtedness of any Person acquired pursuant to an acquisition, provided that such Indebtedness is either (i) not incurred in contemplation of or in connection with such acquisition or (ii) constitutes Indebtedness owing to the seller of the assets acquired in such acquisition;

(vii) Indebtedness existing as of the date hereof and set forth on Exhibit B attached hereto;

(viii) Hedging Obligations incurred in the ordinary course of business not for speculative purposes;

(ix) Indebtedness in respect of letters of credit in an aggregate outstanding amount not to exceed $750,000 at any time;

(x) Performance bonds, surety bonds, bank guaranties and similar instruments incurred in the ordinary course of business;

(xi) Guarantees with respect to any Permitted Indebtedness;

(xii) The Breaking Stick Indebtedness;

(xiii) Indebtedness incurred after the earlier to occur of (a) the date on which all of the Loans have been disbursed, and (b) August 2, 2014, in an aggregate amount outstanding at any time of not more than $15,000,000 that is subordinated in right of payment to the Note pursuant to a Subordination Agreement satisfactory in form and content to the Lender;

(xiv) Unsecured Indebtedness in an aggregate amount of 15,000,000 Euros outstanding at any one time from a Government Authority of The Republic of France; and

(xv) Any refinancings, renewals, extensions, increases or replacements of Indebtedness listed in clauses (iii), (iv), (v) and (vi) so long as no such Indebtedness shall be refinanced for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing.

(xvi) Other unsecured Indebtedness in an aggregate principal amount not to exceed $1,000,000 at any time.

"Permitted Licensing" mean the licensing of Borrowers' Intellectual Property, including the Product Regulatory Rights, by the Borrowers to licensees in the ordinary course of business that is not an IP Asset Disposition.

"Permitted Liens" means:

(i) Liens existing on the date hereof and set forth on Exhibit C attached hereto, and any renewals or extensions thereof, provided that the property covered thereby is not increased and any renewal or extension of the obligations secured or benefited thereby is permitted by clause (iv), (v) or (vii) of the definition of Permitted Indebtedness;

(ii) Liens in favor of the Lender;

(iii) Liens in favor Deerfield and Horizon Sante FLML, SARL under the Deerfield Credit Facility and the related agreements, documents and instruments (including the related royalty agreements);

(iv) Statutory Liens created by operation of applicable law;

(v) Liens arising in the ordinary course of business and securing obligations that are not more than 30 days past due or are being contested in good faith by appropriate proceedings;

(vi) Liens for taxes, assessments or governmental charges or levies not more than 30 days past due and payable or that are being contested in good faith by appropriate proceedings;

(vii) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default;

(viii) Liens in favor of financial institutions arising in connection with the Borrowers' or their Subsidiaries' accounts maintained in the ordinary course of the Borrowers' and their Subsidiaries' business held at such institutions to secure standard fees for services charged by, but not financing made available by, such institutions;

(ix) Liens securing Indebtedness permitted pursuant to clauses (iv), (v) and (vi) of the definition of Permitted Indebtedness;

(x) Lessor liens;

(xi) Pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation;

(xii) Deposits to secure (i) the performance of tenders, bids, trade contracts, licenses and leases, statutory obligations, surety bonds, performance bonds, bank guaranties and other obligations of a like nature incurred in the ordinary course of business (including earnest money deposits in respect of any acquisition), or (ii) indemnification obligations relating to any disposition;

(xiii) Easements, rights of way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, and which do not in any case materially interfere with the ordinary conduct of the business of the applicable Person;

(xiv) Leases, licenses or subleases granted to others not interfering in any material respect with the business of the Borrowers and their Subsidiaries;

(xv) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code (or equivalent in foreign jurisdictions) on items in the course of collection;

(xvi) Permitted Licensing;

(xvii) To the extent constituting a Lien, good faith deposits required in connection with any acquisition and escrow arrangements securing indemnification obligations associated with any acquisition;

(xviii) Liens (i) on advances of cash or cash equivalents in favor of the seller of any property to be acquired by any Borrower or any of its Subsidiaries to be applied against the purchase price for such acquisition; provided, that (x) the aggregate amount of such advances of cash or cash equivalents shall not exceed the purchase price of such acquisition and (y) the property is acquired within 90 days following the date of the first such advance so made; and (ii) consisting of an agreement to dispose of any property in a disposition of assets, in each case, solely to the extent such acquisition or disposition, as the case may be, would have been permitted on the date of the creation of such Lien;

(xix) Liens on cash collateral securing reimbursement obligations of the Borrowers and their Subsidiaries under letters of credit;

(xx) Liens in favor Breaking Stick securing the Breaking Stick Indebtedness and other amounts owing under the Membership Interest Purchase Agreement; and

(xxi) Liens not otherwise permitted hereunder in respect of obligations in an aggregate amount not to exceed $500,000 at any time outstanding.

"Person" means and includes any natural person, individual, partnership, joint venture, corporation, trust, limited liability company, limited company, joint stock company, unincorporated organization, government entity or any political subdivision or agency thereof, or any other entity.

"Product Regulatory Rights" shall mean each and every investigational new drug application or new drug application and/or state license or registration that is held or obtained (if any) by Borrowers that is necessary to develop, conduct clinical trials relating to, manufacture, have manufactured, distribute, promote, market or sell specified drugs in the United States.

"Products" shall mean drugs approved pursuant to the FDA's Drug Efficiency Study Implementation to which Borrowers owns the Product Regulatory Rights.

"Register" has the meaning set forth in Section 1.4.

"Royalty Agreement" means that certain Royalty Agreement between Éclat Pharmaceuticals, LLC and Lender.

"SA" means Flamel Technologies S.A.

"SA Guaranty" means the guaranty made by SA for the benefit of the Lender guaranteeing the liabilities and obligations of the Borrowers under this Agreement and the other Transaction Documents, including the obligations of Éclat Pharmaceuticals, LLC under the Royalty Agreement.

"SA Security Documents" means (i) the Intellectual Property Security Agreement governed by the laws of New York pursuant to which SA grants to the Lender a lien and first priority security interest on the Medusa Technology to secure its obligations under the SA Guaranty, (ii) the security agreements made by SA in favor of Lender granting a lien and first priority security interest on the Medusa Technology to secure SA's obligations under the SA Guaranty that Lender determines are necessary to establish, continue and maintain a valid, enforceable, first priority security interest in the Medusa Technology to preserve Lender's rights and interests granted in the Medusa Technology, as against SA and third parties, with respect to the Medusa Technology registered and in use under the laws of any jurisdiction outside of the United States, and (iii) agreements governed by the laws of France pursuant to which SA grants to the Lender a lien on its property, plant and equipment located in Pessac, France to secure its obligations under the SA Guaranty.

"SEC" means the United States Securities and Exchange Commission.

"SEC Reports" means the annual, quarterly and periodic reports filed by SA with the SEC.

"Securities Act" means the Securities Act of 1933, as amended, including the rules and regulations promulgated thereunder.

"Security Agreements" mean (i) the SA Security Documents, and (ii) the Security Agreement governed by the laws of New York pursuant to which the Borrowers grant liens in all of their assets to the Lender to secure their obligations under the Transaction Documents.

"Successor Entity" means any Person purchasing SA's assets or Ordinary Shares, or any successor entity resulting from such Major Transaction.

"Subsidiary or Subsidiaries" means, as to any Borrower, any entity of which securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions are at the time directly or indirectly owned by such Borrower.

"Taxes" means all present or future taxes, levies, imposts, stamp or other duties, fees, assessments, deductions, withholdings, all other governmental charges, and all liabilities with respect thereto, together with any interest, fees, additions to tax or penalties applicable thereto (including by reason of any delay in payment).

"Transaction Documents" means this Agreement, the Note, the Security Agreements, the SA Guaranty, the Royalty Agreement, the Deerfield Intercreditor Agreement and any other document or instrument delivered in connection with any of the foregoing and dated the date of this Agreement or subsequent to such date, whether or not specifically mentioned herein or therein.

Section 1.2 Interpretation. In this Agreement, unless the context otherwise requires, all words and personal pronouns relating thereto shall be read and construed as the number and gender of the party or parties requires and the verb shall be read and construed as agreeing with the required word and pronoun; the division of this Agreement into Articles and Sections and the use of headings and captions is for convenience of reference only and shall not modify or affect the interpretation or construction of this Agreement or any of its provisions; the words "herein," "hereof," "hereunder," "hereinafter" and "hereto" and words of similar import refer to this Agreement as a whole and not to any particular Article or Section hereof; the words "include," "including," and derivations thereof shall be deemed to have the phrase "without limitation" attached thereto unless otherwise expressly stated; references to a specified Article, Exhibit, Section or Schedule shall be construed as a reference to that specified Article, Exhibit, Section or Schedule of this Agreement; and any reference to any of the Transaction Documents means such document as the same shall be amended, supplemented or modified and from time to time in effect.

Section 1.3 Business Day Adjustment. If the day by which a payment is due to be made is not a Business Day, that payment shall be made by the next succeeding Business Day unless that next succeeding Business Day falls in a different calendar month, in which case that payment shall be made by the Business Day immediately preceding the day by which such payment is due to be made.

Section 1.4 Books and Records and Register.

(a) The Borrowers shall record on their books and records the amount of the Loans, the interest rate applicable, all payments of principal and interest thereon and the principal balance thereof from time to time outstanding. Such record shall, absent manifest error, be conclusive evidence of the amount of the Loans made by the Lender to the Borrowers and the interest and payments thereon.

(b) The Borrowers shall establish and maintain at their address referred to in Section 6.1, a record of ownership (the "Register") in which the Borrowers agree to register by book entry the interests (including any rights to receive payment hereunder) of Lender in the Loans, and any assignment of any such interest, and (ii) accounts in the Register in accordance with its usual practice in which it shall record (1) the name and address of the Lender (and any change thereto pursuant to this Agreement), (2) the amount of the Loans and each funding of any participation therein, (3) the amount of any principal or interest due and payable or paid, and (4) any other payment received by the Lender from the Borrowers and its application to the Loans.

(c) Notwithstanding anything to the contrary contained in this Agreement, the Loans (including any Note evidencing the Loans) is a registered obligation, the right, title and interest of the Lender and its assignees in and to the Loans shall be transferable only upon notation of such transfer in the Register and no assignment thereof shall be effective until recorded therein. This Section 1.4 shall be construed so that the Loans are at all times maintained in "registered form" within the meaning of Sections 163(f), 871(h)(2) and 881(c)(2) of the Code.

(d) The Borrowers and the Lender shall treat each Person whose name is recorded in the Register as a Lender for all purposes of this Agreement. Information contained in the Register with respect to Lender shall be available for access by the Borrowers or Lender at any reasonable time and from time to time upon reasonable prior notice.

ARTICLE 2

AGREEMENT FOR THE LOANS

Section 2.1 Use of Proceeds. The proceeds of the Loans will be used for working capital without limitation as to its use, except as otherwise prohibited by the Transaction Documents.

Section 2.2 Loans.

(a) Subject to the satisfaction of the conditions contained in Article 4, Lender agrees to make loans to Borrowers in an amount up to the $15,000,000, as follows: (i) on the Closing Date, $5,000,000 (the "Initial Loan"), (ii) from the period from November 15, 2013 through August 15, 2014, at the request of the Borrowers, an additional loan in the amount of $5,000,000, and (iii) from the period from November 15, 2013 through August 15, 2014, at the request of the Borrowers, a second additional loan in the amount of $5,000,000 if Éclat has obtained FDA approval for a second Product, with such second Product being one of the three remaining Éclat Products as defined in the Deerfield Facility Agreement (each of the additional loans described in the foregoing clauses (ii) and (iii) is an "Additional Loan", each Additional Loan and the Initial Loan, a "Loan" and collectively, "Loans"). No amounts prepaid (or repaid) on account of any Loan may be reborrowed.

(b) To obtain an Additional Loan, Borrowers shall notify Lender (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by ten (10) Business Days prior to the date of the proposed date of funding.

(c) Borrowers' obligation to repay the Loans shall be evidenced by a promissory note (the "Note") in substantially the form attached hereto as Exhibit A.

(d) Each Borrower acknowledges that it is jointly and severally liable for all of the Obligations. Each Borrower expressly understands, agrees and acknowledges that (i) Borrowers are all affiliated entities by common ownership, (ii) each Borrower desires to have the availability of one common credit facility instead of separate credit facilities, (iii) each Borrower has requested that Lender extend such a common credit facility to Borrowers on the terms provided herein, (iv) Lender will be lending against, and relying on a lien upon, all or substantially all of the assets of Borrowers even though the proceeds of any particular Loan made hereunder may not be advanced directly to or on behalf of a particular Borrower, (v) each Borrower will benefit by the making of the Loans and the availability of a credit facility of a size greater than each could independently warrant, and (vi) all of the representations, warranties, covenants, obligations, conditions, agreements and other terms contained in this Agreement shall be applicable to and shall be binding upon each Borrower.

Section 2.3 Payment and Prepayment.

(a) The Borrowers shall remit the Final Payment to the Lender on the earlier to occur of (i) the Final Payment Date and (ii) the date the principal amount of the Note and all other outstanding Obligations under this Agreement are declared to be or automatically become due and payable following an Event of Default.

(b) The Note may be prepaid in whole or in part, at any time, without any premium or penalty, upon five (5) Business Days' notice to the Lender prior to the date of the proposed prepayment (which notice shall be irrevocable), and such prepayment shall include interest due on such date. Each prepayment shall be applied first, to accrued and unpaid interest and second, to principal.

(c) Subject to the terms of the Deerfield Intercreditor Agreement, upon receipt of net cash proceeds from any IP Asset Disposition, Borrowers shall promptly repay the Loan in an amount equal to 100% of the net cash proceeds arising from such IP Asset Disposition, whether received at the closing of such IP Asset Disposition or at any later date. Notwithstanding the forgoing, if any IP subject to an IP Asset Disposition is subject to a prior lien in favor of Deerfield or Breaking Stick, and Deerfield or Breaking Stick (as applicable) agrees to permit such IP Asset Disposition without requiring a prepayment of any Indebtedness owing to them, then the Borrowers shall not be obligated to make any prepayment or repayment of the Loan in respect of such IP Asset Disposition.

Section 2.4 Payments. Payments of any amounts due to the Lender under this Agreement shall be made in Dollars in immediately available funds prior to 11:00 a.m New York City time on such date that any such payment is due, at such bank or places as the Lender shall from time to time designate in writing at least five (5) Business Days prior to the date such payment is due. The Borrowers shall pay all and any costs (administrative or otherwise) imposed by banks, clearing houses, or any other financial institution, in connection with making any payments under any of the Transaction Documents, except for any costs imposed by the Lender's banking institutions.

Section 2.5 Taxes, Duties and Fees.

(a) Any and all payments hereunder or under any other Transaction Document shall be made, in accordance with this Section 2.5, free and clear of and without deduction for any and all present or future Indemnified Taxes except as required by applicable law. If Borrowers shall be required by law to deduct any Indemnified Taxes from or in respect of any sum payable hereunder or under any other Transaction Document, (i) the sum payable shall be increased by as much as shall be necessary so that after making all required deductions (including deductions applicable to additional sums payable under this Section 2.5) the Lender shall receive an amount equal to the sum they would have received had no such deductions been made (any and all such additional amounts payable to Lender shall hereafter be referred to as the "Additional Amounts"), (ii) Borrowers shall make such deductions, and (iii) Borrowers shall pay the full amount deducted to the relevant taxing or other authority in accordance with applicable law. Within thirty (30) days after the date of any payment of such Taxes, Borrowers shall furnish to the Lender the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to Lender.

(b) In addition, Borrowers agree to pay, and authorize Lender to pay in their respective names, all Other Taxes. Within thirty (30) days after the date of any payment of Other Taxes, Borrowers shall furnish to Lender the original or a certified copy of a receipt evidencing payment thereof or other evidence of such payment reasonably satisfactory to Lender.

(c) Borrowers shall reimburse and indemnify, within ten (10) days after receipt of demand therefor, Lender for all Indemnified Taxes (including all Taxes and Other Taxes imposed by any jurisdiction on amounts payable under this Section 2.5(c)) paid by Lender, whether or not such Indemnified Taxes were correctly or legally asserted. A certificate of the Lender setting forth the amounts to be paid thereunder and delivered to Borrowers shall be conclusive, binding and final for all purposes, absent manifest error.

(d) Lender shall (unless Lender is a Foreign Person) on or before the date hereof provide to Borrowers a properly completed and executed IRS Form W-9 certifying that Lender is organized under the laws of the United States. If Lender is organized under the laws of a jurisdiction outside the United States (a "Foreign Person") and is entitled to an exemption from or reduction in U.S. withholding tax it shall provide Borrowers with a properly completed and executed IRS Form W-8ECI, W-8BEN, W-8IMY or other applicable form, or any other applicable certificate or document reasonably requested by the Borrowers, and, if such Foreign Person that is relying on the portfolio interest exception of Section 871(h) or Section 881(c) of the Code (or any successor provision thereto), shall also provide the Borrowers with a certificate (the "Portfolio Interest Certificate") representing that such Foreign Person is not a "bank" for purposes of Section 881(c) of the Code (or any successor provision thereto), is not a 10% holder of the Borrowers described in Section 871(h)(3)(B) of the Code (or any successor provision thereto), is not a controlled foreign corporation receiving interest from a related person (within the meaning of Sections 881(c)(3)(C) and 864(d)(4) of the Code, or any successor provisions thereto) and is not a conduit entity participating in a conduit Transaction arrangement as defined in Treasury Regulation Section 1.881-3 (or any successor provision thereto). Lender shall provide new forms (or successor forms) upon the expiration or obsolescence of any previously delivered forms and shall promptly notify the Borrowers of any change in circumstances which would modify or render invalid any claimed exemption or reduction.

(e) If Lender determines in good faith that it has received a refund from a Government Authority relating to Taxes in respect of which the Borrowers paid Additional Amounts or made a payment pursuant to Section 2.5(c), Lender shall promptly pay such refund to the Borrowers, net of all out-of-pocket expense (including any Taxes imposed thereon) of Lender incurred in obtaining such refund, provided that the Borrowers, upon the request of Lender, agrees to repay the amount paid over to the Borrowers (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) to Lender if Lender is required to repay such refund to such Governmental Authority. Nothing in this Section shall require Lender to disclose any information it deems confidential (including, without limitation, its tax returns) to any Person, including Borrowers.

Section 2.6 Costs, Expenses and Losses. If, as a result of any failure by the Borrowers to pay any sums due under this Agreement on the due date therefor (after the expiration of any applicable grace periods), the Lender shall incur costs, expenses and/or losses, by reason of the liquidation or redeployment of deposits from third parties or in connection with obtaining funds to make or maintain the Loans, the Borrowers shall pay to the Lender upon request by the Lender, the amount of such costs, expenses and/or losses within fifteen (15) days after receipt by it of a certificate from the Lender setting forth in reasonable detail such costs, expenses and/or losses, along with supporting documentation. For the purposes of the preceding sentence, "costs, expenses and/or losses" shall include, without limitation, any interest paid or payable to carry any unpaid amount and any loss, premium, penalty or expense which may be incurred in obtaining, liquidating or employing deposits of or borrowings from third parties in order to make, maintain or fund the Loans or any portion thereof.

Section 2.7 Interest.

(a) The outstanding principal amount of the Note shall bear interest at the Interest Rate (calculated on the basis of the actual number of days elapsed in each month). Interest shall be paid quarterly in arrears commencing on January 1, 2014 and on the first Business Day of each April, July, October, and January thereafter (each, an "Interest Payment Date").

(b) Without limiting the remedies available to the Lender under the Transaction Documents or otherwise, upon the occurrence and during the continuation of an Event of Default, at the election of the Lender, the outstanding principal amount of the Note and all other outstanding Obligations shall bear interest at the Default Rate.

Section 2.8 Costs and Expenses. On the Closing Date, the Borrowers shall reimburse the Lender for its legal costs and expense incurred in effecting such transaction up to a maximum of $75,000.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES

Section 3.1 Representations and Warranties of the Borrowers. The Borrowers represent and warrant as of the date hereof that except as set forth in a Schedule to this Agreement or the SEC Reports for the year ended December 31, 2012 or the quarterly periods ended March 31, 2013 and June 30, 2013, as in effect on the date hereof:

(a) Each Borrower is conducting its business in compliance with its Organizational Documents, which are in full force and effect with no defaults outstanding thereunder.

(b) No Default or Event of Default (or any other default or event of default, however described) has occurred under any of the Transaction Documents.

(c) Each Borrower (i) is capable of paying its debts as they fall due, is not unable and has not admitted its inability to pay its debts as they fall due, (ii) is not bankrupt or insolvent and (iii) has not taken action, and no such action has been taken by a third party, for such Borrower's winding up, dissolution, or liquidation or similar executory or judicial proceeding or for the appointment of a liquidator, custodian, receiver, trustee, administrator or other similar officer for such Borrower or any or all of its assets or revenues.

(d) No Lien exists on any Borrower's assets, except for Permitted Liens.

(e) The obligation of the Borrowers to make any payment under this Agreement (together with all charges in connection therewith) is absolute and unconditional, and there exists no right of setoff or recoupment, counterclaim, cross-claim or defense of any nature whatsoever to any such payment.

(f) No Indebtedness of the Borrowers exists other than Permitted Indebtedness.

(g) Each of the Borrowers is validly existing as a corporation or limited liability company in good standing under the laws of its state of incorporation or formation. Each Borrower has full power and authority to own its properties and conduct its business, and is duly qualified to do business as a foreign entity and is in good standing in each jurisdiction in which the conduct of its business makes such qualification necessary and in which the failure to so qualify would not have a Material Adverse Effect.

(h) There is not pending or, to the knowledge of the Borrowers, threatened, any action, suit or other proceeding before any Governmental Authority (a) to which any Borrower is a party or (b) which has as the subject thereof any assets owned by the Borrowers that would be expected to result in a Material Adverse Effect. There are no current or, to the knowledge of the Borrowers, pending, legal, governmental or regulatory enforcement actions, suits or other proceedings to which any Borrower or any of its assets is subject that would be expected to result in a Material Adverse Effect.

(i) The Transaction Documents have been duly authorized, executed and delivered by the Borrowers, and constitute a valid, legal and binding obligation of the Borrowers enforceable in accordance with its terms, except as such enforceability may be limited by applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally. The execution, delivery and performance of the Transaction Documents by the Borrowers and the consummation of the transactions therein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any Lien upon any assets of the Borrowers pursuant to, any agreement to which any Borrower is a party or by which any Borrower is bound or to which any of the assets of any Borrower is subject, (B) result in any violation of or conflict with the provisions of the Organizational Documents or (C) result in the violation of any law or any judgment, order, rule, regulation or decree of any Governmental Authority. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority is required for the execution, delivery and performance of any of the Transaction Documents or for the consummation by the Borrowers of the transactions contemplated hereby except filings contemplated with the Security Agreements and each Borrower has the corporate power and authority to enter into the Transaction Documents and to consummate the transactions contemplated under the Transaction Documents.

(j) Each Borrower holds, and is operating in compliance in all material respects with, all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders of any Governmental Authority (collectively, "Necessary Documents") required for the conduct of its business and all Necessary Documents are valid and in full force and effect; and no Borrower has received written notice of any revocation or modification of any of the Necessary Documents and the Borrowers have no reason to believe that any of the Necessary Documents will not be renewed in the ordinary course, and each Borrower is in compliance in all material respects with all applicable federal, state, local and foreign laws, regulations, orders and decrees applicable to the conduct of its business.

(k) Each Borrower has good and marketable title to all of its assets free and clear of all Liens except Permitted Liens. The property held under lease by the Borrowers is held under valid, subsisting and enforceable leases with only such exceptions with respect to any particular lease as do not interfere in any material respect with the conduct of the business of the Borrowers.

(l) Each Borrower owns or has the right to use pursuant to a valid and enforceable written license, implied license or other legally enforceable right, all of the Intellectual Property that is necessary for the conduct of its business as currently conducted (the "IP"). To the knowledge of the Borrowers, the IP that is registered with or issued by a Governmental Authority is valid and enforceable; there is no outstanding, pending, or, to the knowledge of the Borrowers, threatened action, suit, other proceeding or claim by any third person challenging or contesting the validity, scope, use, ownership, enforceability, or other rights of the Borrowers in or to any IP and the Borrowers have not received any written notice regarding, any such action, suit, or other proceeding. To the knowledge of the Borrowers, the Borrowers have not infringed or misappropriated any material rights of others. To the knowledge of the Borrowers, there is no pending or threatened action, suit, other proceeding or claim by others that the Borrowers infringes upon, violates or uses the Intellectual Property rights of others without authorization, and the Borrower have not received any written notice regarding, any such action, suit, other proceeding or claim, which would be expected to result in a Material Adverse Effect.

(m) No Borrower is in violation of the Organizational Documents, or in breach of or otherwise in default under, and no event has occurred which, with notice or lapse of time or both, would constitute such breach or other default in the performance of any agreement or condition contained in any agreement under which it may be bound, or to which any of its assets is subject, except for such breaches or defaults as would not have a Material Adverse Effect.

(n) The Borrowers have timely filed, including pursuant to all extensions, all income and franchise tax returns required to be filed by any Governmental Authority (except where the failure to file would not have a Material Adverse Effect) and are not in default in the payment of any taxes which were payable pursuant to said returns or any assessments with respect thereto. There is no pending dispute with any taxing authority relating to any of such returns, and no Borrower has any knowledge of any proposed liability for any tax to be imposed upon its properties or assets, would be expected to result in a Material Adverse Effect.

(o) The Borrowers have not granted rights to develop, manufacture, produce, assemble, distribute, license, market or sell their products to any other Person except in the ordinary course of business and are not bound by any agreement that affects the exclusive right of the Borrowers to develop, manufacture, produce, assemble, distribute, license, market or sell their products except in the ordinary course of business.

(p) The Borrowers: (A) at all times have complied in all material respects with all Applicable Laws; (B) have not received any warning letter or other correspondence or notice from the FDA or any correspondence or notice from any other Governmental Authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any Applicable Laws (together, the "Authorizations"), which non-compliance would be expected to result in a Material Adverse Effect; (C) possess and comply in all material respects with the Authorizations, which are valid and in full force and effect; (D) have not received written notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorization that be expected to result in a Material Adverse Effect, and have no knowledge that any Governmental Authority is considering such action; (E) have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations, except as would not have a Material Adverse Effect; and (F) have not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Borrowers' knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(q) The studies, tests and preclinical and clinical trials conducted by or on behalf of the Borrowers were and, if still pending, are being conducted in compliance in all material respects with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder; the Borrowers are not aware of any studies, tests or trials, the results of which the Borrowers believe reasonably call into question any of its studies, tests or trial results and the Borrowers have not received any written notices or correspondence from any Governmental Authority requiring the termination, suspension, or material modification of any such studies, tests or preclinical or clinical trials.

(r) The financial statements of the Borrowers provided to the Lender prior to the Closing Date and any funding date in connection with the making of an Additional Loan and identified as subject to this subsection (r) together with the related notes fairly present the financial condition of the Borrowers as of the dates indicated and the results of operations and changes in cash flows for the periods therein specified in conformity with GAAP consistently applied throughout the periods involved, subject, in the case of unaudited financial statements, to year-end adjustments; and, except as disclosed in such Schedule, there are no material off-balance sheet arrangements or any other relationships with unconsolidated entities or other persons, that may have a material current or, to the Borrowers' knowledge, material future effect on the Borrowers' financial condition, results of operations, liquidity, capital expenditures, capital resources or significant components of revenue or expenses.

(s) The Borrowers maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(t) Flamel US Holdings, Inc. has no Subsidiaries other than Flamel Technologies, Inc. and Éclat Pharmaceuticals LLC. Éclat Pharmaceuticals LLC has no Subsidiaries other Talec Pharma, LLC.

(u) The representations and warranties set forth in this Section 3.1 are applicable to the Borrowers' Subsidiaries.

Section 3.2 Borrowers Acknowledgment. The Borrowers acknowledge that they have made the representations and warranties referred to in Section 3.1 with the intention of persuading the Lender to enter into the Transaction Documents and that the Lender has entered into the Transaction Documents on the basis of, and in full reliance on, each of such representations and warranties. The Borrowers represent and warrant to the Lender that none of such representations and warranties omits any matter the omission of which makes any of such representations and warranties misleading.

Section 3.3 Representations and Warranties of the Lender. Lender represents and warrants to the Borrowers as of the date hereof that:

(a) It is acquiring the Note for its account for investment, not as an agent or nominee, and not with a view to or for resale in connection with any distribution of the Note.

(b) The Note must be held indefinitely unless it is subsequently registered under the Securities Act or an exemption for such registration is available.

(c) Each Transaction Document to which it is a party has been duly authorized, executed and delivered by Lender and constitutes its valid and legally binding obligation, enforceable in accordance with its terms, except as such enforceability may be limited by (i) applicable insolvency, bankruptcy, reorganization, moratorium or other similar laws affecting creditors' rights generally, and (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

ARTICLE 4

CONDITIONS PRECEDENT

Section 4.1 Conditions to the Closing the Initial Loan. The obligation of the Lender to make the Initial Loan shall be subject to the fulfillment of the following conditions:

(a) The Lender shall have received executed counterparts of the Transaction Documents;

(b) The Lender shall have received an officer's certificate from each Borrower, certifying as to such Borrower's Organizational Documents, resolutions authorizing the entering into the Transaction Documents, and incumbency;

(c) The Lender shall have received all documents and instruments, including Uniform Commercial Code financing statements, required by law or reasonably requested by the Lender to be filed, registered or recorded to create or perfect the liens intended to be created under the Transaction Documents and all such documents and instruments shall have been, or concurrently with the Closing Date are, so filed, registered or recorded to the reasonable satisfaction of the Lender;

(e) The Lender shall have received certificates of insurance evidencing Borrowers' insurance coverage, together with a lender's loss payable endorsement for property/casualty insurance and additional insured endorsement for liability insurance;

(f) an opinion of Troutman Sanders, LLP, U.S. counsel to the Borrowers, addressed to the Lender, as to such matters concerning the Borrowers and the Transaction Documents as the Lender may reasonably request;

(g) The Lender shall have received a copy of SA's resolutions authorizing the entering into the Transaction Documents; and

(h) The Lender shall have received such other certificates, documents, consents or opinions as the Lender reasonably may require.

Section 4.2 Conditions to the Closing of Any Loan. The obligation of the Lender to make any Loan shall be subject to the fulfillment of the following conditions:

(a) Each of the representations and warranties set forth in Section 3.1 and Section 3.2 and elsewhere in the Transaction Documents shall be true and correct in all material respects on the date of such Loan, except to the extent that such representations and warranties relate solely to an earlier date (in which case such representations and warranties shall have been true and correct on and as of such earlier date).

(b) No Default or Event of Default has occurred and is continuing or would result from the making of such Loan.

ARTICLE 5

PARTICULAR COVENANTS AND EVENTS OF DEFAULT

Section 5.1 Affirmative Covenants. Unless the Lender shall otherwise agree:

(a) Each Borrower shall and shall cause its Subsidiaries to maintain its existence and qualify and remain qualified to do its business as currently conducted, except where the failure to so maintain such qualification would not reasonably be expected to have a Material Adverse Effect.

(b) Each Borrower shall and shall cause its Subsidiaries to comply in all material respects with all Applicable Laws, except where the necessity of compliance therewith is contested in good faith by appropriate proceedings or where the failure to comply would not have a Material Adverse Effect.

(c) Each Borrower shall obtain and shall cause its Subsidiaries to make and keep in full force and effect all licenses, certificates, approvals, registrations, clearances, authorizations and permits required to conduct their businesses, except where the failure to do so would not have a Material Adverse Effect.

(d) The Borrowers shall promptly notify the Lender of the occurrence of (i) any Default or Event of Default and (ii) any claims, litigation, arbitration, mediation or administrative or regulatory proceedings that are instituted or threatened against the any Borrower or any of its Subsidiaries that could reasonably be expected to have a Material Adverse Effect, and (iii) each event which, at the giving of notice, lapse of time, determination of materiality or fulfillment of any other applicable condition (or any combination of the foregoing), would constitute an Event of Default under this Agreement or an event of default (however described) under any Transaction Document.

(e) (i) If SA is not required to file reports pursuant to the Exchange Act, the Borrowers will cause SA to provide unaudited quarterly consolidated financial statements of SA and its Subsidiaries within forty-five (45) days after the end of each of the first three fiscal quarters of each calendar year, and audited annual consolidated financial statements of SA and its Subsidiaries within one hundred (120) days after the end of each calendar year prepared in accordance with GAAP (subject, in the case of unaudited financial statements, to the absence of footnotes and other presentation items and to normal year-end adjustments) with, in the case of annual financial statements, a report thereon by SA's independent certified public accountants, (ii) SA will timely file with the SEC (subject to appropriate extensions made under the Exchange Act) any annual reports, quarterly reports and other periodic reports required to be filed pursuant to the Exchange Act, and (iii) SA and its Subsidiaries will provide to the Lender copies of all documents, reports, financial data and other information that the Lender may reasonably request.

Section 5.2 Negative Covenants. Unless the Lender shall otherwise agree:

(a) No Borrower shall and shall not permit any Subsidiary to (i) liquidate (other than Flamel Technologies Inc. which shall be liquidated and all proceeds thereof distributed to SA), provided that a Subsidiary may merge into any Borrower, or dissolve (unless such Subsidiary ceases to own any operating assets or conduct business), or (ii) enter into any merger, consolidation or reorganization, unless a Borrower is the surviving corporation. The Borrowers shall not maintain or establish any Subsidiary in the United States unless such Subsidiary executes and delivers to the Lender a guarantee substantially in the form of the SA Guaranty if such Subsidiary is organized outside of the United States, in the form of a guaranty to the same effect as the SA Guaranty customary in the jurisdiction in which such Subsidiary is organized.

(b) No Borrower shall, nor shall any Borrower permit any Subsidiary to (i) enter into any partnership, joint venture, syndicate, pool, profit-sharing or royalty agreement or other combination, or engage in any transaction, in any such case with an Affiliate, whereby its income or profits are, or might be, shared with such Affiliate other than Permitted Affiliate Transactions, (ii) enter into any management contract or similar arrangement whereby a substantial part of its business is managed by another Person (other than contracts and similar arrangements between or among Borrowers or SA), or (iii) distribute, or permit the distribution of, any of the Product Regulatory Rights to any Person (other than distributions to another Borrower or in connection with Permitted Licensing).

(c) No Borrower shall, nor shall any Borrower permit any Subsidiary to create, incur or suffer any Lien upon any of its assets, now owned or hereafter acquired, except Permitted Liens, provided that upon the occurrence and continuance of an Event of Default, no Borrower shall license any of its Intellectual Property, including Permitted Licensing, without the prior consent of the Lender.

(d) No Borrower shall, nor shall any Borrower permit any Subsidiary to assign, sell, transfer or otherwise dispose of, any Transaction Document, or the rights and obligations thereunder.

(e) No Borrower shall, nor shall any Borrower permit any Subsidiary to create, incur, assume, guarantee or remain liable with respect to any Indebtedness, other than Permitted Indebtedness.

(f) No Borrower shall, nor shall any Borrower permit any Subsidiary to acquire any assets (other than assets acquired in the ordinary course of business consistent with past practices and other asset acquisitions from SA or another Borrower or Subsidiary of a Borrower), directly or indirectly, in one or more related transaction, for a consideration, in cash or other property (valued at its fair market value) greater than $500,000.

Section 5.3 Major Transaction. The Borrowers shall give the Lender notice of the consummation of a Major Transaction involving SA on the shorter of thirty (30) days prior to such consummation or two (2) days following the public announcement thereof. Within five (5) days after the receipt of such notice, the Lender, in the exercise of its sole discretion, may deliver a notice to the Borrowers (the "Put Notice"), that the Final Payment shall be due and payable upon consummation of such Major Transaction. If the Lender delivers a Put Notice, then simultaneously with consummation of such Major Transaction, the Borrowers shall make or cause to be made the Final Payment to the Lender. The Borrowers shall take such steps as may be required to ensure that SA shall not consummate any Major Transaction until the Borrowers comply with the provisions of this Section 5.3.

Section 5.4 General Acceleration Provision upon Events of Default. If one or more of the events specified in this Section 5.4 shall have occurred and be continuing beyond the applicable cure period (each, an "Event of Default"), the Lender, by written notice to the Borrowers, may declare the principal of, and accrued and unpaid interest on, the Note or any part of any of it (together with any other amounts accrued or payable under the Transaction Documents) to be, and the same shall thereupon become, immediately due and payable, without any further notice and without any presentment, demand, or protest of any kind, all of which are hereby expressly waived by the Borrowers, and take any further action available at law or in equity, including, without limitation, the sale of the Loans and all other rights acquired in connection with the Loans:

(a) The Borrowers shall have failed to make payment of principal and interest under the Note when due.

(b) The Borrowers shall have failed to comply with the due observance or performance of any covenant contained in any Transaction Document (other than the covenants described in clause (a) above), and such failure shall not have been cured by the Borrowers within thirty (30) days.

(c) Any representation or warranty made by the Borrowers in any Transaction Document shall have been incorrect, false or misleading as of the date it was made.

(d) (i) Any Borrower shall generally be unable to pay its debts as such debts become due, or shall admit in writing its inability to pay its debts as they come due or shall make a general assignment for the benefit of creditors; (ii) any Borrower shall declare a moratorium on the payment of its debts; (iii) the commencement by any Borrower of proceedings to be adjudicated bankrupt or insolvent, or the consent by it to the commencement of bankruptcy or insolvency proceedings against it, or the filing by it of a petition or answer or consent seeking reorganization, intervention or other similar relief under any applicable law, or the consent by it to the filing of any such petition or to the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official) of all or substantially all of its assets; (iv) the commencement against any Borrower of a proceeding in any court of competent jurisdiction under any bankruptcy or other applicable law (as now or hereafter in effect) seeking its liquidation, winding up, dissolution, reorganization, arrangement, adjustment, or the appointment of an intervenor, receiver, liquidator, assignee, trustee, sequestrator (or other similar official), and any such proceeding shall continue undismissed, or any order, judgment or decree approving or ordering any of the foregoing shall continue unstayed or otherwise in effect, for a period of thirty (30) days; (v) the making by any Borrower of an assignment for the benefit of creditors, or the admission by it in writing of its inability to pay its debt generally as they become due; or (vi) any other event shall have occurred which under any applicable law would have an effect analogous to any of those events listed above in this subsection.

(e) One or more judgments against any Borrower or any Subsidiary or attachments against any of their respective property that could reasonably be expected to have a Material Adverse Effect remain(s) unpaid, unstayed on appeal, undischarged, unbonded or undismissed for a period of thirty (30) days from the date of entry of such judgment.

(f) Any Authorization held by any Borrower from any Government Authority shall have been suspended, canceled or revoked and such suspension, cancellation or revocation shall not have been cured within thirty (30) days.

(g) Any authorization necessary for the execution, delivery or performance of any Transaction Document or for the validity or enforceability of any of the Obligations under any Transaction Document is not given or is withdrawn or ceases to remain in full force or effect.

(h) The validity of any Transaction Document shall be contested by the Borrowers, or any treaty, law, regulation, communiqué, decree, ordinance or policy of any jurisdiction shall purport to render any material provision of any Transaction Document invalid or unenforceable or shall purport to prevent or materially delay the performance or observance by the Borrowers of the Obligations.

(i) SA has failed to comply in any material respect with the reporting requirements of the Exchange Act, if applicable and such non-compliance shall not have been remedied by the Borrowers within thirty (30) days.

(j) There is a failure to perform in any agreement to which any Borrower or any Subsidiary is a party with a third party or parties resulting in a right by such third party or parties to accelerate the maturity of any Indebtedness for borrowed money in an amount in excess of $500,000.

(k) If an event of default occurs under the Installment Sale Note dated March 12, 2012 from the Borrowers to Éclat Holdings LLC in the principal amount of $12,000,000 and such note shall have been accelerated as a result thereof.

(l) If an event of default occurs under the Deerfield Credit Facility.

Section 5.5 Automatic Acceleration on Dissolution or Bankruptcy. Notwithstanding any other provisions of this Agreement, if an Event of Default under Section 5.4(d) shall occur, the principal of the Note together with any other outstanding Obligations under this Agreement shall thereupon become immediately due and payable without any presentment, demand, protest or notice of any kind, all of which are hereby expressly waived by the Borrowers.

Section 5.6 Recovery of Amounts Due. If any amount payable hereunder is not paid as and when due, the Borrowers hereby authorize the Lender to proceed, to the fullest extent permitted by applicable law, without prior notice, by right of set-off, banker's lien or counterclaim, against any moneys or other assets of the Borrowers to the full extent of all amounts payable to the Lender.

ARTICLE 6

MISCELLANEOUS

Section 6.1 Notices. Any notices required or permitted to be given under the terms hereof shall be sent by certified or registered mail (return receipt requested) or delivered personally or by courier (including a recognized overnight delivery service) or by facsimile or by electronic mail and shall be effective five (5) days after being placed in the mail, if mailed by regular United States mail, or upon receipt, if delivered personally or by courier (including a recognized overnight delivery service) or by facsimile, or when red by electronic mail (sender shall have received a "read by recipient" confirmation) in each case addressed to a party. The addresses for such communications shall be:

If to the Borrowers:

Flamel US Holdings, Inc.
702 Spirit 40 Park Drive, Ste. 108
Chesterfield MO 63005
Fax: 636-449-1850
Email: Anderson@flamel.com
Attn: Michael S. Anderson

With copy to:

Troutman Sanders LLP
The Chrysler Building
405 Lexington Avenue
New York, NY 10174-0700
Fax: (212) 704-6288
Email: clark.sullivan@troutmansanders.com
Attn: Clark G. Sullivan

If to the Lender:

Broadfin Healthcare Master Fund, Ltd.
c/o Broadfin Capital, LLC
237 Park Avenue, Suite 900
New York, NY 10017
Fax: 212-808-2464
Email: kevin@broadfincapital.com
Attn: Kevin Kotler

With a copy to:

Greenberg Traurig, LLP
One International Place
Boston, MA 02110
Fax: 617.279.8433
Email: puopolor@gtlaw.com
Attn: Robert E. Puopolo

Section 6.2 Waiver of Notice. Whenever any notice is required to be given to the Lender or the Borrowers under the any of the Transaction Documents, a waiver thereof in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

Section 6.3 Reimbursement of Legal and Other Expenses. If any amount owing to the Lender under any Transaction Document shall be collected through enforcement of this Agreement, any Transaction Document or restructuring of the Loans in the nature of a work-out, settlement, negotiation, or any process of law, or shall be placed in the hands of third Persons for collection, the Borrowers shall pay (in addition to all monies then due in respect of the Loans or otherwise payable under any Transaction Document) attorneys' and other fees and expenses incurred in respect of such collection.

Section 6.4 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York applicable to contracts made and to be performed in such State. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. The parties hereby waive all rights to a trial by jury.

Section 6.5 Successors and Assigns. This Agreement shall bind and inure to the respective successors and assigns of the Parties, except that no Borrower may assign or otherwise transfer all or any part of its rights under this Agreement or the Obligations without the prior written consent of the Lender.

Section 6.6 Entire Agreement. The Transaction Documents contain the entire understanding of the Parties with respect to the matters covered thereby and supersede any and all other written and oral communications, negotiations, commitments and writings with respect thereto. The provisions of this Agreement may be waived, modified, supplemented or amended only by an instrument in writing signed by the authorized officer of each Party.

Section 6.7 Severability. If any provision of this Agreement shall be invalid, illegal or unenforceable in any respect under any law, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The Parties shall endeavor in good faith negotiations to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the invalid, illegal or unenforceable provision.

Section 6.8 Counterparts. This Agreement may be executed in several counterparts, and by each Party on separate counterparts, each of which and any photocopies and facsimile copies thereof shall be deemed an original, but all of which together shall constitute one and the same agreement.

Section 6.9 Survival.

(a) This Agreement and all agreements, representations and warranties made in the Transaction Documents, and in any document, certificate or statement delivered pursuant thereto or in connection therewith shall be considered to have been relied upon by the other Parties and shall survive the execution and delivery of this Agreement and the making of the Loans hereunder regardless of any investigation made by any such other Party or on its behalf, and shall continue in force until all amounts payable under the Transaction Documents shall have been fully paid in accordance with the provisions thereof, and the Lender shall not be deemed to have waived, by reason of making the Loans, any Event of Default that may arise by reason of such representation or warranty proving to have been false or misleading, notwithstanding that the Lender may have had notice or knowledge of any such Event of Default or may have had notice or knowledge that such representation or warranty was false or misleading at the time any Loan was made.

(b) The obligations of the Borrowers under Section 2.5 and the obligations of the Borrowers and the Lender under this Article 6 shall survive and remain in full force and effect regardless of the consummation of the transactions contemplated hereby, the repayment of the Loans, or the termination of this Agreement or any provision hereof.

Section 6.10 Waiver. Neither the failure of, nor any delay on the part of, any Party in exercising any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder, or under any agreement, document or instrument mentioned herein, preclude other or further exercise thereof or the exercise of any other right, power or privilege; nor shall any waiver of any right, power, privilege or default hereunder, or under any agreement, document or instrument mentioned herein, constitute a waiver of any other right, power, privilege or default or constitute a waiver of any default of the same or of any other term or provision. No course of dealing and no delay in exercising, or omission to exercise, any right, power or remedy accruing to the Lender upon any default under this Agreement, or any other agreement shall impair any such right, power or remedy or be construed to be a waiver thereof or an acquiescence therein; nor shall the action of the Lender in respect of any such default, or any acquiescence by it therein, affect or impair any right, power or remedy of the Lender in respect of any other default. All rights and remedies herein provided are cumulative and not exclusive of any rights or remedies otherwise provided by law.

Section 6.11 Indemnity.

(a) The Parties shall, at all times, indemnify and hold each other harmless (the "Indemnity") and each of their respective directors, partners, officers, employees, agents, counsel and advisors (each, an "Indemnified Person") in connection with any losses, claims (including the cost of defending against such claims), damages, liabilities, penalties, or other expenses arising out of, or relating to, the Transaction Documents, the extension of credit hereunder or the Loans or the use or intended use of the Loans, which an Indemnified Person may incur or to which an Indemnified Person may become subject (each, a "Loss"). The Indemnity shall not apply to the extent that a court or arbitral tribunal with jurisdiction over the subject matter of the Loss, and over the Lender or any Borrower, as applicable, and such other Indemnified Person that had an adequate opportunity to defend its interests, determines that such Loss resulted from the gross negligence or willful misconduct of the Indemnified Person, which determination results in a final, non-appealable judgment or decision of a court or tribunal of competent jurisdiction. The Indemnity is independent of and in addition to any other agreement of any Party under any Transaction Document to pay any amount to the Lender or any Borrower, as applicable, and any exclusion of any obligation to pay any amount under this subsection shall not affect the requirement to pay such amount under any other section hereof or under any other agreement.

(b) Promptly after receipt by an Indemnified Person under this Section 6.11 of notice of the commencement of any action (including any governmental action), such Indemnified Person shall, if a Loss in respect thereof is to be made against the Borrowers under this Section 6.11, deliver to the Borrowers a written notice of the commencement thereof, and the Borrowers shall have the right to participate in, and, to the extent the Borrowers so desire, to assume control of the defense thereof with counsel mutually satisfactory to the Borrowers and the Indemnified Person, as the case may be.

(c) An Indemnified Person shall have the right to retain its own counsel with the reasonable fees and expenses to be paid by the Borrowers, if, in the reasonable opinion of counsel for the Lender, the representation by such counsel of the Indemnified Person and the Borrowers would be inappropriate due to actual or potential differing interests between such Indemnified Person and any other party represented by such counsel in such proceeding. The Borrowers shall pay for only one separate legal counsel for the Indemnified Persons, and such legal counsel shall be selected by the Lender. The failure to deliver written notice to the Borrowers within a reasonable time of the commencement of any such action shall not relieve the Borrowers of any liability to the Indemnified Person under this Section 6.11, except to the extent that the Borrowers are actually prejudiced in their ability to defend such action. The indemnification required by this Section 6.11 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as such expense, loss, damage or liability is incurred and is due and payable.

(d) Without prejudice to the survival of any other agreement of any of the Parties hereunder, the agreements and the obligations of the Parties contained in this Section 6.11 shall survive the termination of each other provision hereof and the payment of all amounts payable to the Lender hereunder.

Section 6.12 No Usury. The Transaction Documents are hereby expressly limited so that in no contingency or event whatsoever, whether by reason of acceleration or otherwise, shall the amount paid or agreed to be paid to the Lender for the Loans exceed the maximum amount permissible under applicable law. If from any circumstance whatsoever fulfillment of any provision hereof, at the time performance of such provision shall be due, shall involve transcending the limit of validity prescribed by law, then, ipso facto, the obligation to be fulfilled shall be reduced to the limit of such validity, and if from any such circumstance the Lender shall ever receive anything which might be deemed interest under applicable law, that would exceed the highest lawful rate, such amount that would be deemed excessive interest shall be applied to the reduction of the principal amount owing on account of the Loans, or if such deemed excessive interest exceeds the unpaid balance of principal of the Loans, such deemed excess shall be refunded to the Borrowers. All sums paid or agreed to be paid to the Lender for the Loans shall, to the extent permitted by applicable law, be deemed to be amortized, prorated, allocated and spread throughout the full term of the Loans until payment in full so that the deemed rate of interest on account of the Loans is uniform throughout the term thereof. The terms and provisions of this Section shall control and supersede every other provision of this Agreement and the Note.

Section 6.13 Further Assurances. From time to time, the Borrowers shall perform any and all acts and execute and deliver to the Lender such additional documents as may be necessary or as requested by the Lender to carry out the purposes of any Transaction Document or any or to preserve and protect the Lender's rights as contemplated therein.

Section 6.14 Independent Transaction Documents. Each Transaction Document constitutes an independent agreement between the parties thereto (the "Transaction Parties") and no Transaction Document shall be construed so as to affect the rights of the Transaction Parties to their rights and remedies under another Transaction Document.

Section 6.15 Currency. All amounts owing under this Agreement, the Note and the Security Agreement shall be paid in Dollars

Section 6.16 Judgment Currency.

(a) If, for the purpose of obtaining or enforcing judgment against the Borrowers in any court in any jurisdiction with respect to any Transaction Document, it becomes necessary to convert into any other currency (such other currency being hereinafter in this Section 6.16 referred to as the "Judgment Currency") an amount due in United States dollars, the conversion shall be made at the last exchange rate published in the Wall Street Journal on the business day immediately preceding (the "Exchange Rate"):

(i) the date actual payment of the amount is due, in the case of any proceeding in the courts of New York or in the courts of any other jurisdiction that will give effect to payment being due on such date; or

(ii) the date on which the French or any other non U.S. court determines, in the case of any proceeding in the courts of any other jurisdiction (the date as of which such payment is made pursuant to this Section 6.16 being hereinafter referred to as the "Judgment Payment Date").

(b) If in the case of any proceeding in the court of any jurisdiction referred to in Section 6.16(a)(ii) above, there is a change in the Exchange Rate on the date of calculation prevailing between the Judgment Payment Date and the date of actual payment of the amount due, the Borrowers shall pay such adjusted amount as may be necessary to ensure that the amount paid in the Judgment Currency, when converted at the Exchange Rate prevailing on the date of payment, will produce the amount of United States dollars which could have been purchased with the amount of Judgment Currency stipulated in the judgment or judicial order at the Exchange Rate prevailing on the Judgment Payment Date.

(c) Any amount due from the Borrowers under this Section 6.16 shall be due as a separate debt and shall not be affected by judgment being obtained for any other amount due under or in respect of this Agreement and/or the Note.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Lender and the Borrowers have caused this Agreement to be duly executed as of the date first above written.

BORROWERS:

FLAMEL US HOLDINGS, INC.

By: _____
Name: Michael S. Anderson
Title: President

ÉCLAT PHARMACEUTICALS, LLC

By: _____
Name: Michael S. Anderson
Title: President and Chief Executive Officer

TALEC PHARMA, LLC

By: _____
Name: Michael S. Anderson
Title: President and Chief Executive Officer

FLAMEL TECHNOLOGIES, INC.

By: _____
Name: Michael S. Anderson
Title: President

LENDER:

BROADFIN HEALTHCARE MASTER FUND, LTD.

By: _____
Name: Kevin Kotler
Title: Director

Exhibit A

PROMISSORY NOTE

$15,000,000 December 3, 2013

FOR VALUE RECEIVED, Flamel US Holdings, Inc., a Delaware corporation, Éclat Pharmaceuticals, LLC, a Delaware limited liability company, and Talec Pharma, LLC, a Delaware limited liability company (each a "Borrower" and collectively, the "Borrowers"), by means of this Promissory Note (this "Note"), hereby jointly and severally, unconditionally promise to pay to Broadfin Healthcare Master Fund, Ltd. (the "Lender"), a principal amount equal to $15,000,000, or, if less, the outstanding principal amount of all Loans (as such term is defined in the Facility Agreement referenced below) in lawful money of the United States of America and in immediately available funds, on the dates provided in the Facility Agreement.

This Note is the "Note" referred to in the Facility Agreement dated as of December 3, 2013 between the Borrowers and the Lender (as modified and supplemented and in effect from time to time, the "Facility Agreement"), with respect to the Loans made or to be made by the Lender thereunder. Capitalized terms used herein and not expressly defined in this Note shall have the respective meanings assigned to them in the Facility Agreement.

This Note shall bear interest on the principal amount hereof pursuant to the provisions of the Facility Agreement.

The Borrowers shall make all payments to the Lender of interest and principal under this Note in the manner provided in and otherwise in accordance with the Facility Agreement. The outstanding principal amount of this Note shall be due and payable in full on the Final Payment Date.

If default is made in the punctual payment of principal or any other amount under this Note in accordance with the Facility Agreement, or if any other Event of Default has occurred and is continuing, this Note shall, at the Lender's option exercised at any time upon or after the occurrence and during the continuance of any Event of Default and in accordance with the applicable provisions of the Facility Agreement, become immediately due and payable.

All payments of any kind due to the Lender from the Borrowers pursuant to this Note shall be made in the full face amount thereof. Subject to the terms of the Facility Agreement, all such payments will be free and clear of, and without deduction or withholding for, any present or future taxes. The Borrowers shall pay all and any costs (administrative or otherwise) imposed by the Borrowers' banks, clearing houses, or any other financial institution, in connection with making any payments hereunder.

The Borrowers shall pay all costs of collection, including, without limitation, all reasonable, documented legal expenses and attorneys' fees, paid or incurred by the Lender in collecting and enforcing this Note.

Other than those notices required to be provided by Lender to Borrowers under the terms of the Facility Agreement, the Borrowers and every endorser of this Note, or the obligations represented hereby, expressly waive presentment, protest, demand, notice of dishonor or default, and notice of any kind with respect to this Note and the Facility Agreement or the performance of the obligations under this Note and/or the Facility Agreement. No renewal or extension of this Note or the Facility Agreement, no release of any Person primarily or secondarily liable on this Note or the Facility Agreement, including the Borrowers and any endorser, no delay in the enforcement of payment of this Note or the Facility Agreement, and no delay or omission in exercising any right or power under this Note or the Facility Agreement shall affect the liability of the Borrowers or any endorser of this Note.

No delay or omission by the Lender in exercising any power or right hereunder shall impair such right or power or be construed to be a waiver of any default, nor shall any single or partial exercise of any power or right hereunder preclude the full exercise thereof or the exercise of any other power or right. The provisions of this Note may be waived or amended only in a writing signed by the Borrowers and the Lender. This Note may be prepaid in whole or in part in accordance with the provisions of the Facility Agreement.

This Note, and any rights of the Lender arising out of or relating to this Note, may, at the option of the Lender, be enforced by the Lender in the courts of the United States of America located in the Southern District of the State of New York or in any other courts having jurisdiction. For the benefit of the Lender, the Borrowers hereby irrevocably agree that any legal action, suit or other proceeding arising out of or relating to this Note may be brought in the courts of the State of New York or of the United States of America for the Southern District of New York, and hereby consents that personal service of summons or other legal process may be made as set forth in Section 5.1 of the Facility Agreement, which service the Borrowers agree shall be sufficient and valid. The Borrowers hereby waive any and all rights to demand a trial by jury in any action, suit or other proceeding arising out of or relating to this Note or the transactions contemplated by this Note.

This Note shall be governed by, and construed in accordance with, the laws of the State of New York applicable to contracts made and to be performed in such State, without giving effect to the conflicts of laws principles thereof other than Sections 5-1401 and 5-1402 of the General Obligations Law of the State of New York.

[Signature page follow]

IN WITNESS WHEREOF, an authorized representative of each Borrower has executed this Note as of the date first written above.

FLAMEL US HOLDINGS, INC.

By: _____
Name:
Title:

ÉCLAT PHARMACEUTICALS, LLC

By: _____
Name:
Title:

TALEC PHARMA, LLC

By: _____
Name:
Title:

FLAMEL TECHNOLOGIES, INC.

By: _____
Name:
Title:

Exhibit B

Indebtedness

In December 2004, Flamel and GSK (GSK) entered into a four year supply agreement whereby Flamel agreed to supply GSK with commercial supplies of product. The provisions of the agreement include payments to Flamel of $20,717,000 to support the costs and capital expenditure relative to the creation of a manufacturing area for the production of commercial supply of the product. The capital expenditures consist of both buildings and fixtures, and production equipment. Flamel acquired immediate title to buildings and fixtures; however title to production equipment remained with GSK for the duration of the supply agreement.

In connection with this 2004 supply agreement, Flamel received funds to finance facilities related assets. A total of $8,188,000 has been spent on the acquisition of buildings and fixtures and a total of $11,138,000 has been spent on behalf of GSK for the purchase of production equipment. As of December 31, 2012 the funds received from GSK to finance the acquisition of assets owned by Flamel are classified as a current liability for $316,000 and as a long term liability for $3,818,000. In July 2006, Flamel and GSK entered into a side agreement to the original agreement whereby GSK partially sponsored the extension of the Micropump development facility. This facility was completed in March 2008. As of December 31, 2007, Flamel had received all installments from GSK for financing of this project. The total installments amounted to $8,097,000. As of December 31, 2012, the funds received from GSK are classified as a current liability for $353,000 and as a long term liability for $2,527,000

If Flamel breaches the supply agreement through gross negligence, GSK can choose to terminate the supply agreement. In the event of a breach and a decision to terminate the agreement, all payments received become repayable to GSK and Flamel will receive immediate title to all production equipment. Upon cessation of the supply agreement, in the normal course of business, GSK will pass title to all production equipment to Flamel without cost of any kind.

Exhibit C

Liens

Pursuant to the 2004 supply agreement with GSK, GSK retains title to certain production equipment financed with advances from GSK for the duration of the supply agreement.

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

ROYALTY AGREEMENT

THIS ROYALTY AGREEMENT (this "***Agreement***") is dated as of December 3, 2013, by and among **ÉCLAT PHARMACEUTICALS, LLC (the** "***Payor***"), and **BROADFIN HEALTHCARE MASTER FUND, LTD.** (the "***Buyer***").

For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the Parties, the Parties to this Agreement, intending to be legally bound, agree as follows:

1. Definitions. Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

2. Royalty.

(a) Royalty Amount. The Payor shall pay to Buyer 0.834% of Net Sales of Products plus 0.583% of Net Sales of Products for each Additional Loan, if any, made to the Payor (as such term is defined in the Facility Agreement) up to a maximum of 2.00% of Net Sales of Products (the "***Royalty***").

(b) Payment of the Royalty. The Royalty shall accrue daily and shall be paid quarterly in arrears for each calendar quarter from and after the date hereof until the expiration of the quarter ending December 31, 2024 (the "***Royalty Term***"). No later than two Business Days following the date Flamel Technologies S.A. ("***Flamel***") files its Earnings Report for each calendar quarter or if Flamel is not obligated to file reports under the Securities Exchange Act of l934, following its preparation of its internal financial statements (but in no event later than sixty days following the last day of each of the first three quarters and one hundred twenty days following the last day of the fourth quarter of each calendar year), the Payor shall pay or cause to be paid to Buyer the Royalty for such quarter (each, a "***Royalty Payment***"), together with a statement showing all Net Sales of Products and the computation of the Royalty for such quarter (each a "***Royalty Calculation***"). All Royalty Payments shall be made by wire transfer of immediately available funds to the account(s) designated in writing by the Buyer no later than five Business Days prior to the date such Royalty Payment shall be due.

(c) Delinquent Royalty Payments. Any Royalty Payment not paid when due shall bear interest at the Default Rate, compounded daily, or the highest rate then permitted by applicable law, whichever is less.

(d) Audit Right. Upon not less than ten Business Days' notice (the "***Audit Notice***"), the Buyer may audit the books and records of the Payor once every calendar year to determine the computation of any Royalty Payment for up to three years prior to the date of the Audit Notice, provided that no audit for a given year shall be repeated pursuant to this provision, but shall be final in all respects for the period reviewed upon completion of the audit. Such audit shall be conducted during normal business hours at the Buyer's cost, provided that any Representative involved enters into a reasonable confidentiality agreement with the Payor (to be approved by the Payor in its sole reasonable discretion) prior to commencing any such audit. The Payor shall provide the Buyer and its Representatives with reasonable access to all such books and records and shall reasonably cooperate with the Buyer's and its Representatives' efforts to conduct such audits. The Buyer may object to any Royalty Calculation by delivering a notice of objection (a "***Royalty Objection Notice***"), which shall specify the disputed items in the Royalty Calculation and shall describe in reasonable detail the basis for such objection, as well as the amount in dispute. If the Buyer delivers Payor such Notice, Payor and Buyer shall negotiate in good faith for up to ten Business Days to resolve the disputed items and agree upon the resulting amount of the disputed Royalty Payment. If Payor and Buyer are unable to reach such agreement, all unresolved disputed items shall be promptly referred to the Reviewing Accountant. The Reviewing Accountant shall render a written report on only such items as promptly as practicable, but in no event greater than 30 days after such referral. If disputed items are submitted to the Reviewing Accountant, Payor and Buyer shall furnish to the Reviewing Accountant such work papers, schedules and other documents and information relating to the items as the Reviewing Accountant may reasonably request. The Reviewing Accountant shall resolve the disputed items based solely on the provisions of this Agreement and the presentations by Payor and Buyer, and not by independent review. The Reviewing Accountant will not have the power to amend this Agreement. The resolution of the dispute and the calculation of the Royalty Payment by the Reviewing Accountant shall be final and binding on the Payor and the Buyer. If there has been an underpayment of the Royalty Payment due for the period being audited of more than five percent (5%) of the amount due for the period, the Payor shall reimburse the Buyer for the reasonable out-of-pocket costs (including the Reviewing Accountants' fees) incurred by the Buyer pursuant to this **Section 2(d)**.

(e) Sale of Products; Assignment or Sublicenses. The Payor shall pay the Royalty Payments on all Product sales by Flamel and its Affiliates and all direct or indirect licensees and assignees or successive licensee and assignees of any rights to sell, market or otherwise distribute Products, and the provisions of this **Section 2** shall apply to all such sales as if made directly by the Payor.

3. [Reserved.]

4. Covenants of the Payor

(a) Regulatory Approvals. The Payor shall use all commercially reasonable efforts to obtain approval of each NDA necessary to sell each Product in the United States of America. Without limiting the foregoing, the Payor shall (A) initiate development and manufacturing of all Products through a third-party (if this has not already occurred as of date of this Agreement) and (B) pursue a pre-IND/pre-NDA meeting with the FDA for each Product (if this has not already occurred as of the date of this Agreement). The Payor shall also use commercially reasonable efforts to (x) cause registration batches of each Product to be manufactured and (y) cause stability testing to be completed for each Product, in each case unless the FDA states in such meeting that such Product would not be approved without clinical trials or other unexpected conditions to approval that would make continued efforts to obtain the NDA necessary to commercialize the Product not commercially viable.

(b) Marketing of Products. Upon approval to market any Product, the Payor shall take all commercially reasonable and appropriate actions to manufacture or have manufactured, package, label, distribute, offer for sale and sell such Product.

(c) Credit Facility Restrictions. The Payor represents and warrants that there are no restrictions or limitations on its ability to make the payments that are or may be required to be paid to the Buyer under this Agreement in any Contract. The Payor shall not enter into, or amend, any Contract of it or its Affiliates after the date hereof the effect of which is to place any restrictions or limitations on the Payor's ability to make the payments that are required to be paid to the Buyer under this Agreement.

(d) No Transfer Without Consent. The Payor shall not transfer (whether by sale, assignment, merger, change of control, conveyance of rights, deed of trust, lien, license, sublicense, seizure or other transfer of any sort, voluntary or involuntary, including by operation of law) any of its right, title or interest in or to the Product Intellectual Property or Product Regulatory Rights unless the assignee/transferee agrees in writing to assume (in addition to the Payor) all of the Payor's obligations under this Agreement; provided, however, that such requirement shall not apply to (i) the direct or indirect license of Product Intellectual Property or Product Regulatory Rights to make, have made, use, promote, import, offer to sell or sell Products solely on behalf of, or for the benefit of, the Payor or (ii) the direct or indirect license of Product Intellectual Property or Product Regulatory Rights for any other reason.

(e) Acceleration. Notwithstanding anything to the contrary contained in this Agreement, upon and at any time after the occurrence of any Acceleration Trigger Event, (x) an amount equal to the Accelerated Value shall automatically become immediately due and payable without presentment, demand, protest, notice of intent to accelerate or other notice or legal process of any kind, all of which are hereby knowingly and expressly waived by the Payor, and (y) the Buyer may exercise any and all other rights and remedies available to it under this Agreement and applicable law. At least once per year, the Payor will update in good faith its sales projections for the Products for such period as the Buyer shall reasonably request.

5. Representations and Warranties of the Payor. The Payor represents and warrants to the Buyer as follows as of the date of this Agreement:

(a) Organization; Good Standing. The Payor is duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation. The Payor has the requisite power and authority to own, lease or use its properties and assets and to conduct its business as presently conducted.

(b) Consents and Approvals; No Violation. Neither the execution and delivery of this Agreement by the Payor nor the performance of its obligations hereunder nor the consummation by the Payor of the transactions contemplated hereby will: (i) conflict with or result in a breach, violation, or default of or under the organizational document of the Payor, (ii) require the consent of, or notice to, any Person under, conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a default under, result in the acceleration of or create in any party the right to accelerate, terminate, modify or cancel any Contract to which the Payor is a party or by which the Payor is bound or to which any of its properties and assets are subject or any Governmental Authorization affecting the properties, assets or business of the Payor, (iii) result in the creation of any Encumbrance (other than Permitted Encumbrances) on the assets of the Payor, or (iv) conflict with or result in a violation or breach of any provision of any Legal Requirement applicable to the Payor.

(c) Absence of Changes. Since March 13, 2012:

(i) There has been no transfer, assignment, sale, distribution, or Encumbrance of any Product or of any Product Intellectual Property or Product Regulatory Rights, and there has been no agreement to do so, except (w) as has been disclosed in the annual, quarterly and periodic reports of Flamel with the U.S. Securities and Exchange Commission (the "***SEC Reports***"), (x) transfers, assignments, sales and distributions in the ordinary course of business, and (y) licenses and security interests granted in favor of Deerfield, Breaking Stick (each as defined in the Facility Agreement), Horizon Sante FLML, SARL and the Buyer;

(ii) The Payor has not adopted any plan of consolidation, reorganization, liquidation or dissolution or filed a petition in bankruptcy under any provisions of federal or state bankruptcy law or consented to the filing of any bankruptcy petition against it under any similar law;

(iii) The Payor has not formed any Affiliates, or made any capital investment in or acquired any equity interest in any other Entity, except as has been disclosed in the SEC Reports;

(iv) As of the date hereof, the FDA has not expressed any disapproval, formally or informally, orally or in writing, of the development program proposed by the Payor for any of the Products.

(v) As of the date hereof, the FDA has not formally or informally, orally or in writing, advised the Payor that it does not intend to approve any Product in the manner proposed by the Payor or based upon the information provided or to be provided by the Payor.

(d) Compliance with Laws. The Payor is in compliance with all Legal Requirements applicable to it or its business, properties or assets. The Payor has not received any written notice from any Governmental Body or any other Person regarding (i) any actual, alleged or potential material violation of or material liability under any Legal Requirement, or (ii) any actual, alleged, or potential material obligation of the Payor to undertake or pay for any response action required by any Legal Requirement.

(e) Regulatory Compliance.

(i) The Payor has not received any notices or correspondence from the FDA or any other Governmental Body exercising comparable authority requiring the recall, termination or suspension of sale of any Product or otherwise alleging that the Payor is not in compliance in all material respects with all applicable Legal Requirements.

(ii) Neither the Payor, nor any officer or employee of the Payor, nor, to the Payor's knowledge, any agents or contractor of the Payor is the subject of any pending or threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, or by any other comparable Governmental Body to invoke any similar policy. None of the Payor nor any officer or employee of the Payor, nor, to the Payor's knowledge, any agent or contractor of the Payor has (A) made any untrue statement of material fact or fraudulent statement to the FDA, DEA, or any other Governmental Body; (B) failed to disclose a material fact required to be disclosed to the FDA, DEA, or any other Governmental Body, or (C) committed an act, made a statement, or failed to make a statement that would reasonably be expected to provide the basis for the FDA or any other Governmental Body to invoke the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy.

(iii) Neither the Payor nor any officer or employee of the Payor has been debarred or been convicted of any crime or engaged in any conduct that did or could result in debarment under 21 U.S.C. § 335a, exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7, disqualification as a clinical investigator under 21 C.F.R. § 312.70 or any similar Legal Requirements, and none of the Payor or any officer or employee of the Payor has engaged in any conduct that would reasonably be expected to result in debarment, exclusion, or disqualification from U.S. federal health care programs.

(iv) Neither the Payor, nor any officer of the Payor has received any written notice or communication from the FDA, DEA, or other Governmental Body requiring termination or suspension of sale of any of Product or alleging noncompliance with any applicable FDA Law, DEA Law, or other applicable Legal Requirements with regard to any Product. Neither the Payor nor any officer of the Payor has been or is subject to any enforcement proceedings by the FDA, DEA, or other Governmental Body and, to the Payor's knowledge, no such proceedings have been threatened.

6. [Reserved]

7. Miscellaneous Provisions.

(a) Further Assurances. Each of the parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to give effect to the transactions contemplated by this Agreement.

(b) Survival of Representations and Warranties. The representations and warranties of the parties contained in this Agreement shall survive and remain in full force and effect through the expiration of the Royalty Term.

(c) Amendment. This Agreement may not be amended except by an instrument in writing signed by the Payor and the Buyer.

(d) Waiver. No failure on the part of any Party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

No Party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Party; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

(e) Entire Agreement; Counterparts; Exchanges by Facsimile. This Agreement, and the other agreements referred to in this Agreement constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, among or between any of the Parties with respect to the subject matter hereof and thereof; provided, however, that any existing confidentiality agreements shall not be superseded and shall remain in full force and effect in accordance with its terms. This Agreement may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. The exchange of a fully executed Agreement (in counterparts or otherwise) by all Parties by facsimile or portable document format (PDF) shall be sufficient to bind the Parties to the terms and conditions of this Agreement.

(f) Applicable Law; Jurisdiction. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS. EACH OF THE PARTIES TO THIS AGREEMENT (A) CONSENTS TO SUBMIT ITSELF TO THE PERSONAL JURISDICTION OF THE FEDERAL AND STATE COURTS OF THE STATE OF NEW YORK IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREUNDER, (B) AGREES THAT ALL CLAIMS IN RESPECT OF SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH COURT, (C) AGREES THAT IT SHALL NOT ATTEMPT TO DENY OR DEFEAT SUCH PERSONAL JURISDICTION BY MOTION OR OTHER REQUEST FOR LEAVE FROM ANY SUCH COURTS, AND (D) AGREES NOT TO BRING ANY ACTION OR PROCEEDING (INCLUDING COUNTER-CLAIMS) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREUNDER IN ANY OTHER COURT. EACH OF THE PARTIES WAIVES ANY DEFENSE OF INCONVENIENT FORUM TO THE MAINTENANCE OF ANY ACTION OR PROCEEDING SO BROUGHT AND WAIVES ANY BOND, SURETY OR OTHER SECURITY THAT MIGHT BE REQUIRED OF ANY OTHER PARTY WITH RESPECT THERETO. ANY PARTY MAY MAKE SERVICE ON ANOTHER PARTY BY SENDING OR DELIVERING A COPY OF THE PROCESS TO THE PARTY TO BE SERVED AT THE ADDRESS AND IN THE MANNER PROVIDED FOR THE GIVING OF NOTICES HEREIN. NOTHING IN THIS **SECTION 7(f)**, HOWEVER, SHALL AFFECT THE RIGHT OF ANY PARTY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

(g) Assignability; No Third Party Beneficiaries. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the Parties and their respective successors and assigns. No Party may assign any of its rights or obligations hereunder without the prior written consent of the other Party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by such Party without the other Party's prior written consent shall be void and of no effect; provided that the Buyer may assign its rights to payments under this Agreement to any other Person without the prior written consent of the Payor or any other Person. Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

(h) Notices. Any notice or other communication required or permitted to be delivered to a Party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered by hand, by registered mail, by courier or express delivery service or by facsimile to such address or facsimile telephone number as each Party shall have specified in a written notice given to the other Party.

(i) Severability. Any provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining provisions of this Agreement or the validity or enforceability of the offending provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such provision, to delete specific words or phrases or to replace such provision with a provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable provision, and this Agreement shall be valid and enforceable as so modified. If such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable provision with a valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

(j) Other Remedies; Specific Performance. Any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage would occur in the event that any provision of this Agreement were not performed in accordance with its specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the provisions hereof, this being in addition to any other remedy to which they are entitled at law or in equity.

(k) Judgment Currency. If, for the purpose of obtaining or enforcing judgment against any Party in any court in any jurisdiction with respect to this Agreement it becomes necessary to convert into any other currency (such other currency being hereinafter referred to as the "Judgment Currency") to an amount due in United States dollars, the conversion shall be made at the last exchange rate published in the Wall Street Journal on the Business Day immediately preceding (the "Exchange Rate"):

the date actual payment of the amount is due, in the case of any proceeding in the courts of Delaware or in the courts of any other jurisdiction that will give effect to payment being due on such date; or

the date on which the French or any other non U.S. court determines, in the case of any proceeding in the courts of any other jurisdiction (the date as of which such payment is made being hereinafter referred to as the "Judgment Payment Date").

If in the case of any proceeding in the court of any jurisdiction referred to above, there is a change in the Exchange Rate on the date of calculation prevailing between the Judgment Payment Date and the date of actual payment of the amount due, the applicable Party shall pay such adjusted amount as may be necessary to ensure that the amount paid in the Judgment Currency, when converted at the Exchange Rate prevailing on the date of payment, will produce the amount of United States dollars which could have been purchased with the amount of Judgment Currency stipulated in the judgment or judicial order at the Exchange Rate prevailing on the Judgment Payment Date.

Any amount due from the Payor under this **Section 7(k)** shall be due as a separate debt and shall not be affected by judgment being obtained for any other amount due under or in respect of this Agreement.

(l) Construction. For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; and any gender shall include all genders.

The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits and Schedules to this Agreement.

The headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

[Remainder of page intentionally left blank; signature pages follow.]

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

ÉCLAT PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: President and Chief Executive Officer

BROADFIN HEALTHCARE MASTER FUND, LTD.

By: /s/ Kevin Kotler
Name: Kevin Kotler
Title: Director

CONFIDENTIAL TREATMENT REQUESTED
[***] – THE CONFIDENTIAL PORTION OF THIS AGREEMENT WHICH HAS BEEN REDACTED IS MARKEED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A

CAPITALIZED TERMS

"**Accelerated Value**" shall mean as of any date of determination, the amount of future Royalty Payments would be paid to Buyer using the Payor's good faith projections of future sales of the Products at the time of the Acceleration Trigger Event, discounted to present value as of the date of the Acceleration Trigger Event using quarterly compounding and a discount rate of 4%.

"**Acceleration Trigger Event**" shall mean the occurrence of any one or more of the following events:

(a) The Payor shall (i) file a voluntary petition or commence a voluntary case seeking liquidation, winding-up, reorganization, dissolution, arrangement, readjustment of debts or any other relief under any applicable bankruptcy, insolvency or similar law now or hereafter in effect, (ii) apply for or consent to the appointment of or taking possession by a custodian, trustee, receiver or similar official for or of itself or all or a substantial part of its properties or assets, (iii) fail generally, or admit in writing its inability, to pay its debts generally as they become due, (iv) make a general assignment for the benefit of creditors or (v) take any action to authorize or approve any of the foregoing; or

(b) Any involuntary petition or case shall be filed or commenced against the Payor seeking liquidation, winding-up, reorganization, dissolution, arrangement, readjustment of debts, the appointment of a custodian, trustee, receiver or similar official for it or all or a substantial part of its properties or any other relief under any other applicable bankruptcy, insolvency or similar law now or hereafter in effect, and such petition or case shall continue undismissed and unstayed for a period of 60 days; or an order, judgment or decree approving or ordering any of the foregoing shall be entered in any such proceeding.

"***Affiliate***". An Entity shall be deemed to be a "***Affiliate***" of another Person if such Person directly or indirectly owns or purports to own, beneficially or of record, (a) an amount of voting securities of other interests in such Entity that is sufficient to enable such Person to elect at least a majority of the members of such Entity's board of directors or other governing body, or (b) at least 50% of the outstanding equity, voting, beneficial or financial interests in such Entity.

"***ANDA***" means Abbreviated New Drug Application.

"***Business Day***" shall mean any day other than a day on which banks in New York, NY or Paris, France are authorized or obligated to be closed.

"***Contract***" shall, with respect to any Person, mean any written, oral or other agreement, contract, subcontract, lease (whether real or personal property), mortgage, understanding, arrangement, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment or undertaking of any nature to which such Person is a party or by which such Person or any of its assets are bound or affected under applicable law.

"***Copyright***" means all copyrights and moral rights, including the legal right provided by the Copyright Act of 1976, as amended, to the expression contained in any work of authorship fixed in any tangible medium of expression together with any similar rights arising in any other country as a result of statute or treaty, and all registrations, applications, renewals, extensions and reversions thereof.

"***DEA***" means the United States Drug Enforcement Administration or any successor agency thereto.

"***Default Rate***" shall mean 15% per annum or such lesser rate as shall be allowable by law.

"***Earnings Report***" means during any period when Flamel is obligated to file reports under the provisions of the Securities Exchange Act of 1934, the Form 6-K filed by Flamel containing its financial information for such quarter.

"***Encumbrance***" shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, easement, condition, preemptive right, community property interest, right of first refusal or right of first offer, or similar restriction of any kind, including any restriction on the voting of any security or equity interest, any restriction on the transfer of any security, equity interest or other asset, and any restriction on the receipt of any income or exercise of any other attribute of ownership, under any Legal Requirement.

"***Entity***" shall mean any corporation (including any non-profit corporation), partnership (including any general partnership, limited partnership or limited liability partnership), joint venture, estate, trust, company (including any company limited by shares, limited liability company or joint stock company), firm, society or other enterprise, association, organization or entity.

"***Facility Agreement***" shall mean that certain Facility Agreement dated as of December 3, 2013 by and among Flamel US Holdings, Inc., Éclat Pharmaceuticals, LLC, Talec Pharma, LLC, Flamel Technologies, Inc. and the Buyer.

"***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

"***Governmental Authorization***" shall mean any: (a) permit, license, certificate, franchise, permission, variance, exceptions, orders, clearance, registration, qualification or authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Body.

"***Governmental Body***" shall mean any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, department, agency, commission, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or other Entity and any court or other tribunal, and for the avoidance of doubt, any Taxing authority); or (d) self-regulatory organization (including the NASDAQ Global Market).

"***Know-How***" means ideas, designs, concepts, compilations of information methods, techniques, methodologies, procedures and processes, compositions, specifications, techniques, technical data and information, designs, drawings, customer lists, supplier lists, pricing and financial information, plans and proposals, algorithms and formulas, whether or not patentable.

"***Legal Requirement***" shall mean any federal, state, foreign, local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, regulation, judgment, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

"***Mark***" means any word, name, symbol, logos or device used by a Person to identify its goods or services, whether or not registered, all goodwill associated therewith, and any right that may exist to obtain a registration with respect thereto from any Governmental Body and any rights arising under any such application, together with all registrations, renewals, extensions and reversions thereof. As used in this Agreement, the term "Mark" includes all of the foregoing, including trademarks and service marks.

"***Net Sales***" shall mean, without duplication, the gross amount invoiced for Products sold globally in *bona fide*, arm's length transactions, less customary deductions determined without duplication in accordance with the selling Person's customary accounting methods as generally and consistently applied for: (i) cash or terms discounts, (ii) sales, use and value added taxes (if and only to the extent included in the gross invoice amount), (iii) reasonable and customary accruals for third party rebates and chargebacks, (iv) returns and (v) recalls.

"***Party***" or "***Parties***" shall mean the Buyer and the Payor.

"***Patent***" means any patent granted by the United States Patent and Trademark Office or by the comparable agency of any other country, and any renewal, thereof, and any rights arising under any patent application filed with the United States Patent and Trademark Office or the comparable agency of any other country and any rights that may exist to file any such application, including all continuations, divisional, continuations-in-part and provisionals and patents issuing thereon, and all reissues, reexaminations, substitutions, renewals and extensions thereof.

"***Permitted Encumbrances***" means (a) statutory liens for Taxes that are not yet due and payable or Taxes that are being contested in good faith by appropriate proceedings; (b) statutory, common law or civil law liens to secure obligations to landlords, lessors or renters under leases or rental agreements confined to the premises rented pursuant to and which are not, individually or in the aggregate, material to the business of the Payor; (c) deposits or pledges made in connection with, or to secure payment of, workers' compensation, unemployment insurance, old age pension or other social security programs mandated under Legal Requirements, which are not, individually or in the aggregate, material to the business of the Payor; (d) statutory, common or civil law liens in favor of carriers, warehousemen, mechanics and materialmen to secure claims for labor, materials or supplies and other like liens with respect to amounts not yet due and payable, which are not, individually or in the aggregate, material to the business of the Payor.

"***Person***" shall mean any individual, Entity or Governmental Body.

"***Product Intellectual Property***" shall mean all Proprietary Rights held or licensed by the Payor and Flamel and their Affiliates that is, or may hereafter be, necessary to develop, make, have made, promote, market or sell the Products in the United States.

"***Product Regulatory Rights***" shall mean each and every investigational new drug application or new drug application and/or state license or registration that is held or obtained (if any) that is necessary to develop, conduct clinical trials relating to, manufacture, have manufactured, distribute, promote, market or sell the Products in the United States.

"***Products***" shall mean (i) the drugs Neostigmine Methylsulfate Injection, [***].

"***Proprietary Rights***" means, with respect to a Person, all Copyrights, Marks, Trade Names, Trade Secrets, Patents, intellectual property rights in inventions and discoveries, intellectual property rights in internet web sites and internet domain names and subdomain names and intellectual property rights in Know-How, owned or used by such Person.

"***Representatives***" shall mean directors, officers, other employees, agents, attorneys, accountants, advisors and representatives.

"***Reviewing Accountant***" means Grant Thornton or such other accounting firm designated by the Buyer.

"***Tax***" shall mean any federal, state, local, foreign or other taxes, levies, charges and fees or other similar assessments or liabilities in the nature of a tax, including, without limitation, any income tax, franchise tax, capital gains tax, gross receipts tax, value-added tax, surtax, estimated tax, unemployment tax, national health insurance tax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, withholding tax, payroll tax, customs duty, alternative or add-on minimum or other tax of any kind whatsoever, and including any fine, penalty, assessment, addition to tax or interest, whether disputed or not.

"***Trade Names***" means any words, name or symbol used by a Person to identify its business.

"***Trade Secrets***" means business or technical information of any Person including, but not limited to, customer lists, marketing data and Know-How, that is not generally known to other Persons who are not subject to an obligation of nondisclosure and that derives actual or potential commercial value from not being generally known to other Persons.

Exhibit 8.1

Operating Subsidiaries of Flamel Technologies S.A.

Flamel Technologies, Inc.

Flamel US Holdings Inc.

Éclat Pharmaceuticals, LLC

Talec LLC

Other Subsidiaries of Flamel Technologies S.A.: Flamel Irish Holdings Limited and Flamel Ireland Limited

Exhibit 12.1

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Anderson, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
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 Company as of, and for, the periods presented in this report;
4. The Company'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 Company 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 Company, 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 Company'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 Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: April 30, 2014

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO
SEC RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Siân Crouzet, certify that:

1. I have reviewed this annual report on Form 20-F of Flamel Technologies S.A. (the "**Company**");
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 Company as of, and for, the periods presented in this report;
4. The Company'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 Company 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 Company, 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 Company'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 Company's internal control over financial reporting that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the Audit Committee of the Company'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 Company'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 Company's internal control over financial reporting.

Date: April 30, 2014

/s/ Siân Crouzet
Siân Crouzet
Principal Financial Officer

Exhibit 13.1

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 Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2013, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Michael S. Anderson, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer
April 30, 2014

Exhibit 13.2

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 Annual Report of Flamel Technologies S.A. (the "**Company**") on Form 20-F for the fiscal year ended December 31, 2013, filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, Siân Crouzet, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Siân Crouzet
Siân Crouzet
Principal Financial Officer
April 30, 2014

Exhibit 23.1

CONSENT OF
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 Nos. 333-137844, 333-134638, 333-111725, 333-109693, 333-12542 and 333-177591 and on Form F-3 Nos. 333-183961 and 333-193898 of Flamel Technologies S.A.,of our report dated April 30, 2014, relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

Lyon, France, April 30, 2014

PricewaterhouseCoopers Audit

Represented by
/s/ Nicolas Brunetaud
Nicolas Brunetaud (signed)