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

FORM 20-F

☐ 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, 2014

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
69200 Vénissieux France
(Address of principal executive offices)

Phillandas T. Thompson
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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.

40,191,264 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☒

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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 platform designations are trademarks of the Company: Bloxiverz®, DeliVax®, Flamel Technologies®, LiquiTime®, Micropump®, Medusa™, Trigger Lock™ 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 the negative of these 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 forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations in our forward-looking statements include, among others, those specified in "Risk Factors" beginning on page 2, including:

- we depend on a small number of products and customers for the majority of our revenues and the loss of any one of these products or customers could reduce our revenues significantly.

- our Bloxiverz® and Vazculep™ products are not patent protected and could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products, which would have a material adverse effect on our revenues and results of operation.

- we could fail to successfully complete the research and development for the two pipeline products we are evaluating for potential application to the FDA pursuant to our UMD strategy, or our competitors could complete the development of such products and apply for FDA approval of such products before us, which would have a material adverse effect on our future business opportunities.

- we may depend on partnership arrangements or strategic alliances for the commercialization of some of our products, and the failure of any third party to fulfill its duties under such an arrangement or alliance could have a material adverse effect on our financial condition and results of operation.

- our products may not gain market acceptance, and lack of such market acceptance would limit our ability to generate revenue which would have a material adverse effect on our business.

- our products may not reach the commercial market for a number of reasons, which would adversely affect our future revenues.

- we must invest substantial sums in research and development ("R&D") in order to remain competitive, and we may not fully recover these investments.

- the development of several of our drug delivery platforms and products depends on the services of a single provider and any interruption of such provider's operations could significantly delay or have a material adverse effect on our product pipeline.

- we depend upon a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products and the failure of any such supplier to timely deliver sufficient quantities of products or raw materials 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.

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

- we depend on key personnel to execute our business plan and the loss of any one or more of these key personnel may limit our ability to effectively pursue our business plan.

- we may cease to qualify as a foreign private issuer, which would increase the costs and expenses we incur to comply with U.S. Securities Laws.

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 December 31, 2014 and December 31, 2013 and for each of the three (3) years ended December 31, 2012 are derived from the Consolidated Financial Statements of the Company (for details see "Item 18. *Financial Statements*"), which have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") and audited by an independent registered accounting firm with the Public Company Accounting Oversight Board (United States). The selected consolidated financial data as of December 31, 2012, December 31, 2011 and December 31, 2010 have been derived from the unaudited financial statement and reflect the retroactive change from Discontinued Operations; for details see note 1 and 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*". 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 on Form 20-F.

Statement of Operations Data

In thousands of U.S. dollars, except share and per share data	Year Ended December 31,				
	2010	**2011**	**2012**	**2013**	**2014**
Revenues	18,794	9,238	7,534	4,179	14,775
Cost and Expenses	(27,408)	(21,496)	(17,447)	(57,879)	(108,632)
Income (Loss) from Operations	(8,614)	(12,258)	(9,913)	(53,700)	(93,857)
Interest and foreign exchange gain (loss), net	549	867	343	(4,626)	3,562
Other income	525	134	102	573	(36)
Income (loss) before income tax	(7,540)	(11,257)	(9,469)	(57,553)	(90,331)
Income tax benefit (expense)	(209)	(192)	4,729	11,244	1,407
Net income (loss) from continuing operations	(7,749)	(11,449)	(4,740)	(46,509)	(88,924)
Net income (loss) from Discontinued Operations	(1,226)	2,675	1,512	3,584	4,018
Net income (loss)	(8,975)	(8,774)	(3,228)	(42,925)	(84,906)
Income (Loss) from Operations per ordinary share	(0.35)	(0.50)	(0.39)	(2.11)	(2.59)
Basic and diluted earnings from continuing operations (loss) per ordinary share	(0.32)	(0.46)	(0.19)	(1.83)	(2.46)
Basic and diluted earnings from Discontinued Operations (loss) per ordinary share	(0.05)	0.11	0.06	0.14	0.11
Basic and diluted earnings (loss) per ordinary share	(0.37)	(0.36)	(0.13)	(1.69)	(2.34)
Basic weighted average number of shares outstanding (in thousands)	24,411	24,669	25,135	25,450	36,214
Diluted weighted average number of shares outstanding (in thousands)	24,411	24,669	25,135	25,450	36,214
Dividends per share	-	-	-	-	-

Balance Sheet Data

	As of December 31,				
In thousands of U.S. dollars	**2010**	**2011**	**2012**	**2013**	**2014**
Cash, cash equivalents & marketable securities	31,344	24,491	9,155	7,037	92,834
Working capital **[1]**	25,941	18,338	10,726	(6,972)	41,480
Total assets	74,614	69,402	117,311	116,252	174,205
Long term liabilities (excluding deferred revenues)	15,641	19,763	72,267	85,169	78,468
Shareholders' equity (deficits)	36,305	29,794	30,504	(9,512)	24,895

[1] 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 and any of its subsidiaries, 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 Flamel'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 (5) years and in each of the previous six months.

Year Ended December 31,			
Euro to U.S. Dollar	**High**	**Low**	**Average Rate [1]**
2014	1.3953	1.2141	1.3288
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

Previous Six Months,			
Euro to U.S. Dollar	**High**	**Low**	**Average Rate [1]**
March 2015	1.1227	1.0557	1.0950
February 2015	1.1447	1.1240	1.1350
January 2015	1.2043	1.1198	1.1621
December 2014	1.2537	1.2141	1.2331
November 2014	1.2539	1.2393	1.2472
October 2014	1.2823	1.2524	1.2673

[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, 2015, was $1.1002 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 products and customers for the majority of our revenues and the loss of any one of these drug products or customers could reduce our revenues significantly.

The majority of our revenues are or will be derived from the commercialization of two (2) products, Bloxiverz® and Vazculep™. Additionally, we depend on a small number of customers for the majority of our revenues from sales of these two drug products. Four customers, AmeriSource Bergen, Cardinal, McKesson and Morris & Dickson accounted for approximately 99% of revenues from sales of these products in 2014. These customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo consolidation marked by mergers and acquisitions among wholesale distributors and retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that continuing consolidation will increase pricing and other competitive pressures on pharmaceutical companies. The loss of any one of these products or the termination of our relationship with any of these customers or 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 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.

We may depend on partnership arrangements or strategic alliances for the commercialization of some of our products in development, in particular those incorporating our drug delivery platforms.

The commercialization of some of our drug delivery platforms-based products in development, such as LiquiTime®-based Over-The-Counter (“OTC”) products (e.g. ibuprofen, guaifenesin) and Medusa™ exenatide, will require resources and expertise that we currently do not have. Therefore, we will need to seek partners, and/or enter into strategic alliances, licenses or other arrangements to successfully commercialize these products. Such arrangements will subject us to a number of risks, including the following:

- we may not be able to control several factors in the commercialization of some of our products, including the amount, timing and quality of resources that our partners may devote to these products;
- our partners may experience financial, regulatory or operational difficulties, which may impair their ability to commercialize these drug products;
- as a requirement of any partnership arrangement, we may be required to relinquish important rights with respect to these drug products, such as marketing and distribution rights;
- legal disputes or disagreements, including the ownership of intellectual property, may occur with one or more of our partners and may lead to lengthy and expensive litigation or arbitration;
- significant changes in a partner’s business strategy may adversely affect a partner’s willingness or ability to satisfactorily complete its commercialization or other obligations under any such arrangement; and,
- a partner could terminate the partnership arrangement, which could negatively impact the continued commercialization of these drug products.

Our products may not gain market acceptance.

Even if we and/or our partners obtain the necessary regulatory approval to market products, 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 safety and efficacy of the product or technology;
- the absence of evidence of undesirable side effects of the product or technology 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 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 approval and 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 products may not 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 ("R&D) of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of previously Unapproved Marketed Drugs ("UMDs") products and development of products that utilize our drug delivery platforms. If the UMDs products and/or the products incorporating our drug delivery platforms 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 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 partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our current drug delivery platforms and drug 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 or our partners may find certain products cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;
- managed care providers may be unwilling or unable to reimburse patients at an economically attractive level for products under development; or
- our products 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 ("R&D) 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 R&D in order to develop new products and enhance our technologies. In 2014, we spent $17.3 million on R&D. Our ongoing investments in R&D for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

The development of several of our drug delivery platforms and products depend on the services of a single provider and any interruption of operations of such provider could significantly delay or have a material adverse effect on our product pipeline.

As part of the divestiture of our development and manufacturing facility ("Pessac Facility") to Recipharm AB ("Recipharm"), we entered into certain agreements with Recipharm for the development, supply of clinical materials and potentially the supply of commercial batches for several of our products incorporating our drug delivery platforms, as well as our Medusa™ polymer(s); for details see "Item 4. *Information on the Company"*. Any disruption in the operations of Recipharm or if Recipharm fails to supply acceptable quantity and quality materials or services to us for any reason, such disruption or failure could delay our product development and 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.

We depend on a limited number of suppliers for the manufacturing of our products and certain raw materials used in of our products and any failure of such suppliers to deliver sufficient quantities of supplies of product or these raw materials could have a material adverse effect on our business.

Currently, we depend on a single manufacturer for both Bloxiverz® and Vazculep™. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. If the supplies of these products or 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 supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of our products by our contract, development, and manufacturing organizations ("CDMOs"). Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

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 drug delivery platforms or niche brand or generic specialty pharmaceutical products. Some of these competitors may be also our business partners.

Our drug delivery platforms compete with technologies provided by several other companies (for details see "Item 4. *Competition and Market Opportunities*"). In particular, New Biological or Chemical Entities ("NBEs" or "NCEs") could be developed that, if successful, could compete against our drug delivery platforms 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 products.

Further, unless and until the FDA has removed the UMDs, our marketed products may compete with products of companies such as Sandoz, with respect to Vazculep™. Additionally, the FDA could also approve generic versions or previously filed NDAs of our marketed products, as was the case with the approval of APP's in January 2015 (a division of Fresenius Kabi USA, LLC) neostigmine methylsulfate product, a competitive product to Bloxiverz®.

Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and R&D 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.

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 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.

We may fail to effectively develop our new products and any new and complementary businesses, products and technologies we may acquire in the future.

Part of our business strategy is to obtain FDA approval and commercialize Éclat's portfolio of potential niche brand and generic specialty pharmaceutical products. We also are attempting 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; and a failure in either of these objectives could negatively impact our business and operating results.

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 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, and could disrupt our ongoing business and distract our management. If we were to be unable to complete these acquisitions or to successfully 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 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 inventions and deprive us of the ability to realize revenues and profits from our products and technologies.

Any patent applications that we 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 and biotechnology fields 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, 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 partnerships with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology or processes confidential.

Further, patent protection once obtained is limited in time, after which competitors may use the covered product or 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 technologies or processes, 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.

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"), 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. 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 AIA 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.

Third parties may claim that our products infringe 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 other 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 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.

If we or our 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 partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our 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.

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 privacy and security 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 may cause fluctuations in our financial results.

For the year ended December 31, 2014, we derived 98.6% of our total revenues from continuing operations from transactions in U.S. dollars, but have 75% of our cash and cash equivalents, and 39% 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 currently engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, but we expect to implement hedging activities to manage exchange rate risk in the future.

Uncertainty remains 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. 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.

Our effective tax rate could be highly volatile and could adversely affect our operating results.

Our future effective tax rate may be adversely affected by a number of factors, many of which are outside of our control, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- adjustments to estimated taxes upon finalization of various tax returns;
- increases in expenses not deductible for tax purposes, including write-offs of acquired in-process R&D and impairment of goodwill in connection with acquisitions;
- changes in available tax credits;
- changes in share-based compensation expense;
- changes in the valuation of our deferred tax assets and liabilities;
- changes in domestic or international tax laws or the interpretation of such tax laws;
- the resolution of issues arising from tax audits with various tax authorities;
- the tax effects of purchase accounting for acquisitions that may cause fluctuations between reporting periods; and
- taxes that may be incurred upon a repatriation of cash from foreign operations.

Any significant increase in our future effective tax rates could impact our results of operations for future periods adversely.

We depend upon consultants, advisors and outside contractors extensively in important roles within our Company.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, advisors and outside contractors. If we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our development activities may be extended, delayed or terminated which would have an adverse effect on our development program and our business.

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.

Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery platforms 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 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 a variety 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 cannot control, and our pharmaceutical and biotechnology partners cannot control, the timing of regulatory approval for any of these products, or if approval is obtained at all. We, or our 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.

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, 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 polymer and cross-references our DMF.

Similarly, although we anticipate submitting applications for approval for our development products 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 (“REMS”), to ensure the safe use of 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 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.

Commercial products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology 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 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;
- active pharmaceutical ingredients and/or product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required clinical trials and/or post-marketing studies;
- 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 CDMOs 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.

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.

Regulatory reforms may adversely affect our ability to sell our products 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.

Any 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, or will license our products or drug delivery platforms and subcontractors we engage for services related to the development and manufacturing 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 products or drug delivery platforms, as well as, companies acting as subcontractors for our product developments, including but not limited to non-clinical, pre-clinical and clinical studies, and manufacturing, 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 for our products or their misuse.

The testing, including through clinical trials, manufacturing and marketing, and the use of our products may expose us to potential product liability and other claims. 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 ("CROs") 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 $10 million for products marketed by the US operations of the Company (Bloxiverz® and Vazculep™). 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, or will develop, our products may not protect us from product liability claims from the consumers of those products or from the costs of related litigation.

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

Our R&D 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 property, business interruption and casualty insurance with aggregate maximum limits of €60 million, which are limits that we believe to be commercially reasonable, but may be inadequate to cover any actual liability or damages.

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, 2014, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $8.15 to $18.89. 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. 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 partnerships, 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 the Éclat products of Bloxiverz® and Vazculep™. 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 and up to December 1, 2014, we have generated revenues from product development fees and licensing arrangements and royalties associated with Coreg CR® classified as Discontinued Operations. 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, Bloxiverz® and Vazculep™.

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 $320 million through December 31, 2014. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for R&D of our products and 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 drug delivery platforms and products;
- the level of product and price competition;
- our ability to develop new 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 products 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 products. 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 drug delivery platforms;
- the progress of our research and product development programs;
- results of our partnership efforts with 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. Alternatively, to obtain needed funds for acquisitions or operations, we may choose to issue shares of our common stock or preferred stock, either through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to our stockholders.

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 under SEC rules, there will be less publicly available information about the Company than there would be if we were a U.S. public company. Foreign private issuers are not required to comply with certain disclosure requirements that apply to public companies organized in the United States. For example, because we are a foreign private issuer, (a) we are exempt from the disclosure and procedural requirements under Section 14 of the Exchange Act applicable to soliciting proxies, consents or authorizations, (b) our officers and directors are exempt from the reporting and "short-swing" profit recovery and reporting provisions under Section 16 of the Exchange Act with respect to their purchases and sales of our securities, and (c) although we expect to submit quarterly interim financial data to the SEC on a Form 6-K, we are not required to file periodic reports on Form 8-K or financial statements on Form 10-Q, each of which forms generally requires more information and is required to be filed more promptly than Form 6-K. In addition, we are not listed in France, as such we are not subject to disclosure requirements of listed companies in France, including any requirements to furnish quarterly or annual financial statements.

We may cease to qualify as a foreign private issuer, which would increase the costs and expenses we incur to comply with U.S. Securities Laws.

As required by SEC rules, we determine our foreign private issuer status annually as of the last business day of our second fiscal quarter. Thus, on June 30, 2015 or any subsequent June 30, we could fail to meet the requirements necessary to maintain our foreign private issuer status. We would fail to qualify as a foreign private issuer if more than 50% of our securities are held by U.S. residents and either (a) more than 50% of our executive officers or members of our board of directors are citizens or residents of the United States, or (b) more than 50% of our assets are located in the United States; or (c) our business is administered principally in the United States. If we fail to qualify as a foreign private issuer, the costs and expenses we incur to comply with U.S. securities laws would likely be significantly higher than the costs we incur as a foreign private issuer. For example, (a) we would be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects, and which must be filed more promptly, than the forms available to a foreign private issuer, and (b) we would be required to comply with the disclosure and procedural requirements under Section 14 of the Exchange Act applicable to soliciting proxies, consents or authorizations.

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, 2015, Deerfield Capital and certain of its affiliates beneficially owned approximately 13.08% of our outstanding shares (in the form of ADRs) and Broadfin Capital and certain of its affiliates beneficially owned approximately 12.82% 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 is a specialty pharmaceutical company utilizing core competencies in drug delivery and formulation to develop safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. The Company has a balanced business model consisting of a successful previously Unapproved Marketed Drugs ("UMDs") business with two approved and marketed products in the USA, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep™ (phenylephrine hydrochloride injection), both obtained through the acquisition of Éclat Pharmaceuticals, LLC's (or "Éclat") portfolio on March 13, 2012, and a branded business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. The branded products are based on proprietary drug delivery platforms and target high-value solid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits. Flamel is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and Dublin, Ireland.

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, 69200 Venissieux, France (a suburb of Lyon); phone number +33 472 78 34 34, fax number +33 472 78 34 35. Its website is www.flamel.com.

The Company currently has two direct wholly owned operating subsidiaries: Flamel US Holdings, Inc., and Flamel Irish Holdings, Ltd. Flamel US Holdings, Inc. is 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. Flamel Irish Holdings, Ltd is a corporation duly organized under the laws of Ireland. Its wholly owned subsidiary, Flamel Ireland, Ltd., a corporation duly organized under the laws of Ireland, is where all intangible property was relocated on December 16, 2014 (see "Item 4. *Developments in 2014 and early 2015*"). A complete list of the Company's subsidiaries can be found in Exhibit 8.1 to this Annual Report.

Our Business Model

Since the acquisition of Éclat, we have implemented a balanced business model allowing Flamel to (i) commercialize niche branded (Bloxiverz® and Vazculep™) and generic pharmaceutical products in the U.S. and other countries as appropriate (for more details, see "Item 4. *Lead Products*"), and (ii) blend novel, high-value internally developed products with our drug delivery and capabilities (for more details, see "Item 4. *Other Products Under Development*").

Flamel's new model allows us now to select, develop, seek approval for, and commercialize niche branded products mainly in the U.S. and most of the opportunities are self-funded. By adopting this revised strategy, the Company makes itself less dependent on the often changing strategies of partners in the future. Nevertheless, Flamel is still exploring development, supply and licensing opportunities for either its 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) or its proprietary products (as the case may be; see "Item 4. *Other Products Under Development*" for details) with carefully selected third parties, but, unlike our historical operations, will not be dependent completely on those partnerships to create revenue and profit opportunities.

Business Strengths and Strategies

Éclat, which has focused on pursuing U.S. Food and Drug Administration ("FDA") approvals through the 505(b)(2) regulatory pathway (see "Item 4. *Patent Restoration and Exclusivity*"), adds to our Company marketing and licensing knowledge of the commercial and regulatory process in the U.S, which we believe enhances 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 both the U.S. and EU.

In addition to 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 and have gained a products portfolio in various stages of development (see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*"). The first product from the acquired Éclat's portfolio, Bloxiverz® (neostigmine methylsulfate injection for the reversal of effects of blocking agents after surgery), was approved by the FDA on May 31, 2013 and is currently being marketed in the U.S. The second product, Vazculep™ (phenylephrine hydrochloride injection for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia), was approved by the FDA on June 27, 2014 and launched in October, 2014 in the U.S. Flamel believes that Bloxiverz® and Vazculep™ could have a significant impact on the Company's revenue generation and favorably impact its progression to profitability.

We anticipate this enhanced commercialization capability will allow us to retain a greater portion of the economic benefits associated with sales not only of two products, but additional "Unapproved to Approved" products as well (see "Item 4. *Other Products Under Development - Additional "Unapproved to Approved" Products using the Unapproved Marketed Drug (or UMD) Strategy*"). In addition, we intend to pursue FDA approval 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*").

Our versatile, proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™, Medusa™) allow us to select unique product development opportunities, representing either "life cycle" opportunities for marketed chemical and biological drugs (via 505(b)(2) or ANDA regulatory paths), or innovative formulation opportunities 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. As part of our new business model, several products formulated using our proprietary drug delivery platforms are currently under various stages of development at Flamel, using a variety of regulatory 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*").

The key elements of our strategy that enable us to build upon our strengths are:

- Maximizing the commercial potential of our "Unapproved to Approved" products;
- Continuing to build commercially successful products utilizing Micropump®;
- Identifying and optimizing time-to-market for our (not yet approved) drug delivery platforms, i.e. LiquiTime®, Trigger Lock™ and Medusa™.
- Maximizing the technical potential of our existing drug delivery platforms for developing new and proprietary products with the appropriated development pathway (as identified above);
- Developing and validating additional drug delivery platforms for unmet applications utilizing our current drug delivery platforms; and,
- Leveraging the capabilities of our existing (and future) proprietary products and/or drug delivery platforms with pharmaceutical and biotechnology partners.

Developments in 2014 and early 2015

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 were 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 sodium oxybate product based on our proprietary Micropump® platform 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 Xyrem® (sodium oxybate), the standard of care product in the U.S. is two equal, divided doses: the first dose to be taken 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 announced to begin a new clinical study before the end of 2014 in a larger number of subjects.

On June 25, 2014, we announced positive preclinical results for our once-a-week formulation of exenatide, a glucagon-like peptide-1 agonist (GLP-1 agonist) used to treat type 2 diabetes. The product demonstrated close to 100% bioavailability with no initial release spike or burst effect in plasma. Two successive injections were administered with very similar release profiles. There were no adverse clinical signs and excellent local tolerability was observed. The pharmacokinetic profile is compatible with a release over one week in humans.

On June 27, 2014 we announced the approval by the FDA of the NDA for Vazculep™ (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. Vazculep™ was approved as 1 mL single use vials, and 5 mL and 10 mL pharmacy bulk package vials and was launched, shipped and reached hospital shelves in October 2014.

On August 4, 2014, we announced that we have received communication from the FDA that all manufacturers of unapproved versions of neostigmine methylsulfate have been notified by the FDA to cease manufacturing of the unapproved product as of July 30, 2014. The Company stated that its inventories were sufficient to provide 100% of the market for neostigmine methylsulfate with Bloxiverz®, its FDA-approved version of the product.

On September 29, 2014, we announced positive results of FIM clinical trial with LiquiTime® ibuprofen. One formulation of LiquiTime® ibuprofen was shown to be bioequivalent to the immediate release ibuprofen oral suspension using the FDA requirements for bioequivalence. There were no safety or tolerability issues raised during the study.

On October 31, 2014, we announced that Dr. David Monteith, who has 25 years of pharmaceutical industry experience, joined the Company as Vice President, Research and Development

On November 28, 2014, we announced that Flamel had entered into an agreement to divest its development and manufacturing facility and associated business located in Pessac, France, to Recipharm AB ("Recipharm"). The sale closed on December 1, 2014. Under the agreement, Recipharm paid the Company $13.2 million. Additionally, Recipharm made an investment of $13.0 million in Flamel's stock at a purchase price equal to the trailing 20-day average price. This divestiture agreement allowed Flamel to retain access to the development and manufacturing capabilities of Pessac and to use Recipharm's other facilities for the development or manufacture of its proprietary pipeline if needed. The Pessac Facility was not currently used for the production of Flamel finished products and Flamel intended to continue to outsource to third party contract manufacturing companies like Recipharm.

On December 16, 2014, we announced the transfer of all of our intangible property from our French entity to our Irish-based entity as a part of a global reorganization. The intangible property included patents on drug delivery platforms, clinical data sets and other intangible assets related to the pipeline of our proprietary products in development. Flamel's proprietary drug delivery platforms include Micropump® (and its applications to the development of liquid formulations LiquiTime® and of abuse-resistant formulations Trigger Lock™) and Medusa™ platforms.

On December 19, 2014, we reported positive results of a second clinical trial with Micropump® sodium oxybate. The results confirmed the elimination of the "middle-of-the-night dose" achieved in previous study. The elimination of the second dose for narcolepsy patients would not only provide more convenience, but could also benefit patients by eliminating or reducing the current disruption in nighttime sleep. The potential for additional benefits, including improved safety, will be studied in the next study(ies).

On January 15, 2015, we announced that the Wholesale Acquisition Cost ("WAC") for Bloxiverz® has been increased to $98.75 per vial for both the 0.5 and 1.0 mg/mL strengths, subsequent to the approval by the FDA of APP's NDA for neostigmine methylsulfate product.

On March 27, 2015, we announced positive results of FIM clinical trial with LiquiTime® guaifenesin. Three different twice-daily formulations of LiquiTime® guaifenesin against immediate release guaifenesin tablets dosed every four hours were evaluated in a 16-healthy volunteers four-way crossover pharmacokinetic study. The trial was intended to provide sufficient data for us to choose the best formulation to move forward into a pivotal study. While none of the formulations in this relatively small pilot study exactly satisfied all of the criteria necessary for proving bioequivalence of Area Under the Curve ("AUC") to the immediate release guaifenesin tablets under FDA requirements, the results clearly met the intention of the study. The chosen formulation will be optimized and scaled up with the aim to perform a pivotal study in 2016. In addition, there were no safety issues raised during the study.

On April 7, 2015, we announced the departure of Mr. Steve Lisi, Senior Vice President of Business and Corporate Development at Flamel. The Company has immediately begun a comprehensive search for a permanent replacement and is expecting to hire a new Vice President of Business and Corporate Development within the next six to eight weeks. Flamel also reaffirmed its product revenue guidance for 2015 of $170 to $185 million for combined sales of Bloxiverz® and Vazculep™.

Lead Products

Bloxiverz® (neostigmine methylsulfate injection), Flamel's first NDA approval. Bloxiver®'s NDA was filed on July 31, 2012. Bloxiverz® was approved by the FDA on May 31, 2013 and was launched in July 2013. Bloxiverz® 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 FDA-approved version of neostigmine methylsulfate. Today, neostigmine is the most frequently used product 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® has been dependent upon, as per FDA guidance (see "Item 4. *Other Products Under Development - Unapproved Marketed Drug (or UMD) Strategy*"), on the FDA removing all unapproved products from the market in a timely manner (typically one year post approval). All manufacturers of unapproved versions of neostigmine methylsulfate have been notified by the FDA to cease manufacturing of the unapproved product as of July 30, 2014. On January 8, 2015, the FDA approved Fresenius Kabi USA ("Fresenius")'s NDA for neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths). On January 15, 2015, Flamel's increased the WAC for Bloxiverz® to $98.75 (from the previous WAC of $35.80) per vial for both the 0.5 and 1.0 mg/mL strengths. In 2014, we recognized a total amount of $10.2 million as revenues from product sales (for more details, see "Item 5. *Results of Operations*"). In the future, the volume of sales of Bloxiverz® is dependent upon the competitive landscape between Flamel, APP, and any subsequent ANDA approvals that may occur.

Vazculep™ (phenylephrine hydrochloride injection), Flamel's second NDA approval. On June 28, 2013, the Company filed an NDA for a second product developed by Éclat and later identified as Vazculep™ (phenylephrine hydrochloride injection). The product was approved by the FDA on June 27, 2014. Flamel's subsidiary Éclat Pharmaceuticals started shipping Vazculep™ (in 1mL single use vials, and 5mL and 10mL pharmacy bulk package vials) to wholesalers in October 2014. There are approximately 7 million vials sold annually in the U.S. Vazculep™ is the only FDA-approved version of phenylephrine hydrochloride to be available in all three vial sizes. West-Ward Pharmaceuticals Corp. ("West Ward") commercializes the 1mL single-dose vial, as an approved product in the U.S. (NDA approved by the FDA on December 20, 2012); and, Sandoz, Inc. commercializes the 5mL and 10mL vials as unapproved products in the U.S.. The volume of sales of Vazculep™ is dependent upon the competitive landscape in the marketplace.

Coreg CR®, the Micropump®-based marketed product. 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 ("GSK") 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) $62.5 million in royalty revenue from Coreg CR®. Up to December 1, 2014, we received royalty revenue of $6.3 million and a total amount of $6.7 million from product sales. In December 2014, as part of the divestiture of our development and manufacturing facility ("Pessac Facility"), the Company transferred the Supply Agreement for Coreg CR® and, transferred and assigned to Recipharm all rights, titles and interests in the royalties of the License Agreements by and between Flamel and GSK (for more details, see "Item 4. *Strategic Alliances*", and note 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*").

Other Products Under Development

Additional "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. 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 two additional opportunities beyond Bloxiverz® and Vazculep™:

- Flamel anticipates one of these two opportunities to be filed mid-2015 (assuming a successful pre-IND meeting with the FDA scheduled in Q2.2015) and the other is still being internally reviewed for subsequent filing in 2016.

- Those products will be marketed by Flamel and its U.S.-based subsidiary, Éclat.

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. The results of Flamel's FIM clinical study in healthy volunteers, published in April 2014, demonstrated elimination of the need for a second, middle of the night dose. This was further confirmed by a second clinical study performed at higher doses, published in December 2014. The elimination of the second dose for narcolepsy patients not only provides more convenience, but could also benefit patients by eliminating or reducing the current disruption in nighttime sleep. The potential for additional benefits of Micropump® Sodium Oxybate, including improved safety, will be examined in future clinical studies. The Company plans to meet with the FDA during the first half of 2015 and begin a pivotal clinical study by the end of 2015.

- **Ibuprofen**, LiquiTime®-based formulation for twice-daily dosing for the treatment of pain. Flamel's pharmacokinetics results, published in September 2014, demonstrated equivalent exposure (or "AUC") to immediate-release ibuprofen, similar onset and similar blood levels at 12 hours, with no safety or tolerability issues. Flamel anticipates a US regulatory filing during the first half of 2016 which will be followed by a later filing in the European Union. LiquiTime® ibuprofen opens the door to the Over-The-Counter ("OTC") cough, cold and allergy markets, where LiquiTime delivery platform can provide significant benefit through combination products containing frequently used together active ingredients with tailored and extended release profiles.

- **Guaifenesin**, LiquiTime®-based formulation for twice-daily dosing for the treatment of chest congestion associated with various indications (common cold, infections, or allergies). Flamel's pharmacokinetics results, published in March 2015, clearly met the intention of the study, i.e. to allow selecting the best formulation prototype, which satisfied most of the criteria necessary for proving bioequivalence of AUC to the immediate release guaifenesin tablets, for further optimization and scale up with the aim to performing a pivotal study in 2016. This second product will expand our twice-daily oral suspension offerings for the OTC market in the near future. Additionally, we believe that LiquiTime®, designed to provide a controlled, extended release of oral liquids principally for pediatric and geriatric patients will be also effective for certain prescription products.

- **Exenatide**, a once-a week Medusa™-based injectable formulation of exenatide, a glucagon-like peptide-1 ("GLP-1") agonist for the treatment of type 2 diabetes. Flamel's preclinical results in minipigs, published in June 2014, demonstrated an improved bioavailability versus commercially available once-a-week exenatide, similar release profiles for two successive injections, no adverse clinical signs and an excellent local tolerability. The pharmacokinetics profile of Medusa-exenatide was compatible with a release over one week in human. The Company expects to have Phase 1 data during the second half of 2015.

- Flamel has several other products based on its proprietary drug delivery platforms at various stages of development, e.g. **hGH XL** (a once-a week Medusa™-based injectable formulation of recombinant human growth hormone ("rhGH") for the treatment of growth disorder; pre-clinical data were published in October 2013). The company also has a **Trigger Lock™-based opioid** (for pain indication) in development. For competitive reasons, the Company has decided not to identify that particular opioid for the time being, but intends to provide additional information upon the achievement of pre-clinical, clinical and regulatory milestones.
- These proprietary pipeline products will be marketed either by Flamel (and/or its subsidiary Éclat) or by partners via licensing/distribution agreements.

Products in development with partners. Following the rationalization of the Company's products pipeline, the four partnerships that remained in effect in 2013, were either terminated in 2014 or transferred to Recipharm AB, as part the divestiture of our Pessac Facility. As a term of this divestiture, Recipharm will be allowed to use Micropump® platform for the continued manufacturing of microparticles for Coreg CR®, marketed by GlaxoSmithKline in the USA (for more details see "Item 4. *Lead Products*", "Item 4. *Strategic Alliances*" and "Item 4. *Manufacturing*").

Proprietary Product Pipeline. The status of Flamel's proprietary 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)
	Phenylephrine Hydrochloride Injection/**Vazculep™[2]**	Anesthesia	Marketed in the U.S.	
	UMD#3 (Undisclosed or "UD") **[2]**	UD	NDA filing expected in 2015 and 2016	
	UMD#4 (UD)	UD		
Micropump®	Sodium oxybate	CNS (narcolepsy)	2 clinical studies completed (pivotal clinical study initiation could be expected as early as 2015y/e)	To be determined**[3]**
LiquiTime®	Ibuprofen	Pain	FIM clinical study completed (pivotal clinical study initiation could be expected by 2015y/e)	LiquiTime®-based product(s) licensing-out expected by 2015y/e
	Guaifenesin	Respiratory	Proof of concept FIM clinical study completed (pivotal clinical study initiation could be expected in 2016)	

Proprietary Product Pipeline

Trigger Lock™	Opioid (UD)	Pain	Proof of concept (certain clinical data and independent in-vitro abuse resitance data could be expected as early as first half of 2015)	To be determined**[3]**
Medusa™	Exenatide (once-a-week)	Diabetes	Pre-clinical study completed (FIM clinical study initiation could be expected by 2015y/e)	
	Recombinant human growth hormone/**hGH XL**	Short stature	Pre-clinical	

[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) or by partners via licensing/distribution agreements.

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 also be 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. Furthermore, 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 others 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 for example 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**	Actavis plc; Alkermes plc; COSMO Pharmaceuticals SpA; Depomed, Inc.; Durect Corp.; 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 resistance**	Acura Pharmaceuticals, Inc.; Alpharma (*Pfizer*), Altus Formulation, Cima (Cephalon); Collegium Pharmaceutical, Inc.; Durect Corp.; Egalet Corporation; Elite Pharmaceuticals, Inc.; Ethypharm; Grünenthal Group; Intellipharmaceutics International, Inc.; 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. (OPKO);, Versartis, Inc.; Xenetic Biosciences plc (*formerly Lipoxen plc*); XL-protein GmbH
	Depot (PLA/PLGA microspheres, liposomes and other technologies)	Alkermes plc.; 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);* Onxeo (*formerly BioAlliance Pharma*); Pacira Pharmaceuticals, Inc.; Q Chip Ltd. (*Midatech*); REcoly N.V.; Soligenix, Inc. (*formerly DOR BioPharma Inc*); Surmodics, Inc.; Xenetic Biosciences plc. (*formerly Lipoxen plc*)

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

"New" Flamel's Specialty Pharma model (focusing on optimized re-formulations development capabilities) primarily competes with the one of other public companies such as: Actavis, Salix, H. Lundbeck or Impax. Flamel as a specialty pharmaceutical company has various capabilities, including the use of the 505(b)(2) regulatory pathway, the life cycle management of drugs (thanks to its drug delivery platforms) and direct commercialization of drugs.

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 $188 billion in 2014. 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. In 2014, FDA's Center for Drug Evaluation and Research ("CDER") approved 41 novel new drugs, approved as new molecular entities ("NMEs") under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications ("BLAs") (*FDA, Novel New Drugs 2014, Summary January 2015*). Conversely, the same year the FDA approved 96 "first time generic drugs" including 14 extended-release products (*FDA, ANDA (Generic) Drug Approvals in 2014, www.fda.gov*).

Market opportunities for its proprietary products are estimated by Flamel to be worth at least several hundred million dollars each (for example, Xyrem® (sodium oxybate) recorded $779 million in sales in the USA for 2014 (*source: Jazz press release Full Year And Fourth Quarter 2014 Financial Results, February 24, 2015*); OTC ibuprofen products recorded sales in the USA beyond $400 million including combination products (*source: IMS*), and several billion dollars for some of them or for indications targeted by these products (the cough and cold US market – targeted by our LiquiTime®-based products, is estimated at $6.5 billion annually – (*source: Nielsen Data Trend*); sales of GLP-1 drugs are expected to exceed $3 billion in 2014 *(source: reports and announcements from various companies commercializing GLP-1 products*) – overall type 2 diabetes market within the G7 countries was valued at more than $26 billion in 2013 (*source: Decision Resources Group*); US market for prescription painkillers exceeded $7 billion in 2013 *(source: IMS*), Oxycontin recorded sales of $2.6 billion during that year (*source: IMS*).

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 (companies 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. The FDA has actually 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. Flamel, resulting from the combination of its existing proprietary drug delivery platforms with the established commercial capability of Éclat, has evolved 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 drug delivery platforms that address key formulation challenges, leading to the development of differentiated drug products for administration in various forms (e.g. capsules, tablets, sachets or liquid suspensions for oral use; or injectables for subcutaneous administration) and can be applied to a broad range of drugs (novel, already-marketed, or off-patent):

- **Micropump**® is a microparticulate system that allows the development and marketing of 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 the E.U., respectively.

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

- **Trigger Lock**™ allows development of abuse-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 including capsules, tablets, sachets and liquid suspensions (LiquiTime®) for oral use. With Trigger Lock™ potentially addressing the issue of narcotic/opioid analgesics abuse, we have broad and versatile presentations to serve most markets from pediatric to geriatric.

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

We believe also that the Medusa™ platform provides a competitive advantage for developing differentiated injectable product profiles. Medusa™-based formulations permit drugs' full activity to be preserved in an extended release format with other potential advantages being, improved solubility, stability, and resistance to aggregation. Overall, Medusa™ can improve the patient experience though a change in the route of administration (e.g. switching from intravenous to subcutaneous injection) and may improve compliance through reduction of administration frequency (e.g. from once-a-day to once-a-week).

The Company will continue to selectively partner its proprietary formulations capabilities and will either commercialize products based on its drug delivery platforms on its own or partner them (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 global oral drug delivery market was estimated at $64.3 billion in 2013 and is expected to increase by more than 9% a year until 2018 – therefore exceeding $70 billion in 2014, due to a variety of factors, including increasing pressure of generics and the search for improved medication and patient compliance (*micromarketmonitor.com, 2015*). .

Flamel's Micropump® platform permits either extended, or both delayed and extended, delivery of small molecule drugs via the oral route. 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 system, releases the drug at an adjustable rate and over an extended period of time. The design of the Micropump microparticles allows an extended release in the Gastro-Intestinal ("GI") tract allowing mean plasma residence times to be extended for up to 24 hours. The microparticles' design can be adapted to each drug's specific characteristics by modifying the coating composition and thickness as well as the composition of the excipients encapsulated with the drug. The resultant formulations can potentially offer improved efficacy (by extending therapeutic coverage), reduced toxicity and/or side effects (by reducing C_{max} or peak drug concentration in the plasma, or by reducing intra- and inter-patient variability), and improved patient compliance (by reducing frequency of administration). The platform is applicable to poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) and to low dose (e.g. 4 mg) or high dose (e.g. 1,000 mg) drugs, while providing excellent mouth feel and taste masking properties. Micropump® allows the achievement of extremely precise pharmacokinetic profiles [extended (and/or delayed) release] of single or combination of drugs, in a variety of formats (such as tablets, capsules, sachet, or liquids (LiquiTime®), while preserving the targeted release rate over the shelf-life of the product.

Considering R&D costs for reformulating a drug are typically substantially lower than for developing NCEs, "reformulation approvals" provide an opportunity to extend the exclusivity period of already marketed drugs or create new market exclusivity for off-patent drug. The Micropump® platform has successfully transitioned to commercial stage with Coreg CR® (see "Item 4. *Lead Products*"). Flamel currently has one additional Micropump®-based internal product in development (Micropump®-Sodium oxybate for narcolepsy, which has been successfully tested in two Phase 1 clinical studies and could enter pivotal clinical study as early as the end of 2015; see "Item 4. *Proprietary Product Pipeline*").

Micropump® (and related products) is patent protected (see "Item 4. *Proprietary Intellectual Property*"). Coreg CR® Micropump®-based microparticles are now being manufactured for GSK by Recipharm (for more details, see "Item 4. *Strategic Alliances*" and "Item 4. *Manufacturing*").

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 approached $ 5.7 billion for the year 2014 (*IMS Health*). Amongst marketed "extended release" (twice-a-day or once-daily) liquid products are Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex combo, branded and generic products, including those based on Neos and Tris drug delivery technologies), 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; 2014 sales were almost $79 M in the USA, according to IMS). These products totaled $210 million sales in 2014 (*IMS Health*).

Flamel's LiquiTime® platform uses Micropump®'s competitive advantages to allow us to develop modified/controlled release (e.g. zero-order kinetics) in liquid suspension formulations. The LiquiTime® products are particularly suitable for dosing to children and for use by patients having issues swallowing tablets or capsules. Unlike the other product examples described in the previous paragraph, which are all based on ion exchange resin technology, LiquiTime® does not have the limitation of having to work solely with ionic drugs and therefore has applicability to a much broader range of drug molecules. As with Micropump®, LiquiTime® can be applied to the development of combination products and it is readily able to be scaled-up to commercial quantities.

The increasing number of geriatric patients and the demand for convenient drug delivery options for children offer striking opportunities for the development of LiquiTime®-based formulations. Flamel has two self-funded LiquiTime®-based products in development: ibuprofen LiquiTime® and guaifenesin LiquiTime® both successfully tested in FIM clinical studies. The first pivotal clinical study could be expected to be initiated as early as in the end of 2015, and the second in 2016 (see "Item 4. *Proprietary Product Pipeline*").

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

Trigger Lock™: Delivery Platform for Abuse-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 attempt to extract the opioids from the drug products for the purposes of injection or otherwise achieve the immediate release of the large doses contained in extended release products. The proportion of narcotic/opioid analgesics abuse associated with emergency room admissions has more than tripled in ten years, 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 whom 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 2014, the U.S. opioid drugs market was evaluated to be above $4.6 billion (*IMS Health*).

Flamel's Trigger Lock™ platform utilizes Micropump®'s competitive advantages to allow the development of abuse-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 formulation modifications are made to prevent other less publicized methods of abusing controlled release technologies are available; and,
- Trigger Lock™ can provide products that are either bioequivalent to or have improved pharmacokinetics over marketed narcotic/opioid analgesics.

The FDA's moves to restrict the prescribing of extended-release opioid analgesics should benefit abuse-resistant formulations, such as Trigger Lock™. The FDA issued a "Draft Guidance for Abuse Deterrent Opioids" on January 9, 2013.

We believe 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-resistant 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 certain clinical data and independent in-vitro abuse resistance data could be expected as early as for the first half of 2015; a pivotal clinical study could be expected to be initiated in 2016 (see "Item 4. *Proprietary Product Pipeline*").

Trigger Lock™ (and related products) is patent protected (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*).

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, proteins and small molecules) without any reduction in activity (as distinguished from chemical modification (e.g. PEGylation) or protein engineering or other conjugation (e.g. HSA-fusion) approaches). Medusa™ is particularly suited to the development of subcutaneously administered formulations.

The Medusa™ platform consists of proprietary and versatile drug carrier polymers that form hydrogel depots 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 have been proven to be safe and biodegradable. A comprehensive ADME and regulatory toxicology package for the key Medusa™ polymer has being completed in 2014 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 the 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 no initial burst effect, lower 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 activity - of the drug. The transient, non-covalent interactions dictate the pharmacokinetic parameters (C_{max} and bioavailability in particular) of the released drugs.

Flamel is focusing on Medusa™-based "biobetter" development opportunities, which can be summarized as follows:

- Proven biologic drugs with established markets and proven clinical development approaches;
- 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 in development (see "Item 4. *Proprietary Product Pipeline*"). The first one is once-a-week Medusa™ exenatide (positive preclinical results in minipigs presented in June 2014; Flamel expects to have Phase 1 data during the second half of 2015), the second is hGH XL (pharmacodynamics pre-clinical proof of concept achieved).

Medusa™ is patent protected (see "Item 4. *Proprietary Intellectual Property*").

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 (as 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.

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.

In 2014, Flamel engaged in a rationalization process of its patent portfolio to focus on key patent families that protect our core drug delivery platforms. As a result of this process, the total number of patents is significantly lower than in previous years. Specifically, during 2014, we were granted 58 (fifty-eight) new patents and we filed 3 (three) new patent applications. As of December 31, 2014, we owned the following patent and patent applications:

	US	EUROPE	ROW*	TOTAL
Granted patents	16	135	94	245
Pending patent applications	11	17	46	74
Patents granted in 2014	6	31	21	58
Patent applications filed in 2014	1	2	0	3

***** ROW: Rest of the Word

The Company's granted 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®	July 2027	July 2023
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026 (pending)
Medusa™	June 2031	June 2027 (pending)

Flamel's key patents include protection for the following:

- **Micropump® platform** is patented under multiple granted 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 7 (seven) Flamel's patent application families. Within these patent families, 11 (eleven) patents are granted in the U.S., Europe and Japan; and, 14 (fourteen) 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 2003/104303 granted in the U.S. and which will expire in July 2023. Equivalent patents to WO 2003/104303 are granted in China, Israel, Mexico, Australia, Japan, South Korea, Canada, Europe, India and South Africa. A patent application is pending in Brazil. These patents will expire in 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 application is pending in Brazil.

- Medusa™-based microgels are protected by granted patents from WO 2007/141344' patents family in the U.S., Australia, Japan, Canada, China, Israel, South Korea, Mexico and South Africa. Patent applications are pending in Europe, India and Brazil. This patents family will expire on June 2027.

Strategic Alliances

The four partnerships left in 2013, after the rationalization of the Company's products pipeline initiated in 2012, have, in 2014, either been terminated or transferred to Recipharm, as part the divestiture of our Pessac Facility, as follows:

- In May 2014: Effective termination of 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);

- In August 2014: Effective termination of the 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 partner. Before the termination, we recognized $2.3 million in development and license fees in 2014;

- In December 2014: The multi-year development partnership agreement with an undisclosed, large international pharmaceutical company was transferred to Recipharm, as part the divestiture of Pessac Facility. Before this divestiture, we received $2.0 million in development fees in 2014 classified as Discontinued Operations; and,

- In December 2014: As part the divestiture of our development and manufacturing facility, the royalty payment under the license agreement and the supply agreement with GSK were, respectively, delegated and transferred to Recipharm. Before the divestiture, we received royalty revenue of $6.3 million and a total amount of $6.7 million as revenues from product sales in 2014 (for more details, see "Item 18. *Financial Statements – Notes to Consolidated Financial Statements*, "*Subcontracting agreements F-17*""). As a result of this divestiture, Flamel and Recipharm have entered into a five year services and manufacturing agreement to support the development of Flamel's proprietary portfolio. Besides, Recipharm has an option, for a certain period of time, to negotiate with Flamel for the European rights to product that Flamel plans to license for sale in the European market. In addition, Recipharm and Flamel have agreed to enter into a license agreement whereby Recipharm will be allowed to selectively offer Flamel's drug delivery platforms in its CDMO business, further enhancing the economic benefits to both companies.

As focus shifts to a more "specialty pharma" model, the Company's business is less dependent on its ability to work with partners to develop products using our drug delivery platforms. Indeed, we now have revenues generating marketed products and products in late stage development that are not dependent on these partnerships (see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*"). While we are moving to a specialty pharma model, in 2014 about 41% of our revenues come, however, from partnerships. Going forward, Flamel believes that Bloxiverz® and Vazculep™ could have a significant impact on the Company's revenue generation and favorably impact its progression to profitability.

However, we are still open to entering into new partnerships, in particular, with pharmaceutical and biotechnology companies providing new formulation development opportunities (especially, based on partners' proprietary or controlled therapeutic compounds), but also for certain of our proprietary products that Flamel and/or its US operations, Éclat, will not market itself (such as the LiquiTime®-based OTC products in late stage developments) and access to complementary expertise (regulatory, medical and commercial). Under such 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.

Manufacturing

The manufacturing facilities for our drug delivery platforms were located in Pessac, France, near Bordeaux (hereinafter referred as "Pessac Facility"; audited and approved by the U.S., the European (EMA) and the French regulatory agencies, ANSM (formerly "AFSSAPS")). This Pessac Facility provided us with two commercial scale production lines for the manufacture of Coreg CR® microparticles, and another production line used for other Micropump®, and LiquiTime®/Trigger Lock™-based formulations (i.e. the production of certain pharmaceutical products, including commercial scale quantities of our intermediate formulated products). During 2014, our commercial manufacturing capacity utilization ranged from 50% to 65% of total capacity.

On December 1, 2014, the Pessac Facility was divested to Recipharm. This divestiture agreement allows Flamel to retain access to the development and manufacturing capabilities of Pessac Facility for all its drug delivery platforms. In particular, this facility can support, like any CDMO, certain of our needs for scale-up activities and clinical batch manufacturing for our Micropump®, LiquiTime® and Trigger Lock™ platforms, as well as for the synthesis of Medusa™'s polymers and technical batch manufacturing for non-clinical studies pertaining to our Medusa™-based formulations. In addition, this agreement permits us to utilize other Recipharm's manufacturing facilities for the development and/or manufacture of our proprietary pipeline if needed.

The Pessac Facility was never used for the production of finished products commercialized by our US operations. Indeed, the manufacture of the UMDs products marketed by the Company's US operations is outsourced to cGMP compliant and FDA-audited CDMOs in accordance with supply agreements that expire in 2017.

Flamel intends to continue to outsource to third party contract manufacturing companies like Recipharm when appropriate. For example, in 2014, Flamel has transferred the scale up of certain of its own proprietary products to CDMOs in the U.S. This will be beneficial to the Company for products that will ultimately be submitted and sold in the United States.

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, a biologic license application (BLA) is submitted for approval for commercialization of some biological products instead of the New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") used for other drugs. Also, unlike other 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. 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 biological products. 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 European Medicines Agency ("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 has a significant impact on the development, manufacture, and marketing of biological and drug products and on 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 must 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 must 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.

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 that 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 UMD products, 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; and, if we were required to do so, would review the continued value of the product.

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 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 such as 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 conducted 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.

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 R&D 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 analytical research laboratories. The lease on this facility expires in 2016. A second facility comprising approximately 12,800 square feet houses equipment dedicated to our Micropump®, LiquiTime® and Trigger Lock™ platforms has a lease which expires in 2015. The third facility of approximately 6,800 square feet houses analytical laboratories and the lease expires in 2016. The fourth facility of approximately 26,000 square feet houses research and biochemistry (Medusa™) laboratories and quality/regulatory affairs. The lease on this facility, expired at the end of 2014 and is being renewed.

We previously owned manufacturing facilities, of approximately 103,900 square feet, located in Pessac, France ("Pessac Facility"), which included (i) approximately 6,800 square feet used for the manufacture of Coreg CR® microparticles for GSK as well as other Micropump®, and LiquiTime®/Trigger Lock™-based formulations (up to commercial scale; altogether the "Micropump® Pilot Development facilities") and housed 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 a heat boiler. This facility was divested to Recipharm on December 1, 2014 (for more detail, see "Item 18. *Financial Statements – Notes to Consolidated Financial Statements*, "6 *Discontinued Operations*").

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

We have intellectual property, clinical, quality, regulatory, and supply chain activities located in Dublin, Ireland. The office space consists of 325 square feet, and the lease has been concluded for a one year period automatically renewable from year to year.

During 2014, we expended $1.8 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 utilizing core competencies in drug delivery and formulation to develop safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. Flamel has a balanced business model consisting of a successful previously-UMDs business with two marketed products in the USA, Bloxiverz® and Vazculep™, and a branded business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms (for details see "Item 4. *Lead Products*" and "Item 4. *Other Products Under Development*"). The branded products are based on proprietary drug delivery platforms and target high-value solid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits. Flamel's new business model allows the Company to select, develop, seek approval for, and commercialize niche branded and generic products, initially targeted for the U.S. market. The Company is able to self-fund the development of most product development opportunities. For more details, see "Item 4. *Information on the Company*".

The acquisition 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 to Flamel. We believe this enhances the ability of Flamel to identify 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 partners in the future. More importantly, we now have revenues generating marketed products in the USA and proprietary products in late stage development that are not dependent on partnerships. The first product from the acquired Éclat portfolio, Bloxiverz® was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S. The second product, Vazculep™, was approved by the FDA on June 27, 2014 and launched in October, 2014 in the USA. Both products are commercialized in the USA by Flamel's subsidiary Éclat (for details see "Item 4. *Lead Products*"). Flamel believes that Bloxiverz® and Vazculep™ will have a significant impact on the Company's revenue generation and will favorably impact its progression to profitability.

To complement the historical science-oriented strengths of Flamel as an innovator of drug delivery platforms, we have now enhanced our ability to identify new product candidates and to pursue commercial opportunities. The Company's drug delivery platforms allow the creation of competitive and differentiated drug product profiles (e.g. with improved pharmacokinetics, efficacy and/or safety). These product development opportunities allow us to grow market share and to protect our products through patent protection and product differentiation. In 2014, we have focused our Research and Development ("R&D") efforts on moving several products formulated using our proprietary drug delivery platforms more rapidly into clinical development stages. On completion of development and successful regulatory approval these products will be marketed either by Flamel 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 this shift to a specialty pharma model, the Company's business is now less dependent on the development activities performed by partners, and relying more on the development of its own, self-funded, products. The difference in the current model and that of the past is that Flamel is no longer solely dependent on partnerships to create revenue and profit. Nevertheless, the Company continues to explore development and licensing opportunities with carefully selected third parties for either its drug delivery platforms or its proprietary products in areas where Flamel and/or its US operations, may choose not to market itself, such as the LiquiTime®-based OTC products. Following the rationalization of the Company's products pipeline, the four partnerships that remained in effect in 2013 were either terminated in 2014 or transferred to Recipharm AB ("Recipharm"), as part the divestiture of our Pessac Facility. Consequently, the loss of this external, partner-based project portfolio resulted in a decrease in R&D revenues in 2014.

Under the divestiture agreement of our Pessac Facility dated December 1, 2014, Recipharm paid the Company $13.2 million. Additionally, Recipharm made an investment of $13.0 million in Flamel's stock at a purchase price equal to the trailing 20-day average price. This divestiture agreement allowed Flamel to retain access to the development and manufacturing capabilities of the acquired Pessac Facility and to use other Recipharm's facilities for the development or manufacture of its proprietary pipeline if needed. The Company transferred to Recipharm the Supply Agreement pertaining to Coreg CR® and delegated the royalty payments under the License agreement with GSK as of December 1, 2014. The divestiture of the Pessac Facility has been classified as Discontinued Operations for the twelve month periods ended December 31, 2014, 2013 and 2012 (see note 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*").

Operating expenses increased in 2014 largely as a result of unfavorable non-cash line items of $72.4 million including the change in fair-value measurement of the liabilities outstanding for the acquisition of Éclat (see note 16 and 21 to the Consolidated Financial Statements in "Item 18. *Financial Statements*") amounting to $57.5 million, acquisition note expenses amounting to $3.0 million in connection with acquisition of Éclat and amortization of intangible R&D assets amounting to $11.7 million. In 2013 non-cash line items amounted to $28.1 million. Commitments in relation to the acquisition of Éclat were valued at $58.9 million as of December 31, 2013 and at $104.7 million, as of December 31, 2014. 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 these non-cash items, operating expenses increased by $6.6 million in 2014. The commercialization of Bloxiverz® results in an increase in cost of sales and our investment in R&D has increased as we pursue development of both our product portfolio, including products formulated using our proprietary drug delivery platforms which are being moved rapidly into clinical development stages. We continue to maintain an aggressive approach to cost controls and are committed to challenging our costs on non-core activities. We expect to see an increase in R&D expenditure in the future as we pursue (a) clinical development, which will include costs of clinical trials, regulatory costs, sub-contracted development and manufacturing costs and (b) commercialization, which includes payment to FDA of NDA filing fees. For UMD products we expect to file for approval, a NDA filing fee in excess of $2 million. Non-cash expenses relative to stock based compensation, amounted to $2.9 million in 2014 and $2.0 million in 2013.

In 2014, our investment in property and equipment was comparable with 2013. 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, the majority 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 0.1% increase in the average value of the US dollar relative to the Euro between 2013 and 2014. 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 decreased by 12% resulting in a corresponding decrease in amounts represented in the balance sheet as of December 31, 2014, compared with December 31, 2013. We do not currently engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, but we expect to implement hedging activities to manage exchange rate risk in the future. There is no outstanding hedging agreement as of December 31, 2014; for details see "Item 3. *Key Information - Risk Factors*"..

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. In fiscal year 2014 and fiscal year 2013, the average value of the US dollar relative to the Euro between 2013 and 2014 was comparable, as such comparison of expenses from one period to another is not impacted by the conversion of expenses into U.S. dollars. That said, we generally 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 R&D of new products or technologies, the length and uncertainty linked to the results of clinical trials and regulatory procedures, 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 development and commercialization of its portfolio of products. The time required for the Company to achieve sustained profitability, remains uncertain. Operating income and losses may also fluctuate from quarter to quarter as a result of differences in timing of revenues recognized or expenses incurred; for details see "Item 3. *Key Information - Risk Factors*".

The Company has incurred substantial losses since its inception, and through December 31, 2014, with an accumulated deficit of approximately $320 million. Flamel expects to maintain its investment in its R&D activities in line with the development of its product 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 R&D costs to increase as we pursue the development of our own products. We currently have two approved UMD products on the market, as a result of these two products, we anticipate that our revenues will increase significantly in 2015 and beyond. This portfolio will be supplemented by further products in subsequent years which could favorably impact its progression to profitability. We may continue to seek partnership opportunities, in particular for certain of our proprietary products that we are not in a position to market ourselves. These partnerships will equally contribute to our future revenue generation.

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. The remaining proceeds along with revenues generated by our UMD products are used to pursue the development of our proprietary products, including clinical trials and associated regulatory costs.

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 and sales of pharmaceutical products.

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

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

- As milestones relate to discrete development steps (i.e. can be used by the partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.

- Non-refundable technology access fees received from partnership agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.

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

For generic products and branded products being sold in mature and stable markets where changes in selling price are rare, the Company recognizes revenues upon shipment. For branded products where market conditions remain volatile and selling price is subject to change the Company recognizes revenue based on net product sales of wholesalers to their customers. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, 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. Estimates for product returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors.

When Flamel receives revenue under signed feasibility study agreements, revenue is then 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 R&D projects are recognized as an offset to R&D expense on a pro-rata basis over the duration of the program. Funding can be received to finance certain R&D 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’.

Flamel benefits from tax credits on a percentage of eligible R&D costs. These tax credits can be refundable in cash or offset against taxable income 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 R&D grant and the tax credit is recognized as an offset to R&D expense.

R&D 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. R&D expenditures are charged to operations as incurred.

Generally, the Company's R&D efforts are either funded internally or by partners. Flamel's R&D efforts are organized to allow both internal products developments and partner-sponsored research programs simultaneously, reflecting the Company's approach and belief that internal projects can benefit from the R&D efforts funded by partners and vice versa. Due to this approach, the Company views R&D costs as a whole across the organization and by drug delivery platforms. The Company monitors progress on the basis of the actual number of hours/days worked and the cost of outside services for pre-clinical, clinical and regulatory 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, re-measurement 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.

Discontinued Operations

The Company followed the guidance in Financial Statements Accounting Standards Board Accounting Standards Codification (ASC) Topic 205 Presentation of Financial Statements (ASC 205), Topic 360 Property, Plant and Equipment (ASC 360) and Accounting Standards Update (ASU 2014-08), Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity in determining the accounting for the divestiture. The Company opted to early adopt the provisions of ASU 2014-08 as its management believes that all criteria for presenting the disposal of Pessac Facility and its business as a discontinued operation were met. Presenting the disposal as a discontinued operation will also provide a better understanding of the results of the Company's new strategy and in assessing the impact of the disposal on the ongoing operations of the entity.

The divestiture represents a strategic shift that has or will have major effect on an entity's operations and financial results. Since 2012, the Company has 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 general pharmaceutical products. Previously, the Company's focus was to develop and license its proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™ and Medusa™) with pharmaceutical companies and biotechnology partners (e.g. the licensing of Micropump® to GSK to develop Coreg CR® with GSK bringing and commercializing the product to market). The divestiture of Pessac Facility to Recipharm and the transfer to Recipharm of the GSK's Supply Agreement and royalty income relating to Coreg CR® is an implementation of this revised strategy. The Company is reducing its sole reliance on products developed with partners, explaining the transfer of its rights and obligations pertaining to Coreg CR®, including the Pessac Facility. Flamel sold over 50% of its historical revenues as a result of this transaction which has a major impact on the Company's operations and results.

The divestiture was accomplished in a single transaction and the assets, contracts and liabilities referred to in the Asset Purchase Agreement signed between Flamel and Recipharm were determined to represent a disposal group. This disposal group is considered to be a component of the Company. While the Pessac Facility and its related business were not identified as reportable segment or operating segment, as the Company operates in only one segment, the Pessac Facility and its related business may be considered as an asset group as the transferred assets, liabilities and contracts represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other group of assets and liabilities. The Company transferred all future cash outflows and inflows relating to the Pessac Facility that can be clearly distinguished operationally and for financial reporting purposes.

The results of Discontinued Operations, less income taxes, have been reported as a separate component of income in the statement of operations. The assets and liabilities of the discontinued operation have been reported separately in the asset and liability sections, of the statement of financial position for the periods presented in the statement (see note 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*") for a description of the facts and circumstances related to the disposal, the gain and loss on disposal and the specific line items included in the statement of operations, statement of financial position and cash-flow statement relative to the disposal group.

Long-Term Debt

Long Term debt associated with the acquisition liabilities arising from the acquisition of Éclat are accounted at fair-value. The Company elected the fair value option for the measurement of the long-term liability associated with the Deerfield Royalty and Broadfin Royalty agreements; for details (see "ITEM 7. *Related Party Transactions*").

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 Continuing Operations

Years Ended December 31, 2014, 2013 and 2012

Operating Revenues

The Company had total revenues of $14.8 million in 2014, $4.2 million in 2013 and $7.6 million in 2012. The following table shows revenues attributable to license and research activities for the last three (3) years, in millions of US dollars:

		2012	2013	2014
LICENSE AND RESEARCH REVENUES		**$ 6.7**	**$ 3.0**	**$ 2.8**
RESEARCH		**$ 2.5**	**$ 1.5**	**$ 2.3**
Research	Eagle Pharmaceuticals	0.7	0.0	0.0
	Undisclosed Partners	1.8	1.5	2.3
LICENSES		**$ 4.3**	**$ 1.5**	**$ 0.5**
Upfront Payment	Merck Serono	2.7	-	-
	Undisclosed Partners	1.3	0.6	0.2
Milestones	Undisclosed Partners	0.3	0.9	0.3
TOTAL		**$ 6.7**	**$ 3.0**	**$ 2.8**
	Merck Serono	2.7	-	-
	Eagle Pharmaceuticals	0.7	-	-
	Undisclosed Partners	3.3	3.0	2.8

In 2014, license and research revenue totaled $2.8 million. License and research revenue in 2013 and 2012 totaled $3.0 million and $6.7 million, respectively. In 2014 R&D revenue totaled $2.3 million and license revenue totaled $0.5 million. In 2013 R&D revenue totaled $1.5 million and license revenue totaled $1.5 million. In 2012 R&D revenue totaled $2.5 million and license revenue totaled $4.3 million. License and research revenues in 2014 are comparable to 2013 and have decreased compared with 2012 due to the termination of certain partnership agreements with Merck Serono and other undisclosed partners. This correlates with our positioning as a specialty pharma company whereby we select, develop, seek approval for, and commercialize niche branded products and most of the opportunities are self-funded, while exploring development, supply and licensing opportunities for either drug delivery platforms or proprietary products with carefully selected third parties, while not being completely dependent on partnerships for revenues as was the case historically.

R&D revenues in 2014 consisted primarily of $2.3 million from undisclosed partners. R&D revenues in 2013 consisted primarily of $1.5 million from undisclosed partners. R&D revenues in 2012 consisted primarily of $0.7 million from Eagle Pharmaceuticals and $1.8 million from undisclosed partners.

License revenues in 2014 consisted primarily of $0.5 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.

In 2014, product sales and services revenues totaled $11.9 million, $1.0 million in 2013 and $0.6 million in 2012. In 2012 and 2013, product sales include solely 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. In 2014, product sales of $10.2 million relate to Bloxiverz®. As of December 31, 2014, the Company had deferred revenue related to Bloxiverz® of $7.0 million compared to $1.1 million as of December 31, 2013. The market conditions and competition for Bloxiverz® remain volatile with changes in sales price occurring in December 2014. As such revenues are recognized when price is determinable, which occurs when product is sold from the wholesaler to the hospital and the chargeback on such sales can be determined.

The Company launched Vazculep™ in October 2014 and determined that market acceptance of this product had not occurred given such short period of time on the market. In addition sufficient data to determine product returns had not yet been achieved. For the twelve months ended December 31, 2014, the criteria for recognizing the revenue were not met and the Company deferred $2.7 million of revenue of Vazculep™ product sales as of December 31, 2014.

Operating Expenses

The Company had total costs and expenses of $108.6 million in 2014, $57.9 million in 2013 and $17.4 million in 2012.

The terms of acquisition of Éclat 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 in “Item 18. *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 $57.5 million adjustment was accounted in 2014 and $28.1 million in 2013 from the updated fair-value measurement of these liabilities. In addition, in 2014 a non-cash expense of $3.0 million was recognized related to the early repayment of the $12.0 million note. An $11.7 million expense was recognized to reflect the amortization of acquired R&D assets in connection with our marketed product Bloxiverz®. These assets are being amortized straight line over a three year period to the end of 2016.

As in previous years, in 2014 the majority of costs were incurred for R&D purposes. R&D costs totaled $17.3 million in 2014, $16.0 million in 2013 and $14.6 million in 2012. At comparable currency exchange rates, R&D costs increased marginally by $1.3 million in 2014.

Our total R&D expenditures can be split in the following categories:

In millions of U.S. Dollars

	2012	2013	2014
Salaries and employee benefits	9.2	7.7	11.5
Materials and Supplies	1.5	1.1	1.1
Pre-clinical, Clinical, Regulatory and Manufacturing outside services	3.9	8.1	5.8
Grants and R&D Tax credit	(6.7)	(6.2)	(6.0)
Depreciation of facilities and equipment	0.1	0.4	0.4
Other Expenses & Taxes	5.7	4.2	3.6
Stock-based Stock Compensation	0.9	0.7	0.9
Total	**14.6**	**16.0**	**17.3**

The human resources allocated to each drug delivery platform over the past three (3) years are as follows:

Full Time Equivalents	2012	2013	2014
Micropump®	9	9	18
LiquiTime®	1	21	19
Trigger Lock™	3	1	7
Medusa™	50	38	13
Discontinued Operations	59	57	62

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 (3) years are as follows:

In millions of U.S. Dollars		2012	2013	2014
Pre-Clinical	LiquiTime®	-	-	0.1
	Medusa™	0.4	0.2	0.6
	Micropump®	-	0.3	-
Clinical	LiquiTime®	-	-	1.3
	Medusa™	0.3	-	-
Contract Manufacturing	UMD	1.7	5.5	0.9
	LiquiTime®	-	-	1.4
Regulatory	UMD	1.5	1.9	1.6
	LiquiTime®	-	-	0.3

As of December 31, 2014, Flamel had total R&D tax credits receivable of $11.5 million. In 2012 the Company obtained an advance secured against the tax credit generated in 2011 valued at $5.4 million as of December 31, 2014. This advance would normally have been received as a cash payment of $5.9 million in 2015. The Company earned a R&D credit of $5.5million in 2014, $5.8 million in 2013 and $6.5 million in 2012. In 2014, the Company received reimbursement of the 2013 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 tax credit generated in 2014 of $5.5 million will be offset against the tax liability generated in France in 2014 (see note 19 – Income Tax).

The average number of employees dedicated to R&D activities paid by third parties has decreased year over year. This decrease was driven by the reduction of partnerships (for details see “Item 4. *Strategic Alliances*”). The Company has spent $2.0 million on pre-clinical and clinical studies in 2014 compared with $0.5 million in 2013 and $0.7 million in 2012. This increase is the consequence of the advance of our products into clinical development. In 2014, costs of $2.5 million have been incurred on the UMD portfolio for contract manufacturing services and regulatory activities. These costs are associated with the development of products with outside contractors and costs for preparation of the NDA filing of our third UMD product, including meetings with the FDA at key points of the development.

Costs of products and services sold were $3.4 million in 2014, $0.6 million in 2013 and $0.4 million in 2012. These costs relate to the cost of product on sales of Bloxiverz®.

SG&A expenses amounted to $15.7 million in 2014, $13.2 million in 2013 and $14.2 million in 2012. SG&A expenses included stock based compensation expense of $1.8 million in 2014, $1.2 million in 2013 and $1.9 million in 2012. SG&A expenses increased by $2.6 million over 2013 expenses at comparable currency exchange rates. This increase is due to legal costs, post marketing studies requested by the FDA for Bloxiverz®, FDA product fees and advisory costs related to the Pessac Facility divestiture and transfer of our intellectual property from our French entity to our Irish based entity.

Non-Operating Items

Interest income and realized gains on the sale of monetary SICAVs (*Sociétés d’Investissement à Capital Variable*) were $0.9 million in 2014 compared with of $0.3 million in 2013 and $0.6 million in 2012. Interest income has increased due to the increase in cash and marketable securities as a consequence of our successful public offering in March 2014 and subsequent placement of funds received. Interest expense was $5.7 million in 2014, $2.6 million in 2013 and $0.1 million in 2012. The increase in interest expense is due to the $15 million debt financing concluded with Deerfield Management Company L.P. (“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 principal amount and outstanding interest was repaid on both debt financing agreements in M arch 2014 resulting in interest expense of $4.7 million. For details see “Item 10. *Material Contracts”*.

At the time of the debt financing a Royalty Agreement was concluded with Deerfield Management amounting to 1.75% and with Broadfin Healthcare Master Fund amounting to 0.834% on net sales of certain products sold by our US operations, Éclat, subject to required regulatory approvals and sales of these products, until December 31, 2024. For details see "Item 10. *Material Contracts"*.

The Royalty agreements generated non-cash expense of $3.5 million in 2014 and $2.0 million in 2013. The fair value option was elected for the measurement of the Royalty liabilities. For details see "Item 10. *Material Contracts"*.

Foreign exchange gain was $11.7 million in 2014, foreign exchange loss was $0.3 in 2013 and $180,000 in 2012. The exchange gain in 2014 relates primarily to unrealized gain on translation of cash and marketable securities and intercompany receivables denominated in USD benefitting from the increase of the Dollar versus Euro as of December 31, 2014 (+13.6% compared to December 31, 2013). Realized gains and losses are generated by transactions denominated in foreign currencies. 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 2014 amounted $0.04 million compared with $0.6 million in 2013 which consisted of reimbursement of the deductible from a 2007 class action that was dismissed in 2013, and $0.1 million in 2012.

Income tax benefit in 2014 amounted to $1.4 million of which $2.8 million reflects tax benefit of statutory net operating losses generated by the operations in the US partially offset by French business tax expense of $1.5 million. Income tax benefit in 2013 amounted to $11.0 million, reflected 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.

As of December 31, 2014, the Company had $142.2 million net operating loss carry-forwards from French operations and $46.9 million net operating losses carry-forwards from US operations. The carry-forward under French tax law 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 (see note 19 to the Consolidated Financial Statements in "Item 18. *Financial Statements*").

Net Income/Loss

For the year ended December 31, 2014, Flamel reported a net loss from continuing operations of $88.9 million or $2.46 per share and a net loss of $84.9 million or $2.34 per share. For the year ended December 31, 2013, Company reported a net loss from continuing operations of $46.5 million or $1.83 per share and a net loss of $42.9 million or $1.69 per share. For the year ended December 31, 2012, the Company reported a net loss from continuing operations of $4.7 million or $0.19 per share and a net loss of $3.2 million or $0.13 per share. For the year ended December 31, 2014 adjusted net loss was $20.3 million or $0.56 per share and for the year ended December 31, 2013 adjusted net loss was $16.1 million or $0.63 per share.

Flamel is providing below adjusted net income, which is a non-GAAP financial measure. The Company 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 measurement on acquisition liabilities and royalty agreements, impairment of intangible assets, amortization expense of intangible assets, effects of accelerated reimbursement of certain debt instruments and unrealized foreign exchange gains and losses on assets and liabilities denominated in foreign currency and includes operating cash flows associated with the commitments to make earn out payments and royalty payments, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. Flamel'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.

in thousands of U.S. Dollars	Twelve months ended December 31,			
	2013		2014	
GAAP Net income (loss) and diluted earnings (loss) per share	$ (42,925)	$ (1.83)	$ (84,906)	$ (2.46)
Fair value remeasurement of acquisition liabilities	28,135		57,491	
Fair value remeasurement of royalty agreement	1,990		3,525	
Amortization of Intangible R&D Assets	-		11,749	
Accelerated reimbursement of acquisition note	-		3,013	
Accelerated reimbursement of facility agreements	-		4,741	
Tax effects of the above items	(2,416)		(2,338)	
Earn-out acquisition payment payable	(840)		(1,678)	
Royalty payable	-		(249)	
Unrealized foreign exchange (gain)/loss	363		(11,667)	
Adjusted Net Income (Loss) and adjusted diluted earnings (loss) per share,	$ (15,694)	$ (0.62)	$ (20,319)	$ (0.56)

Discontinued Operations

On December 1, 2014, Flamel divested its Pessac Facility to Recipharm AB ("Recipharm"). Under the divestiture agreement, Recipharm paid the Company $13.2 million. This divestiture agreement allowed Flamel to use the development and manufacturing capabilities of the acquired Pessac Facility and to use Recipharm's other facilities for the development or manufacture of its proprietary pipeline if needed. The Company transferred to Recipharm the Supply Agreement pertaining to Coreg CR® and delegated the royalty payments under the License agreement with GSK as of December 1, 2014. The divestiture of the Pessac Facility has been classified as Discontinued Operations for the twelve month periods ended December 31, 2014, 2013 and 2012 (see note 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*").

The divestiture of the Pessac Facility has been classified as Discontinued Operations for the twelve month periods ended December 31, 2014, 2013 and 2012, with net income attributable to such Discontinued Operations of $4.0 million for 2014, $3.6 million for 2013 and $1.4 million for 2012. The gain on sale of the Pessac Facility amounted to $5.0 million.

The summary statement of operations of the Discontinued Operations for each of the last three (3) years is as follows:

In thousands of U.S. Dollars	Fiscal Year		
	2012	2013	2014
Revenues	$ 18,570	$ 18,265	$ 14,967
Income (loss) from operations	1,550	3,667	(875)
Gain (loss) on disposal	-	-	5,007
Interest Expense	(11)	(9)	(4)
Income taxes	(27)	(74)	(110)
Income (loss) from discontinued operations, net of tax	$ 1,512	$ 3,584	$ 4,018

Carrying amounts of major classes of assets and liabilities classified as held for sale in the statement of financial position as of December 31, 2013 and 2014 are as follows:

In thousands of U.S. Dollars	December 31, 2013	December 31, 2014
Accounts receivable, net	$ -	$ 730
Inventories	1,352	-
Total major classes of current assets of the discontinued operations	1,352	730
Net Property, plant and equipment	15,044	-
Total major classes of non current assets of the discontinued operations	15,044	-
Total assets of the disposal group classified as held for sale	**16,396**	**730**
Current portion of capital lease obligations	69	
Accounts payable	-	168
Other current liabilities	832	-
Total major classes of Current Liabilities of the discontinued operations	901	168
Capital lease obligations, less current portion	88	-
Other liabilities	7,626	-
Total major classes of Non-Current Liabilities of assets Held for sale	7,714	-
Total liabilities of the disposal group classified as held for sale	**8,615**	**168**

Concurrently with the divestiture of the Pessac Facility, Recipharm made an investment of $13.0 million in Flamel's stock at a purchase price equal to the trailing 20-day average price.

Liquidity and Capital Resources

On December 31, 2014, the Company had $39.8 million in cash and cash equivalents and $53.1 million in marketable securities compared with $6.6 million in cash and cash equivalents and $0.4 million in marketable securities on December 31, 2013. The increase in the level of cash and cash equivalents and marketable securities results from the public offering in March 2014 generating net proceeds of approximately $113.6 million, proceeds from the divesture of the Pessac Facility to Recipharm in December 2014, the investment by Recipharm of $13.0 million in Flamel's stock in December 2014, offset by the reimbursement of substantially all outstanding long-term debt with a principal of $32 million and financing of R&D investment for the development of proprietary products based on our drug delivery platforms, and working capital for launch of Bloxiverz® and Vazculep™.

Net cash used in operating activities was $10.6 million as of December 31, 2014, compared with $20.7 million as of December 31, 2013, and $23.1 million as of December 31, 2012. As of December 31, 2014 net cash used in operating activities reflected a net loss of $84.9 million, offset by non-cash movements of $66.1 million, including $63.8 million of expenses on fair value remeasurement of acquisition and royalty liabilities and impact of accelerated reimbursement of long-term debt, ($2.8) million tax benefit which will be set off against future taxable income, $14.1 million of depreciation on property and equipment and amortization of intangible assets, ($5.0) million of gain on disposal of the Pessac Facility, $2.7 million relative to stock compensation expense and ($6.3) million of unrealized exchange gain from intercompany receivables denominated in USD. Movement in working capital year on year generated an increase in cash of $8.2 million driven by a decrease in accounts receivable of $3.4 million, a decrease in the R&D tax credit of $13.2 million and an increase in accounts payable and other current liabilities of $8.1 million, principally due to the tax liability generated as a result of the move of intellectual property from France to Ireland offset by the 2014 R&D tax credit of $5.5 million. The cash increase generated by the former is offset by a reduction in cash resulting from an increase in inventory of $3.1 million due to inventory build for Bloxiverz® and Vazculep™, an increase in prepayments of $2.3 million decrease in long term liabilities and increase in long term assets relative to a deferred tax charge for a total of $10.7 million.

Net cash provided by investing activities was ($43.1) million in 2014, compared with $6.0 million in 2013. Investing activities included proceeds from the sale of marketable securities for $13.7 million and purchase of marketable securities for $68.3 million. In 2014 the Company implemented a revised investment policy and engaged Morgan Stanley as its primary portfolio manager. The revised investment policy was implemented to leverage an increased return on funds, to the extent the Company is expected to generate positive cash flow in the near term, while maintaining a low risk profile and diversity across different investment categories (fixed income, low risk managed fund or equity funds). In 2014 $1.7 million was spent in the purchase of property and equipment compared with $1.0 million in 2013. In 2014, $13.2 million was received as proceeds from the divestiture of the Pessac Facility. 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 $96.0 million in 2014 and includes $132.3 million of proceeds from issuance of ordinary shares and warrants (net of tax effect on issuance costs) primarily in connection with the underwriter public offering fulfilled in March 2014 and issuance of shares to Recipharm in December 2014, repayment of an amount of $34.4 million including repayment of principal and interest 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, as well as the reimbursement of the advance of $7.1 million received in the second quarter of 2011 from Oseo, secured against the R&D tax credit of $7.7 million earned in 2010. Financing activities include earn-out payments made to Deerfield for a total of $1.4 million. 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 R&D tax credit of $6.1 million earned in 2011.

Since its inception, the Company's operations have consumed substantial amounts of cash and may continue to do so. Flamel believes that ongoing research and product development programs are adequately funded and believe current working capital to be sufficient for the Company's present requirements, including commercial launch of products from the Éclat pipeline. Flamel also believes current financial resources and cash from various grants, 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, 2014, the Company held marketable securities classified as available-for-sale and recorded at fair value. Total marketable securities totaled $53.1 million as of December 31, 2014 and $0.4 million as of December 31, 2013.

As of December 31, 2014, the Company had loans of $1.9 million from Oseo, $1.8 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. Flamel has evaluated the debt due for the purchase of Éclat at $104.3 million as of December 31, 2014. The obligations relative to the acquisition arise from the commitment by Flamel US Holdings, to pay 20% of any gross profit generated by certain Éclat products and two warrants to purchase a total of 3,300,000 ADSs. The Company has evaluated the debt due on the Royalty Agreement concluded with Deerfield management at $6.8 million and the debt due on the Royalty Agreement concluded with Broadfin Healthcare Master Fund at $3.3 million, as of December 31, 2014. 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 of $15.0 million and Broadfin Facility of $5.0 million were fully repaid in March 2014 as described above.

The contractual cash obligations of the Company as of December 31, 2014 are as follows:

In thousands of U.S. Dollars		Payments Due by Period				
		Total	Less than 1 years	1 to 3 years	3 to 5 years	More than 5 years
Long Term Debt Obligations	Note 16	$ 119,341	$ 45,722	$ 29,997	$ 22,309	$ 21,313
Operating Lease Obligations	Note 22	829	732	97		
Other Long-term Liabilities reflected on the Registrant's Balances Sheet under GAAP	Note 20	217	55		12	150
Other contractual Cash Obligations **[1]**		22,694	4,296	8,592	9,806	-
Total Contractual Cash Obligations		$ 143,081	$ 50,805	$ 38,686	$ 32,127	$ 21,463

[1] Relates to purchase commitments including commitment to acquire services from Recipharm for a total of $22.5 million for a five year period commencing January 1, 2015.

Off-Balance Sheet Arrangements

As of December 31, 2014, the Company has no off-balance sheet arrangements.

ITEM 6. Directors, Executive Officers, Senior Management and Employees

Company Governance

In accordance with French law governing a *Société Anonyme*, the Company is managed by its Board of Directors and by its *Directeur Général* (or "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 (5) *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-five.

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.

Directors and Board of Directors

The following table sets forth the name and position of the directors of the Company as of December 31, 2014.

Name	Position	Year of Initial Appointment
Craig Stapleton (1) (2) (3) (4)	Non-Executive Chairman of the Board of Directors	2011
Michael S. Anderson	Chief Executive Officer and Director	2012
Guillaume Cerutti (2) (3)	Director	2011
Dr. Francis J.T. Fildes (1) (2)	Director	2008
Christophe Navarre (1) (3)	Director	2014
Ben Van Assche (1) (2) (3)	Director	2014

(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 Non-Executive Chairman of the Board of Directors in 2014

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

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

- Michael S. Anderson, former Chief Executive Officer of Éclat, appointed Chief Executive Officer of the Company, effective March 13, 2012

- 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;

- Ben Van Assche is a member of the international jury that assists the government of the Walloon Region in its policy towards clusters of competitiveness, in particular the BioWin health cluster;

- Christophe Navarre is Board Member of the Comité Colbert, Member of the Heineken Supervisory Board and Chairman of the FEVS (Fédération des Exportateurs de Vins et Spiritueux).

The term of office of each of the directors expires at the year 2015 ordinary shareholders meeting. With the exception of Mr. Anderson, all of the directors are independent as defined in NASDAQ Marketplace Rule 5605 (a)(2).

Board Practices

Non-executive Directors of the Company receive fees for their services and are entitled to subscribe for warrants (as described in Note 18.3 to our Consolidated Financial Statements in "Item 18. *Financial Statements*"). Directors' fees and warrants are proposed by the Board of Directors and are submitted for the approval of shareholders at the ordinary 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 Board of Directors has the ability to determine its own internal rules for certain procedures. 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 twelve (12) consecutive months have 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.

Compensation Committee. The Board has a Compensation Committee comprised of solely independent directors, namely Francis Fildes (Chairman), Ambassador Craig Stapleton, Christophe Navarre and Ben Van Assche. 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 Compensation Committee has a written charter.

Audit Committee. The Board has an Audit Committee comprised of solely independent directors, namely Guillaume Cerutti (Chairman), Francis Fildes, Ambassador Craig Stapleton, and Ben Van Assche. 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 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. See also "Item 16C. *Audit Committee's Pre-Approval Policies and Procedures*").

Nominating and Corporate Governance Committee. The Board has a Nominating and Corporate Governance Committee, composed of solely independent directors, namely Ben Van Assche (Chairman), Guillaume Cerutti, Christophe Navarre, and Ambassador Craig Stapleton. The Nominating and Corporate Governance Committee has a written charter.

Chief Executive Officer. The Chief Executive Officer of Flamel has full executive authority to manage the affairs of Flamel and its subsidiaries, 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 dismiss, at any time, the Chief Executive Officer. The Chief Executive Officer is appointed for a term of one (1) 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 Executive Officers

During 2014, the amount of compensation paid or accrued for the benefit of the top five executive officers of the Company and its subsidiaries for services in all capacities was $1,797,457.

On June 24, 2014, a shareholders' meeting approved a total amount of annual attendance fees to be allocated to the Board of 325,000 Euros, of which 243,750 Euros was subsequently distributed. For the fiscal year 2014 a total amount of 170,000 Euros ($225,896) 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 and Senior Management

The following table sets forth the name and position of the executive officers and senior managers of the Company.

Name	Position	Year of Initial Appointment
Michael S. Anderson	Chief Executive Officer ("CEO")	2012
Jean Chatellier	Vice President, Alliance Management and Licenseing	2010
Siân Crouzet	Principal Financial Officer	2005
Christian Kalita	Directeur Général Délégué Pharmacien Responsable (Chief Pharmacist)	2005
Steve A. Lisi*	Senior Vice President, Business and Corporate Development	2012
Scott Macke	Vice President, Supply Chain and Operations	2012
Séverine Martin	Director of Human Resources and Corporate Projects	2014
David Monteith	Vice President, Research and Development	2014
Phillandas T. Thompson	Senior Vice President and General Counsel	2013

* Departed the Company on April 7, 2015.

The individuals constituting the Company's executive officers and senior management have the following background:

Mr. Michael S. Anderson has been Chief Executive Officer since March 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.

Dr. Jean Chatellier has been Vice President of Alliance Management & Licensing since October 2010. He has over 15 years of experience in business development and alliance management in the pharmaceutical and biotechnology industry. He served previously as Director of Business Development at Micromet (now Amgen) and added other business development activities for Crucell (now Johnson & Johnson) and Viropro. He also was the founder and CEO of Avidis (now Imaxio), and was CEO and liquidator of Aptanomics. Dr. Chatellier obtained a binational Ph.D. in Protein Engineering from the universities of Strasbourg (France) and Montréal (Canada), and performed post-doctoral research with Sir Allan Fersht and Sir Greg Winter at the Center for Protein Engineering of the Medical Research Council, Cambridge UK.

Mrs. Sian Crouzet has been Principal Financial Officer since March 2008. She has over 18 years of experience in finance. She previously worked as Financial Controller at the French subsidiary of McCormick & Company Inc. Mrs. Crouzet spent five years an external auditor with Ernst and Young in 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 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 has been Senior Vice President, Business and Corporate Development since June 2012 until April 7, 2015. Previously, he served as partner at Deerfield Management, a leading global healthcare focused hedge fund (2007 - 2012). Prior to that, he was founder and managing member/portfolio manager at Panacea Asset Management LLC (New York; 2005 – 2007), and healthcare portfolio manager at Millennium Partners (New York; 2002 – 2005). Between 1994 and 2002, Mr. Lisi served as analyst in several companies. Mr. Lisi is a graduate of Pepperdine University (Malibu, California).

Mr. Scott Macke has been Vice President, Supply Chain and Operations since March 2012. He has over 20 years of experience in the pharmaceutical industry with direct involvement specific to both API and drug product development and commercialization. Prior to assuming his current position, he held positions of increasing leadership with Éclat Pharmaceuticals, L.L.C., most recently as the Chief Operating Officer. Prior to Éclat, he served as Sr. Director of Project Management at KV Pharmaceutical (2007 – 2010) and held various technical and operational positions at Mallinckrodt Pharmaceuticals (1993 – 2007). Mr. Macke holds undergraduate degrees in Biology and Chemistry from Missouri State University and a Master of Business Administration from the John E. Simon School of Business at Maryville University.

Mrs Séverine Martin was appointed Director of Human Resources and Corporate Projects in August 2014. She has over 13 years consulting and Human Resources experience with strong involvement in strategy implementation and change management. She held management consulting positions, most recently with Segeco Consulting. Previously, she worked as Director of Human Resources at Segula Technologies after having held leadership HR roles with large organizations in a variety of sectors. Mrs Martin earned an Executive MBA from HEC in Paris. She is also graduated is Human Resources Management from the Institute of Business Administration of Nancy (France).

Dr. David Monteith was appointed Senior Vice President Research & Development in October 2014. He has over 25 years' experience working in the pharmaceutical and has concentrated most of his career in the areas of drug delivery and pharmaceutical drug product development, mostly in senior leadership roles. He has spent the last 14 years in the USA with Schering-Plough and Merck and most recently served as Associate Vice President of Pharmaceutical Development for Emerging Markets at Merck & Co. He has also worked for Syntex and Merck-Lipha. Dr. Monteith is a graduate in Pharmacy from the University of Strathclyde, Glasgow where he also obtained his Ph.D. from the Department of Pharmaceutics. He later also received a MBA from the University of Warwick, UK.

Mr. Phil Thompson has been 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 is a member of the New York Bar, the Missouri Bar, and the Minnesota Bar and has several other professional affiliations. Mr. Thompson earned a B.A. from Washington University in St. Louis and is also a graduate of the University of Michigan Law School (Juris Doctor) and the University of Michigan Business School (Master of Business Administration).

Options to Purchase Securities from the Company

On June 24, 2014, the shareholders of the Company authorized the issuance of up to 300,000 warrants reserved to a category of beneficiaries comprising directors who are neither authorized agents nor employees of the company, but including the Chairman of the Board of Directors of which 298,000 have been subscribed for.

On June 24, 2014 the shareholders of the Company authorized the creation of a share option plan (the '2014 Plan'), which authorizes the Board of Directors to issue options to subscribe for up to 1,700,000 Shares. This authorization supersedes and cancels previous authorizations granted to the Board of Directors by the shareholders for which options had not been granted as of June 24, 2014. The 2014 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 2014 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 2014 Plan are exercisable up to ten years from the date of grant.

On June 24, 2014, the shareholders of the Company authorized the issuance of 250,000 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, 2014 to March 31, 2015

	Stock Options	Exercise Price in Euros	Exercise Price in USD [1]	Expiration	Free Share Awards
Anderson	200,000	13.15	16.30	December 2024	50,000
Chatellier	30,000	13.15	16.30	December 2024	8,000
Crouzet	50,000	13.15	16.30	December 2024	10,000
Kalita	4,000	13.15	16.30	December 2024	2,500
Lisi*	100,000	13.15	16.30	December 2024	5,000
Macke	50,000	13.15	16.30	December 2024	10,000
Martin	15,000	13.15	16.30	December 2024	3,000
Monteith	110,000	13.15	16.30	December 2024	2,500
Thompson	95,000	13.15	16.30	December 2024	10,000

[1] Historical value at date of grant.
* Departed the Company on April 7, 2015.

Employees

As of December 31, 2014, Flamel had 109 full-time employees and an average of 210 full-time employees over 2014. The divestiture of the Pessac Facility resulted in the transfer of 107 employees on December 1, 2014 to Recipharm. The following table sets forth the average number of employees for each of the last three years based on their principal geographic locations.

Annual average Full-time Employees

Year End	Venissieux [1]	Pessac [2]	U.S. [3]	Ireland [4]	Total
2012	125	131	8		264
2013	118	124	9		251
2014	97	111	11	1	220

[1] Primarily engaged in administrative and R&D activities
[2] Primarily engaged in pharmaceutical development and manufacturing activities
[3] Primarily engaged in administrative, commercial and marketing activities
[4] Primarily engaged in licensing, quality, regulatory, supply chain and clinical activities

The Company's future will depend on its ability to attract and retain highly qualified personnel. Flamel believes that its relationships with employees 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, executive officers and senior managers as of the date indicated:

OWNERSHIP OF SHARES AS OF MARCH 31, 2015

Name	Shares Owned	% of Ordinary Shares Outstanding [1]	Warrants	Number of Options	Exercise Price in Euros €	Exercise Price in USD [2] $	Expiration	Total Free Share awards outstanding	Total	% of shares oustanding and unexercised equity instruments [3]
Stapleton	337,451	0.84%	45,000		4.58	6.14	June 2017			
			100,000		10.94	14.54	June 2018		482,451	1.03%
Cerutti	50,001	0.12%	45,000		4.58	6.14	June 2017			
			60,000		10.94	14.54	June 2018		155,001	0.33%
Fildes	1	0.00%	45,000		4.58	6.14	June 2017			
			46,000		10.94	14.54	June 2018		91,001	0.19%
Navarre			46,000		10.94	14.54	June 2018		46,000	0.10%
Van Assche			46,000		10.94	14.54	June 2018		46,000	0.10%
Anderson	61,250	0.15%		275,000	5.25	6.93	March 2022			
				80,500	3.00	4.07	February 2023			
				200,000	13.15	16.30	December 2024	50,000	666,750	1.42%
Chatellier	26,000	0.06%		75,000	4.89	6.75	October 2020			
				7,000	3.00	4.07	February 2023			
				20,000	5.35	7.36	December 2023			
				30,000	13.15	16.30	December 2024	18,000	176,000	0.37%
Crouzet	54,560	0.14%		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			
				50,000	13.15	16.30	December 2024	20,000	228,300	0.49%
Kalita	34,500	0.09%		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			
				4,000	13.15	16.30	December 2024	7,500	128,500	0.27%
Lisi *	117,000	0.29%		275,000	4.09	5.01	July 2022			
				25,000	3.00	4.07	February 2023			
				95,000	5.35	7.36	December 2023			
				100,000	13.15	16.30	December 2024	7,500	619,500	1.32%
Macke	-			7,500	3.00	4.07	February 2023			
				20,000	5.35	7.36	December 2023			
				50,000	13.15	16.30	December 2024	27,000	104,500	0.22%
Martin	-			15,000	13.15	16.30	December 2024	3,000	18,000	0.04%
Monteith	-			110,000	13.15	16.30	December 2024	2,500	112,500	0.24%
Thompson	-			100,000	5.35	7.36	December 2023			
				95,000	13.15	16.30	December 2024	10,000	205,000	0.44%

[1] % of total shares outstanding of 40,253,014 as of March 31, 2015.
[2] Historical value at date of grant.
[3] % of total shares outstanding and unexercised warrants, free shares, stock options.
* Departed the Company on April 7, 2015.

ITEM 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth as of March 31, 2015 the percentage of Ordinary Shares owned by Deerfield Capital Management L.P. ("Deerfield") and Broadfin Capital LLC. ("Broadfin"), 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/Gs on file with the SEC as of March 31, 2015. Percentages are calculated based on 40,253,014 total shares, which was the total number of shares outstanding as of March 31, 2015.

Identity of Person or Group	Amount of Ordinary Shares Owned	Percentage of Class
Deerfield Capital L.P	5,258,475(1)	13.06%
Broadfin Capital LLC	5,153,190(2)	12.80%

1) Information as to the amount and nature of beneficial ownership was obtained from the Schedule 13G/A filed with the SEC on March 17, 2015 by Deerfield. Deerfield shares beneficial ownership with Deerfield Special Situations International Master Fund LP in respect of 684,626 Ordinary shares, with Deerfield Special Situations Funds L.P. in respect of 843,559 Ordinary Shares, Deerfield Private Design Fund II L.P. in respect of 1,738,315 Ordinary Shares, Deerfield Private Design International II in respect of 1,991,975 Ordinary Shares, and Deerfield Management Company L.P., James E Flynn and Deerfield Special Situations Fund International Limited in respect of all 5,258,475 Ordinary Shares. Such reported amount excludes warrants to purchase ADSs representing 3,300,000 ordinary shares of Flamel held by Breaking Stick Holdings, L.L.C. (formerly Éclat Holdings), the manager of which is Deerfield Management Company, L.P. 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 17, 2015 by Broadfin. As of the close of business on December 31, 2014, Broadfin beneficially owned 5,153,190 ADRs. The address of Broadfin is 300 Park Avenue, 25th Floor, New York, New York 10022.

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, 2015, the Company has Ordinary shareholders of record including the Bank of New York Mellon. Approximately 97.7 % of the Company's outstanding shares are represented by American Depositary Shares (ADS). Approximately 3% 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 (3) 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%
	February 17, 2015	12.82%
Deerfield Capital L.P.	August 31, 2011	4.90%
	December 5, 2011	5.01%
	January 4, 2012 **[1]**	11.32%
	March 17, 2015	13.08%
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, 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 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 R&D 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.

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.

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.

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 and the obligations under the Royalty agreement (see below) 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.

Interests of Experts and Counsel

Not applicable

ITEM 8. Financial Information

Financial Statements

The financial statements contained in this Annual Report on Form 20-F 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.

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 Pharmaceuticals LLC. For more information about this transaction see "Item 10. *Additional Information – Material Contracts"*.

In March 2014, 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.

In December 2014, the Company divested its Pessac Facility to Recipharm AB. For more information about this transaction, see "Item 10. *Additional Information – Material Contracts*".

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 Mellon is the Depositary for the ADRs. As of December 31, 2014, there were 38,987,732 ADSs outstanding in the United States and there were 30 holders of ADSs on record. As of December 31, 2014, there were 40,191,264 Shares outstanding. In 2014, the number of ADSs and shares outstanding was significantly increased (i) by 12.6 million ADSs, as a result of the public offering completed in March 2014, (ii) by 1,026,364 ADS as a result of Recipharm's investment completed in December 2014and (iii) by 923,750 ADS as a result of the exercise of stock warrants and stock options during the year ending on December 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**
2010	9.60	6.02
2011	6.97	3.85
2012	7.67	2.99
2013	8.21	3.25
2014	18.89	8.15

	Price Per ADS (U.S.$)	
Quarter Ended	**High**	**Low**
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
2nd Quarter, 2014	15.17	9.94
3rd Quarter, 2014	15.78	13.21
4th Quarter, 2014	18.89	11.76
1st Quarter, 2015	18.47	11.50

	Price Per ADS (U.S.$)	
Month Ended	**High**	**Low**
October 31, 2014	14.24	12.07
November 30, 2014	14.33	11.76
December 31, 2014	18.89	14.34
January 31, 2015	18.47	11.5
February 28, 2015	15.30	13.29
March 31, 2015	18.28	15.72

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-five.

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 the Company 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"*. We have also entered into material contracts in connection with our divestiture of the Pessac Facility. 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-developed product is approved by the FDA. After FDA approval 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 and Royalty Agreements

The Deerfield Facility Agreement was effective as of December 31, 2012, and allowed Flamel to use the funds for working capital, including continued investment in its R&D 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.

The Deerfield 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 UMD products in the United States and to market the UMD products after receiving such approvals.

Broadfin Facility and Royalty Agreements

The Broadfin Facility Agreement was effective as of December 3, 2013 and allowed Flamel to use the funds for working capital, including continued investment in its R&D 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 Agreement, 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 and any of its affiliates until December 31, 2024.

Pessac Facility Divestiture Agreements

On November 26, 2014, we entered into an Asset Purchase Agreement with Recipharm for the sale of our Pessac Facility. The sale of the Pessac Facility was completed on December 1, 2014. Under the Asset Purchase Agreement, Recipharm paid Flamel $13.2 million in cash. Additionally, in a separate transaction, Recipharm made an investment of $13.0 million in our stock. As part of the divestiture, we also entered into a Master Service Agreement, a Service Agreement and a Supply Agreement under which we retain access to the development and manufacturing capabilities of the Pessac Facility and gain the use of any of Recipharm's other facilities for the development and/or manufacture of our products. Also included in the divestiture was the transfer of the Supply Agreement for Coreg CR® with GSK and, transfer and assignment of all rights, titles and interests in the royalties of the License Agreements between Flamel and GSK.

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 might 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 resident individuals.

In addition, anti-avoidance rules regarding transactions concluded with non-cooperative jurisdictions provide that dividends distributed to non-cooperative jurisdictions residents as of January 1, 2013, as per the criteria defined by the French tax code, would be subject to a 75% withholding tax.

The following countries were considered by the French tax authorities as non-cooperative jurisdictions in 2014:

Botswana	Guatemala	Montserrat	Niue
Brunei	Marshall Islands	Nauru	British Virgin Islands

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 favorable 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 subject to exceptions (see above). 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 (BOI-INT-DG-20-20-20-20 n°100, 12-09-2012). 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 be subject to French gift or inheritance tax, and possibly in the US in the case of US citizens 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, 2014 revenues from continuing operations denominated in U.S. dollars represented 98.6% 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, 75.2 % of the Company's cash and cash equivalents, totaling $39.8 million as of December 31, 2014, and 39% of the Company's marketable securities, totaling $53.1 million, as of December 31, 2014, 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 $4.6 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 $5.6 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, 2014. 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, 2014.

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, 2014 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, 2014. Management based this assessment on criteria for effective internal control over financial reporting described in "Internal Control – Integrated Framework (COSO 2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management determined that, as of December 31, 2014, 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 accounting firm, as stated in their report on the Company's internal control over reporting as of December 31, 2014, 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 Guillaume Cerutti and Craig Stapleton are 'audit committee financial experts,' as defined by the rules of the SEC. Messrs. Cerutti and Stapleton 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 2014:

Fee Category	Fiscal 2013 Fees (Euros)	Fiscal 2014 Fees (Euros)
Audit Fees	263,000	409,000
Audit-Related Fees	8,500	79,500
Tax Fees		
All Other Fees		
Total Fees	**271,500**	**488,500**

All fees were billed in Euros. Using the average exchange rate of 1.3282 U.S dollars per Euro for 2013, and 1.3288 U.S dollars per Euro for 2014 audit fees equaled $360,606 for Fiscal 2013 and $398,640 for Fiscal 2014.

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 2014 and 2013 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. On June 24, 2014, the Shareholders decided to renew the office of PricewaterhouseCoopers audit as permanent auditor and Mr. Etienne Boris as deputy auditor for six (6) years, expiring at the end of the Ordinary Shareholders' Meeting to be held to approve the financial statements for the financial year ending on December 31, 2019.

See also "Item 6. *Directors, Executive Officers,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 follows its home country requirements in lieu of NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the required quorum for ordinary resolutions is one fifth (20%) and for extraordinary resolutions is one fourth (25%) of the total outstanding shares represented in person or by proxy or expressed by postal vote. 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. 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 extraordinary general meeting.

The Company also follows its home country requirements relating to the solicitation and provision of proxy statements in lieu of 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 and written notice, which notice states the requirements for admission to the meeting. Shareholders will be admitted to the General Meeting whatever the number of shares they hold, provided they are owner of registered shares and their shares have been registered in a share account held by the Company at least one day prior to the date of the meeting. Holders of ADS shall take part in the General Meeting by voting by post provided that their shares have been registered in a bearer share account held by an accredited banking or financial intermediary. Holders of registered shares may take part in the General Meeting by attending the Meeting in person, appointing a proxy of their choosing to represent them or voting by post.

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 subsequently 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-40

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 **(5)**
4.10*	Broadfin Royalty Agreement, dated as of December 3, 2013 **(5)**
4.11	Asset Purchase Agreement by and among Flamel Technologies and Recipharm Pessac, dated November 26, 2014 (filed herewith)
4.12	Master Agreement on Supply of Services and Products by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)

Exhibit Number	(Continued) Description
4.13	Service Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)
4.14	Supply Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)
4.15*	Membership Interest Purchase Agreement by and among Éclat Holdings LLC., Éclat Pharmaceuticals LLC., Flamel Technologies S.A., and Flamel US Holdings Inc., dated March 13, 2012 (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)
101.1NS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

(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.
(5) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014
***** 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.

FLAMEL TECHNOLOGIES S.A.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Flamel Technologies SA

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive income, shareholders' equity and cash flows present fairly, in all material respects, the financial position of Flamel Technologies SA and its subsidiaries at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in *Internal Control - Integrated Framework (2013)* 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 under Item 15. 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, 2015

PricewaterhouseCoopers Audit

Represented by
/s/ Nicolas Brunetaud
Nicolas Brunetaud

FLAMEL TECHNOLOGIES S.A.

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

	Note	December 31, 2013	December 31, 2014
ASSETS			
Current assets:			
Cash and cash equivalents	8	$ 6,636	$ 39,760
Marketable securities	9	401	53,074
Accounts receivable (net of allowance of $144 and $127 at December 31, 2013 and 2014 respectively)		6,204	1,679
Inventory	10	2,410	6,729
Research and development tax credit receivable current portion	19	14,139	5,932
Prepaid expenses and other current assets	11	2,481	4,418
Total current assets from continuing operations		$ 32,271	$ 111,592
Total current assets from Assets held for sale	6	$ 1,352	$ 730
Goodwill	13	18,491	18,491
Property and equipment, net	12	2,391	1,776
Intangible assets, net	13	40,139	28,389
Other assets:			
Income tax deferred charge	19		13,102
Research and development tax credit receivable less current portion	19	6,410	-
Other long-term assets from continuing operations		154	125
Total long-term assets from continuing operations		$ 67,585	$ 61,883
Total long term from assets held for sale	6	$ 15,044	$ 0
Total assets including "assets held for sale"		**$ 116,252**	**$ 174,205**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Current portion of long-term debt	16 - 24	19,194	42,332
Current portion of capital lease obligations		16	13
Accounts payable		5,099	8,024
Deferred revenue	4	1,264	1,336
Advances from customers		116	-
Accrued expenses	14	6,527	5,667
Other current liabilities	15	7,478	5,659
Income tax payable	19	-	7,643
Total current liabilities from continuing operations		39,694	70,674
Total current liabilities from liabilities held for sale		901	168
Long-term debt, less current portion	16	66,320	76,135
Capital lease obligations, less current portion		15	-
Deferred tax liabilities	19	2,806	-
Other long-term liabilities	15-20	8,314	2,333
Total long-term liabilities from continuing operations		77,455	78,468
Total long-term liabilities from liabilities held for sale		7,714	0
Shareholders' equity :			
Ordinary shares: 25,612,5500 issued and outstanding at December 31, 2013 and 40,191,264 at December 31, 2014 (shares authorised 52,683,254) at nominal value of 0.122 euro	18	3,746	6,188
Additional paid-in capital		211,473	346,582
Accumulated deficit		(235,546)	(320,452)
Accumulated other comprehensive income (loss)		10,815	(7,423)
Total shareholders' equity		(9,512)	24,895
Total Liabilities and shareholder's equity including held for sale		**$ 116,252**	**$ 174,205**

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)

	Note	Year ended December 31, 2012	2013	2014
Revenue:				
License and research revenue	3	$ 6,724	$ 3,026	$ 2,782
Product sales and services	4	$ 560	983	11,920
Other revenues		$ 250	170	73
Total revenue		7,534	4,179	14,775
Costs and expenses:				
Cost of products and services sold		(400)	(562)	(3,383)
Research and development	5	(14,558)	(15,966)	(17,298)
Selling, general and administrative		(14,153)	(13,216)	(15,698)
Fair value remeasurement of acquisition liabilities, incl. related parties	2-16-24	18,834	(28,135)	(57,491)
Impairment of assets	13	(7,170)	-	-
Amortisation of intangible R&D assets	13	-		(11,749)
Acquisition note expenses, incl. related parties	24	-		(3,013)
Total		(17,447)	(57,879)	(108,632)
Income (loss) from operations		(9,913)	(53,700)	(93,857)
Interest expense	9-16-24	(118)	(2,602)	(5,747)
Interest expense on debt related to the royalty agreement with related parties	16	-	(1,990)	(3,525)
Interest income	9	640	254	963
Foreign exchange gain (loss)	1	(180)	(288)	11,871
Other Income		102	573	(36)
Income (loss) before income taxes		(9,469)	(57,753)	(90,331)
Income tax	19	4,729	11,244	1,407
Net income (loss) from continuing operations		(4,740)	$ (46,509)	(88,924)
Net income from discontinued operations		$ 1,512	$ 3,584	4,018
Net income (loss)		(3,228)	(42,925)	(84,906)
Earnings (loss) per ordinary share (basic)	19			
Continuing operations		$ (0.19)	$ (1.83)	$ (2.45)
Discontinued operations		$ 0.06	$ 0.14	$ 0.11
Net income (loss)		$ (0.13)	$ (1.69)	$ (2.34)
Earnings (loss) per share (diluted):	19			
Continuing operations		$ (0.19)	$ (1.83)	$ (2.45)
Discontinued operations		$ 0.06	$ 0.14	$ 0.11
Net income (loss)		$ (0.13)	$ (1.69)	$ (2.34)
Weighted average number of shares outstanding (in thousands) :				
Basic		25,135	25,450	36,214
Diluted		25,135	25,450	36,214

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,	
	2013	**2014**
Net loss	$ (42,925)	$ (84,906)
Other comprehensive income (loss):		
Net foreign currency translation gain (loss)	561	(18,040)
Unrealized gain (loss) on Marketable Securities		(198)
Other comprehensive income (loss), net of tax	561	(18,238)
Comprehensive loss	$ (42,364)	$ (103,144)

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, 2012	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)
Subscription of warrants			351			351
Issuance of ordinary shares on capital raise	12,400,000	2,099	113,133			115,232
Issuance of ordinary shares to Recipharm AB	1,026,364	156	12,894			13,050
Issuance of ordinary shares on exercise of stock options or warrants	1,001,750	164	5,861			6,025
Issuance of ordinary shares on vesting of free shares	150,600	24	(24)			-
Stock-based compensation expense			2,893			2,893
Net loss				(84,906)		(84,906)
Other comprehensive income (loss)					(18,238)	(18,238)
Comprehensive loss						$ (103,144)
Balance at December 31, 2014	40,191,264	$ 6,188	$ 346,581	$ (320,452)	$ (7,423)	$ 24,895

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,		
	2012	**2013**	**2014**
Cash flows from operating activities:			
Net income (loss)	$ (3,228)	$ 42,925)	$ (84,906)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of property and equipment and intangible assets	3,183	3,062	14,141
Loss (gain) on disposal of property and equipment	(37)	14	(4,952)
Unrealized exchange gain	-	-	(6,252)
Gains on sales of marketable securities	(6)	-	-
Grants recognized in other income and income from operations	(975)	(676)	(589)
Remeasurement of acquisition liabilities and royalty agreements (Note 21)	(18,834)	28,135	60,503
Interest expenses on debt related to the royalty agreement including related party (Note 24)	-	1,990	3,319
Impairment of assets (Note 13)	7,170	-	-
Calculated interest on amortized method	-	712	-
Change in deferred tax (Note 19)	(4,758)	(11,320)	(2,806)
Stock compensation expense (Note 7)	3,040	2,029	2,690
Increase (decrease) in cash from:			
Accounts receivable	2,610	(511)	3,426
Inventory (Note 10)	176	(2,186)	(3,112)
Prepaid expenses and other current assets (Note 11)	800	315	(2,330)
Research and development tax credit receivable	(6,642)	665	13,210
Accounts payable	(613)	1,318	1,092
Deferred revenue	(4,984)	(14)	(55)
Accrued expenses	(742)	1,211	(265)
Other current liabilities	(682)	(517)	6,998
Other long-term assets and liabilities	1,383	(1,977)	(10,730)
Net cash used in operating activities	(23,139)	(20,676)	(10,618)
Cash flows from investing activities:			
Purchases of property and equipment	(1,069)	(1,029)	(1,728)
Proceeds from disposal of property and equipment (Note 6)	67	1,007	13,242
Proceeds from sales of marketable securities (Note 9)	18,246	7,152	13,678
Purchase of marketable securities (Note 9)	(3,567)	(1,085)	(68,275)
Cash transferred on acquisition	1,771	-	-
Net cash provided by (used in) investing activities	15,448	6,044	(43,083)
Cash flows from financing activities:			
Reimbursment of loans	(223)	(475)	(34,392)
Reimbursment of conditional grants (Note 21)	-	-	(355)
Proceeds from loans or conditional grants (Note 21)	6,668	19,333	-
Principal payments on capital lease obligations	(97)	(77)	(161)
Earn-out payment for acquisition	-	(907)	(1,357)
Cash proceeds from issuance of ordinary shares and warrants (Note 18)	607	400	132,260
Net cash provided by financing activities	6,955	18,274	95,995
Effect of exchange rate changes on cash and cash equivalents	22	252	(9,170)
Net increase (decrease) in cash and cash equivalents	(714)	3,894	33,124
Cash and cash equivalents, beginning of year	3,456	2,742	6,636
Cash and cash equivalents, end of year	$ 2,742	$ 6,636	$ 39,760
Supplemental disclosures of cash flow information:			
Income tax paid	56	153	403
Interest paid	118	1,701	4,431
The supplemental schedule of non cash investing and financing activities is as follows			
Capital lease obligations incurred	-	-	-
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. (“Flamel” or 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. Flamel is a specialty pharmaceutical company with drug delivery and formulation expertise. The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, USA, and Dublin, Ireland.

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. Discontinued Operations

The company divested its development and manufacturing facility in Pessac, France on December 1, 2014 to Recipharm.

The Company followed the guidance in Financial Statements Accounting Standards Board Accounting Standards Codification (“ASC”) Topic 205 Presentation of Financial Statements (ASC 205), Topic 360 Property, Plant and Equipment (ASC 360) and Accounting Standards Update (ASU 2014-08), Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity in determining the accounting for the divestiture. The Company opted to early adopt the provisions of ASU 2014-08 as its management believes that all criteria for presenting the divestiture of the Pessac Facility and its business as a discontinued operation were met. Presenting the divestiture as a discontinued operation will also provide a better understanding of the results of the Company’s new strategy and in assessing the impact of the disposal on the ongoing operations of the entity.

The divestiture represents a strategic shift that had or will have a major effect on our operations and financial results. Since consummating the Éclat acquisition in March 2012, the Company has implemented an altered business model allowing Flamel to blend novel, high-value internally developed products with its drug delivery capabilities and to commercialize niche branded and general pharmaceutical products. Previously, the Company’s focus was to develop and license its proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™ and Medusa™) with pharmaceutical companies and biotechnology partners (e.g. the licensing of Micropump® to GSK to develop Coreg CR® with GSK commercializing the product). The divestiture of the Pessac Facility to Recipharm and the transfer to Recipharm of the GSK’s Supply Agreement and royalty income relating to Coreg CR® is an implementation of this revised strategy. Flamel sold over 50% of its historical revenues as a result of this transaction which had or will have a major impact on the Company’s operations and financial results.

The divestiture was accomplished in a single transaction and the assets, contracts and liabilities referred to in the Asset Purchase Agreement signed between Flamel and Recipharm were determined to represent a disposal group. This disposal group is considered to be a component of the Company. While the Pessac Facility and its related business were not identified as a reportable segment or operating segment, as the Company operates in only one segment, the Pessac Facility and its related business may be considered as an asset group as the transferred assets, liabilities and contracts represent the lowest level for which identifiable cash flows are largely independent of the cash flows of any other group of assets and liabilities. Flamel transferred all future cash outflows and inflows relating to the Pessac Facility that can be clearly distinguished operationally and for financial reporting purposes.

The results of Discontinued Operations, less income taxes, have been reported as a separate component of income in the statement of operations. The assets and liabilities of the discontinued operation have been reported separately in the asset and liability sections, of the balance sheet for the periods presented therein. See note 6 to the Consolidated Financial Statements in "Item 18. *Financial Statements*" for a description of the facts and circumstances related to the disposal, the gain and loss on disposal and the specific line items included in the statement of operations, balance sheet and cashflow statement relative to the disposal group.

1.4. Going concern

Management believes that the cash and cash equivalents and marketable securities of $92.8 million as of December 2014 are sufficient for the Company to continue as a going concern for at least the next twelve (12) months and does not have substantial doubt as to the organization's ability to continue as a going concern.

1.5. Principles of consolidation

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

1.6. Translation of financial statements of foreign entities and foreign currency transactions

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 financial statement amounts of the Company and any other subsidiary for which the functional currency is the Euro or any other currency other than 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.

Transactions involving foreign currencies are translated into the functional currency using the exchange rate prevailing at the time of the transactions. Receivables and payables denominated in foreign currencies are translated at year-end exchange rates. The resulting unrealized exchange gains and losses are carried to the statement of operations. As of December 31, 2014 the conversion generates an unrealized exchange rate gain of approximately $11.6 million.

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

1.7. Revenue recognition

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

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

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

- As milestones relate to discrete development steps (i.e. can be used by the partners to decide whether to continue the development under the agreement), the Company views that milestone events have substance and represent the achievement of defined goals worthy of the payments. Therefore, milestone payments based on performance are recognized when the performance criteria are met and there are no further performance obligations.

- Non-refundable technology access fees received from collaboration agreements that require the Company's continuing involvement in the form of development efforts are recognized as revenue ratably over the development period.

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

For generic products and branded products sold in mature and stable markets where changes in selling price are rare, the Company recognizes revenues upon shipment. For branded products where market conditions remain volatile and selling price is subject to change the Company recognizes revenue based on net product sales of wholesalers to their customers. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, 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. Estimates for product returns are adjusted periodically based upon historical rates of returns, inventory levels in the distribution channel and other related factors.

When Flamel receives revenue under signed feasibility study agreements, revenue is then 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. Revenues from unconditional grants for R&D projects are recognized as an offset to R&D expense on a pro-rata basis over the duration of the program. Funding can be received to finance certain R&D 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'.

Flamel benefits from tax credits on a percentage of eligible R&D costs. These tax credits can be refundable in cash or offset against taxable income 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 R&D grant and the tax credit is recognized as an offset to R&D expense.

1.8. 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 R&D (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 R&D to which the funding is associated, the granting authorities must be informed.

1.9. R&D costs

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. R&D 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.

1.10. Concentration of credit risk

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

The marketable securities issued by Morgan Stanley and from Crédit Agricole have strong credit ratings.

The Company's revenues are derived mainly from product sales and services and collaborative R&D contracts with pharmaceutical companies based in Europe and the United States and wholesalers based in the United States. All significant customers are discussed in Note 3.

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 $139,000, $144,000 and $127,000 at December 31, 2012, 2013 and 2014, respectively.

1.11. Earnings per share

Basic earnings (loss) per share are 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.

1.12. 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.

1.13. 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.

1.14. 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.

1.15. 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 R&D costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

1.16. 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

1.17. 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 intangible assets corresponding to acquired, in progress R&D recognized as part of the Éclat 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. Amortization of acquired IPR&D is computed using the straight-line method over estimated useful life of the assets.

1.18. 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.

1.19. 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.

1.20. Research credit tax

The Company is eligible to receive a French research tax credit that is calculated based on a percentage of eligible R&D 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.

1.21. 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.

1.22. 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 and were fully reimbursed in March 2014. 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.

1.23. Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from contracts with customers (topic 606)" ("ASU 2014-09"). ASU 2014-09 is effective for reporting periods beginning after December 15, 2016. The Company is assessing the impact of the provisions of ASU 2014-09 on the consolidated financial position and results of operations of the Company.

In April 2014, the FASB issued ASU No. 2014-08, "Presentation of Financial Statements (topic 205) and Property, Plant, and Equipment (Topic 360)" ("ASU 2014-08"). ASU 2014-08 requires new disclosures related to Discontinued Operations. ASU 2014-08 is effective for reporting periods beginning after December 15, 2014. The company has elected to adopt ASU No. 2014-08 as of December 31, 2014. See 1.3 and note 6 – Discontinued Operations.

In August 2014, the FASB issued ASU Update No. 2014-15, Presentation of Financial Statements – Going Concern: Disclosure of Uncertainties about an Entity's Ability to continue as a Going Concern (subtopic 205-40). Update 2014-15 requires management to assess an entity's ability to continue as a going concern every reporting period, and provide certain disclosures if management has substantial doubt about the entity's ability to operate as a going concern, or an express statement if not, by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Update 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. Upon adoption the Company will use the guidance in ASU 2014-15 to assess going concern. Management believes that the cash and cash equivalents of $92.8 million as of December 2014 are sufficient for the company to continue as a going concern for at least the next twelve months and does not have substantial doubt as to the organization's ability to continue as a going concern.

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 operates as 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")
- a commitment to make earn out payments of 20% of any gross profit generated by certain Éclat Pharmaceuticals 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.

The $12 million senior secured six-year note that accrued interest at an annual rate of 7.5% was repaid on March 24, 2014 (see note 16 – Long Term Debt).

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

(Amounts in thousands of US dollars)	
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 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. (See note 16 Long Term Debt and note 21 Fair Value of Financial Instruments).

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.

A total of $47.3 million of the acquired intangible assets was allocated to in-process R&D (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. 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.
(See note 13 *Goodwill and Intangible Assets*).

3. License, research and consulting agreements:

3.1. 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™ 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, which has been amortized over the initial feasibility period. In February 2009 Merck Serono exercised the option to license Medusa™ triggering a payment of $ 6.5 million (€5.0 million). Under the terms of the agreement, the Company was eligible to receive up to $53.0 million (€41.0 million) in milestone payments upon certain agreed-upon development events.

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.

3.2. Eagle Pharmaceuticals

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 R&D 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 R&D revenues of $659,000. The Company also recognized $43,000 of amortization of the initial up-front fee.

In 2013, the Company recognized R&D revenues of $31,600 as amortization of the initial up-front fee

3.3. *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 received royalties on the sales of Corning products that utilize Flamel's innovations.

The Company recognized royalties on Corning's sales of $152,000 in 2012, $111,000 in 2013 and on February 12, 2014 the Company signed an amendment effectively terminating the research and product development agreement and received a payment of $336,000 excluding sales taxes.

3.4. *Others*

The Company recognized license and R&D revenues with undisclosed partners for an amount of $3.3 million in 2012; $3.0 million in 2013 and $2.8 million in 2014.

4. Product sales and services

Flamel recognized product sales of $11.9 million in 2014 compared to $1.0 million in 2013 and $0.6 million in 2012.

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 determined as of March 31, 2014 that given significant wholesaler reorders and sufficient data obtained from the independent wholesaler tracking service regarding product returns from its customers, the Company could begin recognizing net product sales of Bloxiverz® based on indirect sales. Net product sales of wholesalers to their customers are determined using sales data from an independent, wholesaler inventory tracking service and are calculated by deducting estimates for returns for wholesalers' customers, chargebacks, payment discounts and other sales or discounts offered from the applicable gross sales value. Bloxiverz® product is purchased by hospitals from the wholesalers primarily through contractual agreements with group purchasing organizations ("GPOs"). The Company recognized net product sales of $10.2 million in the twelve months ended December 31, 2014 for Bloxiverz® sales from wholesalers to hospitals. A total of $7.0M of net revenue on shipments to wholesalers has been deferred as of December 31, 2014. Gross product sales to hospitals amounted to $15.8 million in the twelve months ended December 31, 2014.

The Company launched Vazculep™ in October of 2014 and determined that market acceptance of the product had not occurred given its short period of time on the market and that sufficient data to determine product returns had not yet been achieved. For the twelve months ended December 31, 2014, the criteria for recognizing the revenue were not met and the Company deferred $2.7 million of revenue as of December 31, 2014.

A summary of recognized net sales for the twelve months ended December 31, 2014 and ending net deferred sales as of December 31, 2014 for the Company's two (2) FDA-approved products as of December 31, 2014 is presented below:

Year Ended December 31, 2014 ($ in thousands)	Sales Recognized in the Current Period	Deferred Sales	Deferred Sales reclassed against outstanding Accounts Receivable	Ending Deferred Sales for which Payment has been Collected
Gross Sales	$ 15,789	$ 11,051	$ (9,420)	$ 1,630
Less:				
Chargebacks	$ 3,363	$ 132	$ (23)	$ 109
Wholesaler distribution fees	1,470	972	(823)	149
Cash discounts and other	326	225	(188)	37
Fees and returns	419	-	-	-
Net Sales	$ 10,211	$ 9,722	$ (8,386)	$ 1,335

The sales deductions discussed above are presented in the consolidated financial statements as reductions to gross revenues or deferred revenue, as presented above, and a decrease to accounts receivable or an increase to accrued liabilities. A summary of fiscal year 2014 changes for each reserve or liability for Bloxiverz®, Vazculep™ and the Company's generic pharmaceutical product is as follows:

Year Ended December 31, 2014 ($ in Thousands)	Beginning Balance	Additions	Reductions	Ending Balance
Accounts Receivable Reserves:				
Chargebacks	$ 483	$ 4,832	$ (4,307)	$ 1,008
Wholesaler distribution fees	102	2,619	(1,642)	1,079
Cash Discounts and other	28	733	(508)	252
Liabilities:				
GPO fees	$ 6	$ 267	$ (161)	$ 112
Sales returns	42	200	(8)	234
Medicaid rebates	37	16	(29)	24
Total	698	8,667	(6,656)	2,709

Actual product returns and other allowances incurred are dependent upon future events and may be different from the Company's recorded provisions. The Company continually monitors the factors that influence such estimates and makes adjustments when it is believed that deductions may differ from established allowances.

5. R&D expenses

Total R&D expenditures can be disaggregated in the following significant type of expenses ($USD in millions):

In millions of U.S. Dollars	2012	2013	2014
R&D Expenses	21.2	21.8	22.8
R&D Tax Credit	(6.5)	(5.8)	(5.5)
Grants	(0.1)	-	-
Total	14.6	16.0	17.3

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 and 2014.

6. Discontinued Operations

On December 1, 2014, the Company signed an Asset Purchase Agreement with Recipharm for the divestiture of its development and manufacturing facility located in Pessac, France.

The assets included in the divestiture were tangible equipment, furniture and fixtures, inventories and all intellectual property rights relating to the operation and technological know-how necessary in manufacturing the products that are produced in the facility and the assignment to Recipharm of all employees, customer contracts and liabilities which primarily relate to agreements of the Company with GlaxoSmithKline ("GSK") for the manufacture and sale of Coreg CR®. Coreg CR® was Flamel's lead product using the Micropump drug delivery platform that was developed with GSK and has been approved and sold in the US since 2007. The semi-finished product is manufactured in the Pessac Facility. The contracts assigned to Recipharm exclude the Amended 2003 License Agreement and 2004 License Agreement (collectively "License Agreements") between Flamel and GSK for the development of Coreg CR®. However, the royalties to be earned by Flamel from the sales of Coreg CR® were transferred to Recipharm as part of the Asset Purchase Agreement. All costs and future revenues relating to the manufacture and sale of Coreg CR® were transferred to Recipharm.

Royalties from Coreg CR® sales amounted to $6.9 million in 2012, $6.8 in 2013 and $6.3 in 2014. Revenues from sales of Coreg CR® microparticles to GSK amounted to $9.1 in 2012, $8.0 million in 2013 and $6.7 million for 2014. Revenues from research revenues with undisclosed partners amounted to $2.6 million in 2012, $3.5 million in 2013 and $2.0 million in 2014.

The supply Agreement originally signed between Flamel and GSK in December 2004, included 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 with Flamel having immediate title to buildings and fixtures. However, title to production equipment remains with GSK for the duration of the supply agreement. A total of $8,188,000 was incurred on the acquisition of buildings and fixtures and a total of $11,138,000 was incurred on behalf of GSK for the purchase of production equipment and associated costs.

In July 2006, Flamel and GSK entered into a further agreement whereby GSK partly sponsored the extension of the then existing Pessac Facility from two lines to three. GSK had exclusive use of part of this equipment for the production of Coreg CR® microparticles. The total funding provided by GSK amounted to $8.1 million to finance the acquisition of equipment, buildings and fixtures.

The funds received from GSK to finance the acquisition of assets owned by Flamel were classified as other liabilities (current and long-term) and amortized on a pro-rata basis over the expected life of the related assets and as an offset of the depreciation of the related assets. On the divestiture of the facility the remaining liability was offset against the gain on sale of the tangible assets.

The aggregate consideration paid for the acquired assets and business was $13.2 million, plus the value of acquired inventory determined using inventory valuation methodology as defined by the two parties. All cash and receivables pertaining to Pessac Facility business prior to the sale were retained by Flamel. A contribution of $0.7 million was made to finance potential future retirement indemnities payable on transferred employees. The business was accounted for as a discontinued operation in the fourth quarter of 2014 and, therefore, the operating results of our Pessac Facility business were included in Discontinued Operations in our consolidated financial statements for all years presented. We recognized a $5.0 million gain on disposal, which was included in our income from Discontinued Operations, in fiscal year 2014.

Summary results of operations for the Pessac business were as follows:

In thousands of U.S. Dollars	Fiscal Year 2012	2013	2014
Revenues	$ 18,570	$ 18,265	$ 14,967
Income (loss) from operations	1,550	3,667	(875)
Gain (loss) on disposal	-	-	5,007
Interest Expense	(11)	(9)	(4)
Income taxes	(27)	(74)	(110)
Income (loss) from discontinued operations, net of tax	$ 1,512	$ 3,584	$ 4,018

Carrying amounts of major classes of assets and liabilities classified as held for sale in the statement of financial position are as follows:

In thousands of U.S. Dollars	December 31, 2013	2014
Accounts receivable, net	$ -	$ 730
Inventories	1,352	-
Total major classes of current assets of the discontinued operations	1,352	730
Net Property, plant and equipment	15,044	-
Total major classes of non current assets of the discontinued operations	15,044	-
Total assets of the disposal group classified as held for sale	16,396	730
Current portion of capital lease obligations	69	
Accounts payable	-	168
Other current liabilities	832	-
Total major classes of Current Liabilities of the discontinued operations	901	168
Capital lease obligations, less current portion	88	-
Other liabilities	7,626	-
Total major classes of Non-Current Liabilities of assets Held for sale	7,714	-
Total liabilities of the disposal group classified as held for sale	8,615	168

The major cash-flows related to Discontinued Operations presented in the statement of cash-flows are as follows

	2012	2013	2014
Capital Expenditures	$ 766	$ 872	$ 1,271
Depreciation and Amortization	1,910	1,751	1,709
Operating and Investing non-cash elements	(975)	(676)	(740)

In connection with the Asset Purchase Agreement, the Company entered into a number of other agreements with Recipharm.

Master Agreement on Supply and Services of Products ("MSA")

Recipharm will provide various services in the domain of R&D and manufacture of pharmaceutical products for an initial non-cancellable period of five years.

Over the initial term, any services to be provided to shall include internal and external costs incurred by Recipharm plus 20%, which has been determined to be fair value for such services. The minimum amount of services per year, for a cumulative total of $22.5 million as follows:

First Year	$ 4.25 millions
Second Year	$ 4.25 millions
Third Year	$ 4.25 millions
Fourth and Fifth Year each	$ 4.86 millions

Transitional Service Agreement

In order to provide for the orderly transition of the Pessac Facility business to Recipharm, transitional services will be provided over a period of six months. The Transition services include primarily back office support such as information technology, human resources, accounting and other services as defined in the Transition Services Agreement.

Option Agreement

Recipharm has a first option (right of first refusal) to discuss and negotiate licenses of Flamel's intellectual property rights for the sale certain products in Europe. Upon exercise of the option, Recipharm and Flamel shall agree in good faith on terms and conditions of related license agreement within forty-five (45) days from the exercise of the option. The term of the Option Agreement is from the signing of the agreement through December 31, 2017. Flamel received no compensation related to the option agreement.

Concurrently with the above, Recipharm made an investment of $13.0 million in newly issued Flamel shares which corresponds to approximately 2.3% of Flamel's shareholdings. The purchase price for the shares purchased by Recipharm was based on the average of the trailing 20 days' trading prices of Flamel's shares prior to the closing date.

7. Stock based compensation

7.1. 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		
	2012	**2013**	**2014**
Weighted-average expected life (years)	$ 5.70	$ 5.43	$ 4.26
Expected volatility rate	62.50%	61.00%	61.00%
Expected dividend yield	-	-	-
Risk-free interest rate	0.95%	1.40%	1.23%
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.

As of December 31, 2014, the projected compensation expense related to non-vested options or warrants amounted to $10,899,000 and are expected to be recognized over a weighted average period of 2.15 years.

(In thousands of U.S dollars except per share data)	**Options**			**Free of charge share awards**			**Warrants**			**Total**		
	2012	**2013**	**2014**	**2012**	**2013**	**2014**	**2012**	**2013**	**2014**	**2012**	**2013**	**2014**
Research and development	419	398	327	649	320	494	-	61	206	1,068	779	1,027
Cost of goods sold	2	1	1	46	19	38	-	-	-	49	20	38
Selling, general and administrative	1,280	903	765	464	211	390	179	116	643	1,923	1,230	1,798
Total stock-based compensation expense	1,701	1,302	1,093	1,160	550	921	179	177	850	3,040	2,029	2,863
Effect on earnings per share												
Basic	0.07	0.05	0.03	0.05	0.02	0.03	0.01	0.01	0.02	0.12	0.08	0.08
Diluted	0.07	0.05	0.03	0.05	0.02	0.03	0.01	0.01	0.02	0.12	0.08	0.08

7.2. 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, 2012	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
Warrants granted	298,000	$ 14.54	€ 10.94
Warrants exercised	445,000	$ 6.12	€ 4.49
Warrants cancelled	50,000	$ 7.02	€ 5.44
Balance at December 31, 2014	3,853,000	$ 8.86	€ 6.76

[1] Historical exchange rate at date of grant

445,000 warrants were exercised in 2014, 50,000 warrants were exercised in 2013 and no warrants were exercised in 2012.

Exercise prices and intrinsic value for warrants outstanding as of December 31, 2014 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	255,000	1.69	4.17	9.94	255,000	4.17	9.94
5.44 to 6.57	2,200,000	3.20	5.70	8.41	2,200,000	5.70	8.41
6.58 to 8.52	1,100,000	3.20	8.42	5.69	1,100,000	8.42	5.69
8.52 to 10.94	298,000	3.62	10.94	3.17			
	3,853,000	**3.13**	**6.78**	**7.33**	**3,600,000**	**6.43**	**7.68**

The total fair value of warrants vested during 2012 amounted to €271,000 or $348,000 (average exchange rate of the year).
No warrants were vested during 2013.
The total fair value of warrants vested during 2014 amounted to €225,500 or $300,000 (average exchange rate of the year).
Intrinsic value represents the variance between the share price and the exercise price. As of December 31, 2014 the aggregate intrinsic value of warrants outstanding amounted to €28,237,000 or $37,070,000 (historical exchange rate at date of grant).

7.3. 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, 2012	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
Options authorized	1,700,000	-	-	-
cancelled	(628,000)	-	-	-
Granted	(669,500)	669,500	$ 16.30	€ 13.15
Exercised	-	(550,750)	$ 6.28	€ 4.57
Forfeited	-	(955,500)	$ 19.19	€ 15.00
Balance at December 31, 2014	1,030,500	2,498,240	$ 11.45	€ 9.02

[1] Historical exchange rate at date of grant

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.

The total intrinsic value of options exercised during 2014 amounted to €2,864,000 or $3,789,000 (historical exchange rate at date of exercise).

Stock options outstanding at December 31, 2014, which expire from 2015 to 2024, had exercise prices ranging from €3.00 to € 25.39. The weighted average remaining contractual life of all options is 7 years. As of December 31, 2014, there were 2,498,440 outstanding options at a weighted average exercise price of €9.02, of which 1,266,990 were exercisable at a weighted average price of €8.90. Exercise prices and intrinsic value for options outstanding as of December 31, 2014 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	284,750	7.98	3.02	11.09	84,500	3.06	11.05
4.03 to 5.44	1,069,250	7.72	4.96	9.15	707,750	4.89	9.22
6.40 to 12.02	62,000	0.19	11.42	2.69	62,000	11.42	2.69
12.86 to 16.56	970,990	7.09	13.49	0.88	301,490	14.25	1.19
19.2 to 25.39	111,250	1.59	22.98	-	111,250	22.98	-
	2,498,240	**7.05**	**9.02**	**8.34**	**1,266,990**	**8.90**	**7.57**

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 total fair value of options vested during 2014 amounted to €952,000 or $1,265,000 (average exchange rate of the year).

The aggregate intrinsic value of options outstanding amounted to €13,964,000 or $18,555,000 (historical exchange rate at date of grant). The aggregate intrinsic value of options exercisable amounted to €7,981,000 or $10,606,000 (historical exchange rate at date of grant).

7.4. Free share awards

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, 2012	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
Options authorized	250,000	-	-	-
Granted	(188,300)	188,300	$ 16.30	€ 13.15
Exercised	-	(150,600)	$ 3.07	€ 2.38
Forfeited	0	(3,750)	$ 7.36	€ 5.35
Cancelled	(86,550)			
Balance at December 31, 2014	61,700	401,550	$ 11.29	€ 8.82

[1] Historical exchange rate at date of grant

As of December 31, 2012 the total fair value (or intrinsic value) of Free Share Awards 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 Awards outstanding amounted to €1,446,000 or $1,954,000 (historical exchange rate at date of grant).

As of December 31, 2014 the total fair value (or intrinsic value) of Free Share Awards outstanding amounted to €3,544,000 or $4,533,000 (historical exchange rate at date of grant).

8. 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, 2013	December 31, 2014
Morgan Stanley	$ 0	$ 7,784
HSBC	3,657	16,480
Credit Agricole	48	13,529
Commerce Bank	2,898	1,916
Other	33	51
Total cash and cash equivalents	$ 6,636	$ 39,760

9. 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.

As of December 31, 2012, 2013 and 2014 marketable securities amounted respectively to $6.4 million, $0.4 million and $53.1 million.

As of December 31, 2012, 2013 there were no unrealized gains or losses. As of December 31, 2014, an unrealized loss of $0.2 million has been recognized.

(in thousands of U.S dollars)	Fair value			Value at cost			Unrealized Gains (Losses)		
	2012	2013	2014	2012	2013	2014	2012	2013	2014
Credit Agricole securities	6,413	401	12,494	6,413	401	12,494	-	-	-
Morgan Stanley securities		-	40,580		-	40,382		-	(198)
Total	6,413	401	53,074	6,413	401	52,876	-	-	(198)

Gross realized gains on sales of these available-for-sale securities amounted to $6,000, $0 and $963,000 for the years ended December 31, 2012, 2013 and 2014, respectively.

(in thousands of U.S dollars)	Proceeds from sales			Purchase of securities			Gross gains			Gross Losses		
	2012	2013	2014	2012	2013	2014	2012	2013	2014	2012	2013	2014
Credit Agricole securities	15,030	7,152	13,678	3,573	1,085	27,752	3	-	243	-	-	-
Morgan Stanley securities		-	-		-	40,523			720	-	-	(416)
HSBC securities	3,216	-	-	-	-	-	3	-	-	-	-	-
Total	18,246	7,152	13,678	3,573	1,085	68,275	6	-	963	-	-	(416)

10. Inventory

The components of inventories were as follows:

(In thousands of U.S. dollars)	December 31,	
	2013	2014
Raw materials	918	1,661
Finished goods	1,492	5,068
Inventories, net	2,410	6,729

11. 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,	
	2013	2014
Valued-added tax recoverable	689	1,077
Prepaid expenses	1,478	3,225
Advance to suppliers	219	111
Others current assets	95	5
Total Prepaid expenses and other current assets	2,481	4,418

The increase in prepaid expenses relates to deferred income tax expense, see note 19 – Income taxes.

12. Property and Equipment

The components of property and equipment were as follows:

(In thousands of U.S. dollars)	December 31, 2013	December 31, 2014
Land and buildings	-	-
Laboratory equipment	10,985	9,801
Office and computer equipment	3,423	3,289
Furniture, fixtures and fittings	5,067	4,544
Construction in progress	-	-
Total property and equipment	19,475	17,633
Less accumulated depreciation and amortization	(17,084)	(15,857)
Property and equipment, net	2,391	1,776

Depreciation expense related to property and equipment amounted to $0.8 million, $0.8 million and $0.7 million for the years ended December 31, 2012, 2013 and 2014, respectively.

13. Goodwill and intangible assets

	December 31,							
	2013				2014			
(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)	-	-	$ -	-	-	-
Goodwill Eclat acquisition	18,491	-	-	18,491	18,491	-	-	18,491
Total Goodwill	$ 19,035	$ (544)	$ -	$ 18,491	$ 18,491	$ -	$ -	$ 18,491
Intangible asset corresponding to acquired IPR&D of Bloxiverz	35,248	-		35,248	35,248	(11,749)		23,499
Intangible asset corresponding to acquired IPR&D of Vazculep	12,061		(7,170)	4,891	12,061		(7,170)	4,890
Total Intangible assets	$ 47,309	$ -	$ (7,170)	$ 40,139	$ 47,309	$ (11,749)	$ (7,170)	$ 28,389

Intangible assets corresponding to acquired in-process R&D of Bloxiverz® is being amortized straight-line over a 3 year period as of January 1, 2014. Intangible assets corresponding to acquired in-process R&D of Vazculep™ will be amortized straight-line over a 6-year period as of January 1, 2015.

The Company conducts impairment tests of intangible assets 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. The impairment of these assets resulted from new facts and circumstances that occurred regarding the potential competitive landscape of Vazculep™ at that time.

Total future amortization of intangible assets related to Bloxiverz® and Vazculep™ for the next five years ending December 31 are as follows:

(In thousands of U.S. dollars)	December 31,
2015	12,565
2016	12,565
2017	815
2018	815
2019	815
	27,575

14. 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, 2013	2014
Accrued compensation	2,440	3,792
Accrued social charges	3,566	1,866
Accrued Interest	521	-
Other	-	9
Total accrued expenses	6,527	5,667

15. Other current and Long Term liabilities

15.1. Other current liabilities

Other current liabilities comprise the following:

(In thousands of U.S. dollars)	December 31, 2013	2014
R&D tax credit financing short term	7,121	5,382
Employee service award provision short term	285	-
Provision for retirement indemnity short term	-	55
Other	72	222
Total Other current liabilities	7,478	5,659

In 2012, the Company obtained an advance from OSEO, a governmental agency supporting innovation, for $5,848,000 (€4,432,000) secured against the research tax credits due to the company by the tax authorities for expenditure incurred in 2011. 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 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 15.2). As of December 31, 2014 the total funding amounted to $5,382,000 of which the totality was classified as short term liability.

The Service award provision is accrued over the respective service period (5, 10, 15 and 20 years). 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, 2013 the total provision amounted to $285,000 and is classified as short term.

15.2. Other long term liabilities

Other long term liabilities are composed of the following:

(In thousands of U.S. dollars)	December 31, 2013	2014
R&D tax credit financing long term	6,113	-
Provision for retirement indemnity (see note 20)	2,142	2,296
Other	59	37
Total Other long term liabilities	8,314	2,333

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 15.1).

As of December 31, 2014 other long term liabilities are mainly composed of the provision for retirement indemnity (see note 21).

16. Long-term Debt:

Long-term debt comprises:

(In thousands of U.S. dollars)	December 31, 2013	2014
Oseo ANVAR loans (a)	2,553	1,927
French Ministry of Research (b)	2,033	1,790
Acquisition liability contingent consideration (c)	37,991	70,112
Acquisition liability note (c)	10,405	-
Acquisition liability warrant consideration (c)	10,497	34,542
Deerfield Facility agreement (d)	12,492	-
Deerfield Royalty agreement (d)	4,590	6,837
Broadfin Facility agreement (e)	2,767	-
Broadfin Royalty agreement (e)	2,187	3,259
Total	85,514	118,467
Current portion	19,194	42,332
Long-term portion	66,320	76,135

(a) OSEO Anvar is an agency of the French government that provides financing to French companies for R&D. At December 31, 2013 and 2014, the Company had outstanding loans from Anvar of $2,553,000 and $1,927,000, 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 2014 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 2015. The loan is non-interest bearing and is repayable only in the event the research project is technically or commercially successful. The company has not received official acceptance notice of commercial and technical success.

(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 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 and was fully repaid in March 2014 generating an expense of $3.0 million.

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:

	2013	2014
Share price	$8.05	$17.13
Risk-free interest rate	1.27%	1.17%
Dividend yield	-	-
Expected volatility	50.0%	56.5%
Expected term	4.3 years	3.3 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, 2014, 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% was used.

See also Note 21 – 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 was permitted to use the funds for working capital, including continued investment in its R&D 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. The indebtedness was repaid on March 24, 2014 in its entirety; the accelerated reimbursement of this note resulted in interest expenses of $2.5 million.
- $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.

As of December 31, 2014, 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 21 – 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 into 3 tranches of $5 million each, Under the terms of the Facility, upon closing Broadfin made an initial loan of $5.0 million and the Company was entitled 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. Subject to certain limitations, the Company was permitted to use the funds for working capital, including continued investment in its R&D 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. The indebtedness was repaid on March 24, 2014 in its entirety; the accelerated reimbursement of this note resulted in interest expenses of $ 2.2 million.
- $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 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.

As of December 31, 2014, 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)	
2015	45,722
2016	18,163
2017	11,834
2018	13,551
2019	8,758
	98,028

17. 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, 2012	2013	2014
Numerator:			
Net income (loss) from continuing operations	$ (4,740)	$ (46,511)	$ (88,924)
Net income (loss) from discontinuing operations	$ 1,512	$ 3,587	$ 4,018
Denominator:			
Weighted average shares outstanding used for basic earnings (loss) per share	25,135,416	25,450,175	36,214,384
Effect of dilutive securities:			
Stock-options and warrants	-	-	-
Weighted average shares outstanding and dilutive securities used for diluted earnings (loss) per share	25,135,416	25,450,175	36,214,384
Earnings (loss) per ordinary share (Basic)			
Continuing Operations	$ (0.19)	$ (1.83)	$ (2.45)
Discontinued Operations	$ 0.06	$ 0.14	$ 0.11
Net income (loss)	$ (0.13)	$ (1.69)	$ (2.34)
Earnings (loss) per share (diluted) :			
Continuing Operations	$ (0.19)	$ (1.83)	$ (2.45)
Discontinued Operations	$ 0.06	$ 0.14	$ 0.11
Net income (loss)	$ (0.13)	$ (1.69)	$ (2.34)

For the years ended December 31, 2012, 2013 and 2014, 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 6,396,240 shares of common stock at an average of $9.87 per share were outstanding during 2014. The options, which expire in December 2024, were still outstanding at the end of year 2014.

18. Shareholders' Equity

18.1. 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.

18.2. 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 $148.4 million at December 31, 2014. Dividend distributions, if any, will be made in euros. The Company has no plan to distribute dividends in the foreseeable future.

18.3. Warrants

The effects of applying the fair value method provided in accordance with ASC 718 are shown in Note 7.

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. As of December 31, 2014, 200,000 Warrants were exercised and 50,000 warrants were cancelled.

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. As of December 31, 2014, 200,000 Warrants were exercised.

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 June 24, 2014, the Company authorized the Directors of the Company, to subscribe to 300,000 warrants for a subscription price of €0.89 per warrant ($1.22). 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 €10.94 ($14.87). These warrants are issued for a four-year period and will vest over one year from the date of issuance. 298,000 warrants were subscribed in September 2014.

On exercise of warrants by beneficiaries, the Company issues new shares.

18.4. Stock options

The Company issued stock options under plans approved by shareholders in 1990, 1993, 1996, 2000, 2001, 2003, 2004, 2005, 2007, 2010, 2012, 2013 and 2014. 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.

18.5. Free Share Awards

On June 24, 2014, the shareholders of the Company authorized the issuance of 250,000 new shares that the Board of Directors was authorized to award and issue free of charge to the employees, or certain categories of them, of the Company or of the companies or organizations affiliated with it under the conditions set forth in Article L.225-197-2, 1° of the French Commercial Code and the corporate officers of the Company or organizations affiliated with it and that satisfy the conditions set forth in Article L.225-197-1, II of the French Commercial Code as compensation for services rendered. Under the terms of the awards the shares are definitively owned by French and Ireland 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. This authorization supersedes any unused portion of the previous authorizations granted to the Board of Directors by the shareholders.

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 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 11, 2014, the Company issued 6 000 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 11, 2014 the Company issued 150,600 new shares related to this grant.

On December 12, 2013 the company granted 192,500 free shares to officers and employees.

On December 11, 2014 the company granted 188,300 free shares to officers and employees.

18.6. 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. This authorization was granted for a term of eighteen (18) months. As of December 20, 2014, no shares have been issued as a result of this authorization.

18.7. Accumulated other comprehensive income

The components of accumulated other comprehensive income is as follows:

	December 31,	
(In thousands of U.S. dollars)	**2013**	**2014**
Foreign currency translation	10,815	(7,225)
Unrealized gain (loss) on marketable secuirities		(198)
Total	10,815	(7,423)

18.8. Capital raise

During the twelve month period ended December 31, 2014, the Company issued 12,400,000 shares as a result of an underwritten public offering in March 2014. The offering price to the public was $9.75 per American Depositary Share, each representing one ordinary share ("ADS"), and included payment of a commission of $0.585 per ADS. Total increase in shareholders equity amounted to $115.2 million, including $113.6 million in net proceeds, ($0.7) million in issuance costs and $2.4 million in tax relief from issuance costs and underwriter commission.

In December 1,026,364 shares were acquired by Recipharm as a private placement. The offering price to Recipharm AB was $12.71 per American Depositary Share, each representing one ordinary share ("ADS"). Total net proceeds amounted to $13,049,000.

19. Income taxes

Income (loss) before income taxes comprises the following:

(in thousands of U.S. dollars)	Year ended December 31, 2012	2013	2014
France	(15,755)	(3,889)	(392)
United States	6,286	(53,864)	(89,939)
Total	$ (9,469)	$ (57,753)	$ (90,331)

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, 2012	2013	2014
Income tax benefit (provision) computed at the statutory rate (US & France)	2,737	22,842	36,106
Deferred Tax Allowance	(5,251)	(1,930)	(10,973)
Business Tax	(59)	(76)	(1,400)
Non Taxable remeasurement of fair value accounting of earn out	7,303	(9,592)	(22,326)
Total	$ 4,729	$ 11,244	$ 1,407

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, 2012, 2013 and December 31, 2014 the amount of this component was $29,000, $76,000 and $1,400,000 respectively. The increase in business tax for the year ended December 31, 2014 is due to the taxable income generated from French based operations following the divestiture of the Pessac Facility and income generated from the sale of intellectual property to the Irish operations.

Significant components of the Company's deferred taxes consist of the following:

(In thousands of U.S. dollars)	December 31, 2012	2013	2014
Deferred income tax assets:			
Net taxable operating loss carry-forwards (not utilized)	65,657	81,769	66,167
Other deferred income tax assets	3,656	1,898	1,052
Valuation allowance	(64,356)	(69,940)	(57,980)
Net deferred income tax assets	4,957	13,728	9,238
Deferred income tax liabilities	(19,086)	(16,534)	(9,238)
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 and US due to the Company's history of losses. As of December 31, 2012 and 2013, deferred tax assets have been recognized on losses from US operations to the extent of the deferred tax liabilities.

As of December 31, 2014, the Company had $142.2 million in French net operating losses carry-forwards. Annual utilization is normally limited to €1,000,000 plus fifty per cent (50%) of any taxable income in excess of this threshold. The net operating losses carry-forwards are forfeited on substantial change in operations. Substantial change in operations occurs when the following criteria are met:

- Reduction of more than fifty per cent (50%) in revenues from one fiscal year to another,
- Reduction of more than fifty per cent (50%) in the average employees employed or in the gross book value of assets from one fiscal year to another.

Following the divestiture of the Pessac Facility the above criteria were met for the French operations. However, the Company filed a request with the French tax administration in November 2014, in accordance with French tax legislation, to limit the forfeiture of the net operating losses carry-forwards to those pertaining to the Pessac Facility and to maintain the net operating losses carry-forwards pertaining to the R&D operations that remain in the French operations. The request was filed on the basis that the divestiture was part of a strategic shift in the Company operations to maintain the operations and employment related to the R&D operations in France and with an objective of becoming profitable. The Company expects to receive a response from the French tax administration in the next twelve months. The ability for the Company to carry forward net operating losses from French operations is deemed uncertain.

As of December 31, 2014, the Company had $46.9 million in US net operating losses carry-forwards which expire from 2030 to 2032, for which utilization of pre-acquisition tax losses of $4.9 million is limited to $1.8 million per year.

The decrease in available net operating losses carry-forwards in 2014 is due to taxable income from French operations in 2014 of $69.3 million, on which $35.3 million net operating losses have been utilized, offset by an increase in net operating losses from US operations of $10.2 million.

The French government provides tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D 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, 2014, Flamel had total net income tax payable of $7.6 million reflecting income tax payable of $11.7 million, offset by a research tax credit of $5.5 million and business tax payable of $1.5 million. The income tax will be paid in May 2015.

On December 16, 2014, Flamel transferred all of its intangible property from its French entity to its Irish-based entity as a part of a global reorganization. The intangible property includes patents on drug delivery platforms, clinical data sets and other intangible assets related to the pipeline of proprietary products in development. As of December 31, 2014, and as a result of the intra-entity transaction, an income tax expense has been deferred for $14.1 million, of which $1.0 million is classified as prepaid expenses and $13.1 million as a long term asset. The deferred tax expense will be amortized over the tax life of the asset which is 14.3 years, at a rate of 7% per year and result in tax relief of $9.7 million from 2015 to 2029. No deferred tax asset has been recognized on this intra-entity transaction.

As of December 31, 2014, Flamel had a research tax receivable of $5.9 million from the tax credit generated in 2011. In 2012, the Company obtained an advance from OSEO, a governmental agency supporting innovation, secured against the Research tax credit generated in fiscal year 2011(see Note 15.1). 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.

The scheduled payments are shown in the following table:

(In thousands of U.S. dollars)	December 31,
2015	5,930
Total current portion	**5,930**

20. 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 $815,000 in 2012, $701,000 in 2013, and $719,000 in 2014.

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 $2,142,000 and $2,350,000 as of December 31, 2013 and 2014, 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:

	2012	2013	2014
Average increase of salaries	3%	3%	3%
Discounted interest rate	3%	3.25%	1.49%
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 actuarial standard based on age and professional status	60 to 65 years actuarial standard based on age and professional status	60 to 65 years actuarial standard based on age and professional status

Changes in the funded status of the benefit plans were as follows:

In thousands of U.S. dollars	December 31, 2013	December 31, 2014
Benefit obligations at beginning of year	1,159	2,142
Service cost	1,106	99
Interest cost	36	36
Plan amendments	-	-
Benefits paids	-	(87)
Actuarial loss (gain)	(233)	460
Exchange rate changes	74	(300)
Benefit obligations at end of year	2,142	2,350

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: **In thousands of U.S. dollars**	Year Ending:	
	12/31/2015	55
	12/31/2016	-
	12/31/2017	-
	12/31/2018	-
	12/31/2019	12
	Next 5 Years	150

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 2012. The Company made and accrued contributions of approximately $140,000 in 2012.

21. Fair value of financial instruments:

At December 31, 2013 and 2014, 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 9, 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, 2013 and 2014 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 2014 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

In thousands of U.S. Dollars	Net Carrying Value as of December 31, 2014	Fair Value Measured and Recorded Using			Operational Gain (losses) recognized in earnings	Financial Gain (losses) recognized in earnings	Total
		Level 1	Level 2	Level 3			
Assets							
Cash and cash equivalent	39,760	39,760	-	-	-	-	-
Marketable securities	53,074	53,074	-	-	-	547	547
Total					-	**547**	**547**
Liabilities							
Acquisition liability contingent consideration (a)	70,112	-	-	70,112	(33,445)	-	(33,445)
Acquisition liability note (b)	-	-	-	-	(3,013)	-	(3,013)
Acquisition liability warrant consideration (c)	34,542	-	-	34,542	(24,045)	-	(24,045)
Deerfield Royalty Agreement (d)	6,837			6,837	-	(2,386)	(2,386)
Broadfin Royalty Agreement (e)	3,259			3,259	-	(1,139)	(1,139)
Total					**(60,503)**	**(3,525)**	**(64,028)**

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			Operational Gain (losses) recognized in earnings	Financial Gain (losses) recognized in earnings	Total
		Level 1	Level 2	Level 3			
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)**	**(30,126)**

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
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 January 1, 2014	$ (58,893)
Operational gain (loss) recognized in earnings for fiscal year 2014	(60,503)
Reimbursment of acquisition liability note	12,000
Payment of interest on acquisition liability note	1,389
Payment of deferred consideration	1,354
Net carrying value at December 31, 2014	$ (104,653)

	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)	-
Interest expense recognized in earnings for fiscal year 2014	(2,386)	(1,139)
Payment of Royalty	140	67
Net carrying value at December 31, 2014	$ (6,837)	$ (3,259)

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.

22. Commitments and Contingencies

22.1. Operating leases

The Company leases its facilities and certain equipment under non-cancelable operating leases, which expire through 2016. Future minimum lease payments under operating leases due for the fiscal years ending December 31, 2014 are as follows:

In thousands of U.S. Dollars	December 31,
2015	841
2016	177
TOTAL	**1,018**

Rental expense for the years ended December 31, 2012, 2013 and 2014 was approximately $863,000, $759,000 and $844,000, respectively.

22.2. 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.

22.3. Purchase Commitments

The Company has commitments to purchase to acquire services from Recipharm Pessac for a total of $22.5 million for a five year period commencing January 1, 2015 (see Note 6 Discontinued Operations) and to purchase one batch per year for the next five years of the generic pharmaceutical product it markets for $46,000 per year.

23. 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.

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; $983,000 in 2013 and $11,920,000 in 2014 (see note 4 product sales).

Revenues by geographic location of customers are as follows:

(in thousands of U.S. dollars)	**As of December 31,**		
	2012	**2013**	**2014**
Revenues			
USA	3,894	3,368	14,302
Europe	3,640	811	473
Total Revenues	7,534	4,179	14,775

The following is a summary of long-lived assets by geographic location:

(in thousands of U.S. dollars)	**As of December 31,**		
	2012	**2013**	**2014**
Long-lived assets:			
USA	$ 60,260	$ 58,868	$ 47,077
France	$ 31,966	$ 2,307	$ 1,703
Total long-lived assets	$ 92,226	$ 61,175	$ 48,780

24. 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 products and 100% of the gross profit generated by our former product Hycet®, up to a maximum of $1 million, which we 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 and the Hycet asset was disposed of in November 2013. 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. The senior secured note was repaid in full in March 2014 (see also note 16. *Long Term debt*).

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 R&D projects. Interest accrued at 12.5% per annum to be paid quarterly in arrears, commencing on April 1, 2013. 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.

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.

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. The loans under the Facility and the obligations under the Royalty agreement 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 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. 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. See also note 16 Long-Term Debt.

25. Post Balance Sheet Events

On January 15, 2015, the Wholesale Acquisition Cost ("WAC") for Bloxiverz® was increased to $98.75 per vial from $35.80 subsequent to the approval by the FDA of APP's NDA for neostigmine methylsulfate product. The price increase is effective on contract prices with hospitals and GPOs 30 days after announcement of the increased WAC. Due to arrangements in place with wholesalers, wholesalers will receive a chargeback in the amount of $19.0 million for units sold by the wholesalers for the period from January 16 to February 15, 2015, which will be recognized as a reduction in revenue for the three-month period ended March 31, 2015.

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 Annual Report on Form 20-F 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, 2015

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 **(5)**
4.10*	Broadfin Royalty Agreement, dated as of December 3, 2013 **(5)**
4.11	Asset Purchase Agreement by and among Flamel Technologies and Recipharm Pessac, dated November 26, 2014 (filed herewith)
4.12	Master Agreement on Supply of Services and Products by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)
4.13	Service Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)
4.14	Supply Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 (filed herewith)
4.15*	Membership Interest Purchase Agreement by and among Éclat Holdings LLC., Éclat Pharmaceuticals LLC., Flamel Technologies S.A., and Flamel US Holdings Inc., dated March 13, 2012 (filed herwith)
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)
101.1NS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

(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.
(5) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014
***** 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 € 4,901,727
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 3, 2015

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 nine hundred one thousand seven hundred and twenty seven Euros (4,901,727 €), divided into 40,191,264 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.

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.

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 75 years may not, at any time, exceed one third of the total number of Directors in office.

The Board of Directors shall determine its own rules of procedure.

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.

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.

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. In case of an equality of votes, the tie is resolved in accordance with the conditions set forth by the internal rules of procedure of the Board of Directors. Without prejudice to provisions of the above mentioned rules of procedure, 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 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 must always be a natural person under the age of 75, as of the date of the appointment. The duties of the Chairman who reaches this age end following the Shareholders' Meeting called to approve the financial statements of the year in which this age is reached.

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.

At its sole discretion, the Board may appoint one or more Vice-Chairmen whose functions are solely, in the absence of the Chairman, to chair the meetings of the directors as well as of the shareholders. In the absence of the Chairman and the Vice-Chairmen, the Board designates one of the directors present, who will chair the meeting. The Board may appoint, at each session, a Secretary who may be chosen outside shareholders.

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 amongst its members, and having the title of Managing Director ("*Directeur Général*" or "Chief Executive Officer").

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. Should the Board of Directors appoint a Managing Director, he should meet the same age requirements as specified to the Chairman.

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 scrutinizers 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

Exhibit 4.11

Private & Confidential

Dated November 26, 2014

BY AND AMONG

FLAMEL TECHNOLOGIES (1)

and

RECIPHARM PESSAC (2)

ASSET PURCHASE AGREEMENT

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ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT, dated as of November 26, 2014 (the "Agreement"), is made and entered into by and among FLAMEL TECHNOLOGIES, a French corporation having its principal place of business at Parc Club du Moulin à Vent, 33 avenue du Docteur Georges Lévy, Venissieux France 69693, registered with the registry of companies and trade of Lyon under number 379 001 530 ("FLAMEL" or the "Seller"), on one hand, and RECIPHARM PESSAC, a French *Société par Actions Simplifiée* having its principal place of business at 5, rue Archimède, 33600 Pessac France, registered with the registry of companies and trade of Bordeaux under number 807 679 386 (the "Purchaser"), on the other hand.

Capitalized terms used but not otherwise defined in this Agreement shall have the meaning assigned to them in **Schedule A** (terms defined herein in the singular having the same meaning when used in the plural and vice versa).

WITNESSETH:

WHEREAS, FLAMEL is a specialty pharmaceutical company focusing on the development of safer and more efficacious formulations, tackling unmet medical needs in the process. On the date hereof, FLAMEL focuses on (1) the development and licensing of proprietary drug delivery platforms, (2) the development of novel, high-value products based on its drug delivery platforms and (3) the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S. FLAMEL's proprietary drug delivery platforms are intended for more effectively and safely administering medicines to patients, and include the Medusa technology, Micropump (a technology that allows for the modified release of solid, oral dosage forms) as well derivatives of Micropump (including TriggerLock and LiquiTime) (collectively, "FLAMEL Drug Delivery Platforms"). Most of the manufacturing, and some of the development and scale-up for FLAMEL Drug Delivery Platforms and products based thereupon, take place in the facilities owned by FLAMEL in Pessac, France, 11, avenue Gustave Eiffel (the "Pessac Facility").

WHEREAS, the business conducted at the Pessac Facility (the "Pessac Business") consists of (i) the manufacturing of the Product for commercial use as well as the manufacturing of other products, whether or not based upon FLAMEL Drug Delivery Platforms, for research and development use, including clinical use and (ii) the conduct of non-commercial development activities for FLAMEL Drug Delivery Platforms and products based thereupon.

WHEREAS, after having conducted a regulatory, marketing, manufacturing, financial, legal and technical due diligence exercise, subject to the limitations and exclusions contained in this Agreement and on the terms and conditions hereinafter set forth, the Purchaser desires to purchase from the Seller, and the Seller desires to assign to the Purchaser, the assets, real estate and rights used or held for use primarily in the conduct of the Pessac Business, together with certain related liabilities and contracts.

WHEREAS, as part of the transaction, the Seller and the Purchaser also wish to enter into commercial arrangements as follows: (i) an agreement for the supply of services by the Purchaser to the Seller, namely a Supply Agreement and a Service Agreement under the head of a Master Service Agreement, (ii) a Transitional Services Agreement whereby Seller shall provide transitional services to Purchaser for the operation of the Pessac Facility, (iii) a Quality Agreement, (iv) a Real Estate Transfer Deed providing for the transfer of the Pessac Facility to the Purchaser.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this Agreement, the parties hereto hereby agree as follows:

ARTICLE I. PURCHASE, SALE AND ASSUMPTION OF LIABILITIES

1.1 Purchase and Sale of the Acquired Assets.

1.1.1 Acquired Assets. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing and effective as of the Closing Date, Seller shall sell, assign, transfer, convey and deliver, free and clear of any Liens other than Permitted Liens, to Purchaser, and Purchaser shall purchase and acquire from Seller all of Seller's right, title and interest in the following assets, properties and rights owned or held by Seller on the Closing Date.

(a) all tangible assets (including all machinery, equipment, tools, spare and replacement parts and components, furnishings, furniture, office supplies, transport and logistical equipment, office and computer equipment and hardware, but excluding any such items constituting Acquired Real Property), used or held for use by Seller or any of its Affiliates primarily in the operation or conduct of the Pessac Business, as the same shall exist as of the Closing Date (the "Business Assets"), including without limitation the items listed in **Part A** of **Schedule 1.1.1 (a),** being understood that said list shall be regarded as an indication of the main items present on the Pessac Facility and does not preclude Purchaser to claim for the sale and transfer under this Agreement of any other furniture, office equipment, machinery, office supplies, tools, spare and replacement parts, communication equipment, computer hardware and other tangible personal property owned by Seller which are not listed in said Schedule for any reason provided they are primarily used in the Pessac Business as at the Closing Date.

For the avoidance of doubt, **Part A** of **Schedule 1.1.1 (a)** includes any and all equipment and machinery purchased by Seller under the GSK Agreements as well as any assets financed by GSK under the same agreements but which have become the Seller's property within the frame of, and in compliance with, the GSK Agreements. **Part B** of **Schedule 1.1.1 (a)** lists the equipment and machinery that were financed by GSK under the GSK Agreements and are not proprietary to Seller but are GSK's sole ownership as at the date of this Agreement; such items shall not be transferred to Purchaser at Closing, but shall become Purchaser's ownership under the terms and conditions provided for in the GSK Agreements.

(b) the goodwill and the clientele of the Pessac Business as a going concern (*fonds de commerce*) pursuant to this Agreement including, without limitation, the customer records, statistics and credit information data relating specifically to such clientele ;

(c) all originals or, to the extent Seller is required to keep originals pursuant to applicable Law, copies of all laboratory and manufacturing books, files and records, including, ledgers, general, financial and accounting records, files, supplier invoices, of Seller that are used or held for use by Seller in the operation or conduct of the Pessac Business, as the same shall exist as of the Closing Date (the "Pessac Records"), without prejudice to the provisions of Section 7.3.5 hereof;

(d) the rights in the softwares listed in **Schedule 1.1.1**(d) subject to and in accordance with the inclusions and exclusions provided in such schedule, together with a non-exclusive, royalty free manufacturing and commercialization license (with the right to sublicense) of the Pessac Know-How (together, the "Acquired IP Rights") as defined herein;

(e) the right to hold itself out as successor to the Pessac Business, together with the "fonds de commerce" related to the foregoing assets, properties and rights;

All of the assets, property and rights referred to in the preceding paragraphs of this Section 1.1.1 in each case as necessary for, used in and dedicated to the conduct of the Pessac Business on the Closing Date are collectively referred to herein as the "Acquired Assets"; provided, however, that the Acquired Assets do not include the Retained Assets.

1.1.2. Retained Assets. Notwithstanding the foregoing, the Acquired Assets shall not include any of the following (the "Retained Assets"):

(a) the corporate seals, certificates of incorporation, minute books, stock books, tax returns, books of account or other records relating to the corporate organization, maintenance and existence of the Seller which the Seller must retain pursuant to applicable Laws;

(b) cash on hand or in banks, cash equivalents and financial investments including without limitation cash, cash equivalents and financial investments used as collateral for liabilities relating to the Pessac Business;

(c) rights to security deposits and any prepaid expenses relating to the Pessac Business (including those that would carry over post-Closing);

(d) all rights and claims against third parties (including, without limitation, any rights under insurance contracts for claims caused by facts which have occurred prior to the Closing Date) pertaining to any Retained Assets or Retained Liability and all other rights related to Retained Assets and Retained Liabilities,

(e) subject to ARTICLE VIII, the rights to any claims of the Seller for any tax or social security refunds whatsoever arising in relation to the period prior to Closing;

(f) all contracts between solely Seller and its Affiliates and inter-company non trading receivables between Seller and its Affiliates;

(g) all Business Receivables;

(h) any assets, properties or rights used and/or operated by the Seller located on the Pessac Facility but not primarily dedicated to the Pessac Business, as listed in **Schedule 1.1.2(h)** that are, subject, however, to the rights granted to the Purchaser under the Ancillary Agreements;

(i) any assets, properties or rights used and/or operated by the Seller not located on the Pessac Facility that are not primarily dedicated to the Pessac Business,

(j) Intellectual Property Rights of the Seller, except for the Acquired IP Rights and the limited license rights granted to Purchaser under the Ancillary Agreements,

(k) all rights, claims and credits of Seller to the extent relating to any Retained Assets (including any such items arising under insurance policies, guaranties, warranties, indemnities and similar rights in favor of Seller in respect of any Retained Assets).

The Parties acknowledge that exclusion of the Retained Assets from the scope of the Acquired Assets shall be without prejudice to the rights of Purchaser or its Affiliates pursuant to the Transitional Services Agreement.

1.2 Assumption of Contracts.

On the terms and subject to the conditions set forth in this Agreement, at the Closing and effective as of the Closing Date, Seller shall transfer and assign to Purchaser, and Purchaser shall assume and shall thereafter pay, perform and discharge as and when due, the Assumed Contracts.

Except as otherwise provided for herein, and subject to Section 7.1.1(a), "Assumed Contracts" shall mean all rights and obligations under any contract, agreement, purchase order, bid, quotation, proposal or other document, commitment, arrangement, undertaking, including, but not limited to, all rights under the contracts and orders listed in **Schedule 1.2** hereto (the "Material Contracts"), and all rights and obligations under such agreements arising after the date hereof, in each case as necessary for, used in and dedicated to the conduct of the Pessac Business on the Closing Date.

1.3 Assumption of Liabilities.

1.3.1. **Assumed Liabilities**. On the terms and subject to the conditions set forth in this Agreement, at the Closing and effective as of the Closing Date, Seller shall transfer and assign to Purchaser, and Purchaser shall assume and shall thereafter pay, perform and discharge as and when due, the Assumed Liabilities.

"Assumed Liabilities" is defined, subject to the cut-off rules set forth in ARTICLE VIII, as (i) all Liabilities of Seller pursuant to the terms of the Assumed Contracts for performance from and after the Closing, including any payments required to be made thereunder accruing after the Closing, and any obligations of Seller to deliver Product following the Closing, and, in each case, excluding Liabilities arising out of any breach of such Assumed Contract by Seller prior to Closing, (ii) all Liabilities arising in connection with the conduct of the Pessac Business from and after the Closing, and (iii) any Liability for Taxes that will arise as a result of the consummation of the transactions contemplated by this Agreement, including the Transfer Taxes.

For avoidance of doubt, the Assumed Liabilities shall not include any Liabilities expressly identified as Retained Liabilities.

1.3.2. Retained Liabilities. The Seller shall in no way be deemed to have transferred or assigned to Purchaser, and Purchaser shall not be obligated to assume and shall in no way be deemed to have assumed, any liabilities of the Seller other than the Assumed Liabilities (the "Retained Liabilities"), it being agreed that the Seller shall continue to pay, perform and discharge as and when due, the Retained Liabilities.

For the avoidance of doubt, and subject to the provisions of ARTICLE VIII, Retained Liabilities include all Liabilities of Seller other than the Assumed Liabilities with respect to (i) any current or former employees or agents of Seller and their compensation and benefits, including any severance, retention, paid time off, vacation pay or similar payments due or that become payable in connection with this Agreement through the Closing Date, (ii) bonus payments accrued through the Closing Date, (iii) all liabilities of Seller for recalls and product liability claims with respect to Product sold prior to Closing and any adverse events with respect thereto, (vi) any liability for Taxes arising as a result of or with respect to the Pessac Business or the Acquired Assets with respect to any taxable period or portion thereof ending on or prior to the Closing Date, and (vii) any other liability for Taxes of Seller, as well as (viii) for the avoidance of doubt, all Liabilities arising from (y) Actions of employees made redundant under a redundancy plan (*Plan de Sauvegarde de l'Emploi*) implemented by Seller prior to the Closing Date, and (z) Actions of employees at any time prior to or beyond the Closing Date claiming the transfer of its employment agreement to Purchaser under Article L. 1224-1 of the French Labor Code.

1.4 Acquired Inventory

On the terms and subject to the conditions set forth in this Agreement, at the Closing and effective as of the Closing Date, Seller shall sell, assign, transfer, convey and deliver, free and clear of any Liens other than Permitted Liens, to Purchaser, and Purchaser shall purchase and acquire from Seller, all of Seller's right, title and interest in, to and under the Acquired Inventory as valued in accordance with the terms of **Schedule 2.1.3**.

"Acquired Inventory" is defined as all finished goods held by Seller as trading stock for supply in the course of the Pessac Business, semi-manufactured or partly finished goods which are in the course of conversion, manufacture or assembly by the Seller into finished products for supply in the course of the Pessac Business or are held by the Seller for such purpose, raw materials, components, packaging supplies and work in progress of the Pessac Business on the Closing Date (including, subject to and in accordance with the inclusions and exclusions provided in the Transitional Services Agreement, all records, documents and correspondence relating thereto) all such finished goods, semi-manufactured or partly finished goods, raw materials, components, packaging supplies and work in progress having a shelf life complying with shelf life required under the related Assumed Contract, but excluding (i) any items forming part of the Acquired Real Property, (ii) the Retained Assets or (iii) any items located on the Pessac Facility that is either (x) held by Seller on behalf of third parties as such items are listed in **Part A** of **Schedule 1.4** (including the GSK Inventory) or (y) proprietary to Seller and retained by Seller as such items are listed in **Part B** of **Schedule 1.4**.

1.5 Acquired Real Property

On the terms and subject to the conditions set forth in this Agreement and the Real Estate Transfer Deed, at the Closing and effective as of the Closing Date, Seller shall sell, assign, transfer, convey and deliver, free and clear of any Liens other than Permitted Liens, to Purchaser, and Purchaser shall acquire from Seller all of Seller's rights, title and interest in and to the Acquired Real Property (including all records, and documents relating thereto).

ARTICLE II. CONSIDERATION

2.1 Closing Purchase Price

2.1.1. The aggregate consideration to be paid for the Acquired Assets shall be equal to FOUR MILLION SIX HUNDRED THOUSAND EUROS (€4 600 000) (the "Acquired Assets Purchase Price");

2.1.2. The aggregate consideration to be paid for the Acquired Real Property shall be equal to SIX MILLION EUROS (€ 6 000 000) (the "Acquired Real Property Purchase Price");

2.1.3. The aggregate consideration to be paid for the Acquired Inventory shall be determined as follows (the "Acquired Inventory Purchase Price"):

(a) No later than five (5) Business Days prior to the date scheduled for the Closing, Seller shall deliver to Purchaser an estimate of the Acquired Inventory as of the Closing Date (the "Acquired Inventory Base Purchase Price"), which shall be prepared by Seller in good faith in accordance with the principles, methodologies, and line items set forth on **Schedule 2.1.3** hereto and, to the extent applicable, in accordance with applicable French GAAP; provided, that in the event of a conflict between French GAAP and the principles, methodologies, and line items set forth on **Schedule 2.1.3** hereto, the principles, methodologies, and line items set forth on **Schedule 2.1.3** hereto shall control (collectively, the "Methodology for Inventory Valuation"). Simultaneously with the delivery of the Acquired Inventory Base Purchase Price, Seller shall deliver to Purchaser detail listing of such Acquired Inventories and appropriate documentation sufficient to confirm the accuracy of the Acquired Inventory.

(b) The Acquired Inventory Base Purchase Price shall be updated as of the last business day immediately preceding the Closing Date (the "Determination Date") to reflect the Acquired Inventory, as follows. On the Determination Date, Seller will (x) cause a physical inventory to be taken of the semi-finished and finished goods Inventory related to the Product at the Pessac Facility, (y) appropriate documentation sufficient to confirm the accuracy of the remaining Acquired Inventory and (z), obtain a list of all Inventory held at any third-party location as of the Determination Date. Seller and Purchaser shall have the right to have representatives present during the physical inventory, and shall mutually agree to the amount of the Inventory as of the Closing Date based on the results of the physical inventory, as supplemented by the list of Inventory held at any third-party. Upon agreement of the Parties on the purchase price for the Acquired Inventory, the Acquired Inventory Purchase Price shall be final, binding and conclusive on the Parties.

The sum of the Acquired Assets Purchase Price, the Acquired Real Property Purchase Price and the Acquired Inventory Purchase Price is being referred to herein as the "Closing Purchase Price".

2.2 Payment of the Closing Purchase Price

The Closing Purchase Price shall be paid by Purchaser to Seller on the Closing Date in Euros by wire transfer of immediately available funds to the account of Seller, such account to be designated at least three (3) Business Days prior to the Closing Date.

2.3 Allocation for Purposes of the French Commercial Code

a) For purposes of Articles L. 141-5 et seq. of the French Commercial Code, the amount of FOUR MILLION SIX HUNDRED THOUSAND EUROS (€4,600,00.00) (being the portion of the Acquired Assets Purchase Price paid for the assets of the *fonds de commerce*) shall be allocated as follows:

Intangible Assets	€ 1.00
Tangible Assets	€ 4,599,999.00

The Parties acknowledge that the above allocation is provided solely for purposes of Articles L. 141-5 et seq. of the French Commercial Code and that neither Party shall be entitled to rely thereon for any reason whatsoever.

b) The Parties hereby waive all rights to have a portion of the Closing Purchase Price set forth in Sections 2.1.1 held in escrow for the period running from the Closing Date until the end of the time period for creditors to exercise their rights of objection under Article L.141-14 and seq. of the French Commercial Code (*Code de Commerce*). Seller shall take any and all necessary steps and shall pay such amount due to satisfy such objecting creditors within sixty (60) days from the Closing Date. The Parties hereby fully and definitely, discharge legal counsels who have negotiated, prepared and drafted this Agreement from all and any liability whatsoever with respect to the potential consequences of such a waiver.

c) The Parties acknowledge and agree that the amount set forth in Section 2.1.1 and in paragraph a) of this section 2.3 is the total consideration payable for the Acquired Assets including the goodwill and the clientele of the Pessac Business as a going concern (*fonds de commerce*) as at the Closing Date, and accordingly that such amount will be subject to registration duties (*droits d'enregistrement*) (article 719 of the French Tax Code) which will be payable by the Purchaser. The Purchaser agrees to timely file the appropriate declarations and pay any registration duties (*droits d'enregistrement*) owing, and provide proof of such declaration and payment upon request of Seller. The Parties acknowledge that they have been informed of the sanctions applicable in the event of any insufficiency or intentional misstatement of the Acquired Assets Purchase Price and the Acquired Inventory Base Purchase Price agreed to by the Parties and any false declarations of sincerity with respect thereto. The Parties declare that this Agreement is neither modified by nor contradicted by any other agreement between the Parties increasing the Acquired Assets Purchase Price and the Acquired Inventory Base Purchase Price.

ARTICLE III.CONDITIONS PRECEDENT

3.1 [Intentionally omitted]

3.2 Conditions to Obligations of the Purchaser.

The obligations of the Purchaser to consummate the transactions contemplated by this Agreement is further subject to the fulfillment, at or prior to the Closing, of the following additional conditions (which may be waived in writing in whole or in part by the Purchaser in its sole discretion):

- Provision by Seller of a certificate whereby Seller declares and warrants that the Migration Systems have been subjected to the Initial Migration Plan and have been subjected to a non-regression testing process, as provided for under paragraph 7.1.3 hereof, in the form attached as **Schedule 3.2**.

3.3 Conditions to Obligations of the Seller.

The obligations of the Seller to consummate the transactions contemplated by this Agreement are further subject to the satisfaction, at or prior to the Closing, of the following additional conditions (all or any of which may be waived in writing in whole or in part by the Seller in its sole discretion):

- Appointment of a Pharmacist in charge (*pharmacien responsable*) for Pessac Facility by Purchaser.

3.4 Further condition to Closing for the Seller and the Purchaser. Material Adverse Change.

If there has occurred a Material Adverse Change between the date of signature hereof and the Closing Date, no Party will be obligated to carry out the Closing pursuant to ARTICLE IV and either Party may terminate this Agreement by written notice to the other Party, provided that to exercise such right of termination, the Party claiming that a Material Adverse Change has occurred shall submit reasonable evidence thereof to the other Party together with its notice of termination.

If the right to terminate is exercised pursuant to this paragraph 3.4, neither Party shall have any right of recourse against the other Party for any costs or expenses incurred in the context of this Agreement and the Transactions contemplated hereby.

Neither the Purchaser nor the Seller may waive the conditions set forth in this paragraph 3.4 without the prior written consent of the other party.

ARTICLE IV.CLOSING

4.1 Closing.

The Closing of the Transaction shall take place in Paris at the offices of FIDAL, Tour Prisma, 4-6, avenue d'Alsace, 92982 PARIS LA DEFENSE CEDEX, France, at 10 AM, local time, on December 1st, 2014 subject to the conditions precedent set forth in ARTICLE III (other than conditions with respect to actions the respective Parties will take at the Closing itself) being satisfied on such date. Should such conditions not be fulfilled by December 1st, 2014, then Closing shall be postponed and take place within five (5) calendar days following the satisfaction of the conditions set forth in ARTICLE III (other than conditions with respect to actions the respective Parties will take at the Closing itself), or at such other time, date or place as shall be mutually agreed upon in writing by the Parties, provided that if such date is not a Business Day, the Closing shall take place on the next succeeding Business Day (the date on which the Closing shall take place being referred to as the "Closing Date").

4.2 Closing Deliveries.

At the Closing, all of the events listed below shall occur, each event being conditional upon the occurrence of all of the others:

4.2.1. Deliveries by the Seller. The Seller shall deliver or make available to the Purchaser (or procure the delivery or the making available of, as the case may be) the following:

- certified copies of the organizational documents of Seller and to the extent required, original powers of attorney or other proof of authorization for the signatories of this Agreement and any and all documents to be executed and/or exchanged for implementing the Transaction;
- counterparts of all Ancillary Agreements substantially in the form attached in **Schedule 4.2.1 (i)** (a) to (f) hereto executed by the Seller;
- counterpart of the Option Agreement substantially in the form attached in **Schedule 4.2.1(ii)** hereto executed by the Seller;
- the joint notification to *Agence Nationale de Sécurité du Médicament et des Produits de Santé* as of the Closing Date as the effective date of transfer to the Purchaser of the pharmaceutical authorization relating to the Pessac Facility in accordance with applicable Laws, duly signed by the pharmacist in charge (*pharmacien responsable*) of the Seller

- evidence that, in accordance with applicable Laws, the relevant employee representative bodies have issued an advice (*avis*) with regard to the Transaction;

- evidence that the French companies Technologie Servier and Laboratoires Servier consent and authorize the transfer of the agreements listed in **Schedule 4.2.1 (iii)** (the "Servier Agreements") to the Purchaser;

- a certificate reiterating the Seller's representations and warranties referred to in ARTICLE V as true and correct on Closing as though made on the Closing Date (the "Certificate");

- an invoice with respect to the sale of the Acquired Inventory;

- the joint notification to be provided to GSK under the Consent to Assignment of Supply Arrangement signed between the Parties and GSK on November 26, 2014 duly signed by Seller;

- to the extent necessary, any other appropriate documents, duly executed by Seller, transferring in accordance with applicable Laws the Acquired Inventory and the Acquired Assets, in the form customary with respect to such types of assets, duly executed by Seller (such other documents, the "Asset Transfer Documents") (it being understood and agreed between the Parties that the Asset Transfer Documents shall not (x) include any representation or warranty other than as required by Law and in no event shall any such representation or warranty give more right to Purchaser than the representations and warranties contained in this Agreement, and (y) in no event shall any provision in any Asset Transfer Document impose upon the Purchaser any obligations or liabilities to Seller or its Affiliates in relation to the relevant transfer, assignment or assumption other than as expressly contemplated by this Agreement).

4.2.2. Deliveries by the Purchaser. The Purchaser shall deliver to the Seller at the Closing the following:

- certified copies of the organizational documents of Purchaser and to the extent required, original powers of attorney or other proof of authorization for the signatories of this Agreement and any and all documents to be executed and/or exchanged for implementing the Transaction

- the Closing Purchase Price provided for under Section 2.21 less (i) an amount of FIVE HUNDRED AND FIFTY THOUSAND EUROS (€ 550 000), as compensation from Seller for the retirement benefits, pensions or accruals owed to any Transferred Employees retiring after the Closing Date and (ii) TWENTY THOUSAND THREE HUNDRED NINETY NINE EUROS AND FIFTY CENTS (€ 20 399.50) as participation of Seller to premium to the Pollution and Remediation Legal Liability Policy (PARLL) taken out by Purchaser, to be wired on the account of the Seller the details of which will be provided to Purchaser no later than ten (10) days prior to Closing;

- counterparts of all Ancillary Agreements substantially in the form attached in **Schedule 4.2.1 (i)** (a) to (f) hereto executed by the Purchaser;

- counterpart of the Option Agreement substantially in the form attached in **Schedule 4.2.1(ii)** hereto executed by the Purchaser;

- all relevant documentation confirming the appointment of the pharmacist in charge *(pharmacien responsable)* of the Purchaser;

- the joint notification to *Agence Nationale de Sécurité du Médicament et des Produits de Santé* as of the Closing Date as the effective date of transfer to the Purchaser of the pharmaceutical authorization relating to the Pessac Facility in accordance with applicable Laws, duly signed by the pharmacist in charge (*pharmacien responsable*) of the Purchaser;

- the joint notification to be provided to GSK under the Consent to Assignment of Supply Arrangement signed between the Parties and GSK on November 26, 2014 duly signed by Purchaser;

- a certificate reiterating the Purchaser's representations and warranties referred to in ARTICLE VI as true and correct on Closing as though made on the Closing Date.

4.2.3. Execution of Real Estate Transfer Deed by the Parties. The Parties shall execute the Real Estate Transfer Deed at the Closing, and perform any and all actions and sign any and all documents that may prove necessary for carrying out the transfer of the Acquired Real Property to Purchaser in compliance with the Real Estate Transfer Deed.

ARTICLE V. REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as set forth in the disclosure schedules referred to in each of the paragraph or section of this ARTICLE V (the "Disclosure Schedules"), the Seller represents and warrants to the Purchaser that all of the statements contained in this ARTICLE V are true and correct at the Effective Date unless the statement refers to a specific date in which case it is made solely with respect to such date. For purposes of the representations and warranties of the Seller contained herein, disclosure, in any paragraph or section of this ARTICLE V, of any facts or circumstances shall be deemed to be adequate response and disclosure of such fact or circumstances with respect to all representations or warranties by the Seller calling for disclosure of such information. The "Effective Date" shall be, up to Closing, the date of execution of this Agreement; subject to the contents of the Certificate referred to in paragraph 4.2.1 with respect to the reiteration of the Seller's representations and warranties referred to in ARTICLE V, the "Effective Date" shall be the Closing Date. For the avoidance of doubt, and subject to Section 6.5, when any Disclosure Schedule refers to a document, such reference shall be deemed a reference to the full content of such document to the extent such document was included in the DR Documents.

5.1 Organization and Standing; Power and Authority.

Seller is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of France. It has full corporate power and authority to enter into and perform this Agreement or any other document implementing the Transaction, including without limitation the Ancillary Agreements (all together referred to as the "**Transaction Documents**") as referred to into this Agreement. Whenever required under applicable Law, the competent corporate body of Seller has duly authorized the execution of this Agreement or any of the Transaction Document.

5.2 Authority and Binding Effect.

The Transaction Documents have been, or upon execution thereof will be, duly executed and delivered by Seller, and constitute the valid and binding obligations of Seller, enforceable against Seller, in accordance with their respective terms. No insolvency proceedings against Seller regarding the Acquired Property are pending which would prevent or jeopardize the effectiveness of the Transaction Documents, nor has Seller been informed by any third party of the intent of such party to commence any such insolvency proceedings against Seller.

5.3 Conflicts; Defaults.

Neither the execution, nor delivery nor performance of the Transaction Documents by Seller will violate any of the terms of the articles of incorporation, the by-laws or of other organizational documents of Seller.

5.4 Governmental Approvals.

The execution, delivery and performance of this Agreement by Seller do not and will not require any consent, approval, authorization or other order of, action by, filing with or notification to, any Governmental Authority, except (i) as described in **Schedule 5.4**, and (ii) any notification or filing required to be made by Purchaser under this Agreement, and (iii) where failure to obtain such consent, approval, authorization or action or to make such filing or notification, would not prevent or materially delay the consummation by Seller of the transactions contemplated by this Agreement and (iv) as may be necessary as a result of any facts or circumstances relating solely to Purchaser.

5.5 Acquired Assets and Acquired Inventory.

5.5.1. Except as disclosed in **Schedule 5.5.1**, Seller is the sole owner of and has good title to the Acquired Assets and Acquired Inventory which are free and clear of any other third party rights (except for the ordinary customary retention rights), and Seller is entitled to freely dispose of the Acquired Assets and Acquired Inventory.

5.5.2. The Acquired Property and Assumed Contracts, together with the rights and assets made available pursuant to the Ancillary Agreements, include all the rights and assets necessary for, used in and dedicated to the conduct of the Pessac Business in the same manner as it was conducted as at the Effective Date (the "Required Assets"). Seller retaining any materials or equipment removed from the Pessac Facility prior to Closing and such assets, properties or rights listed in **Schedule 1.1.2(h)**, shall not by any mean or in any measure affect or modify the operation of the Pessac Business as operated as at the date of this Agreement.

5.5.3. The Acquired Assets, along with the rights under the Assumed Contracts (including the GSK equipment as listed in Part B of **Schedule 1.1.1** and the GSK inventory as listed in Part A of Schedule 1.4 are complete and sufficient for carrying on the Pessac Business as conducted at Closing Date in accordance with current good manufacturing practices (cGMP) / current good laboratory practices (cGLP) and pursuant to the relevant specifications and requirements of the Supply Agreement, the Services Agreement, the GSK Agreements (to the exclusion of the payments to be made under any of the GSK Agreements) and any Material Contract and the Acquired Assets and Acquired Inventory are in normal operational condition having regard to the normal wear and tear and, up to the Effective Date, have been properly maintained and/or replaced in the ordinary course of business. In case Required Assets should not be listed on Part A or Part B of **Schedule 1.1.1** for any reason, Seller shall either transfer said missing machinery, equipment, tools, spare and replacement parts and components, furnishings, furniture, office supplies, transport and logistical equipment, office, computer equipment and hardware without further cost or expenses to Purchaser under the terms and conditions of this Agreement or otherwise make said missing machinery, equipment, tools, spare and replacement parts and components available to Purchaser in the same manner they were made available to the Pessac Business prior to the Closing.

5.5.4. **Schedule 5.5.4 (a)** contains a list of Acquired Assets used for the conduct of the Pessac Business which is not owned by Seller but has been leased from a third party; **Schedule 5.5.4(b)** contains a summary of the respective lease agreements.

5.5.5. The Acquired Assets and Acquired Inventory are not subject to any security or other rights in favor of Seller or any Affiliate of Seller.

5.6 Acquired Real Property.

5.6.1. Seller is the sole owner and has full and good title to the Acquired Real Property free of any third party rights and, subject to the preemption right (*droit de preemption urbain renforcé*) of the Communauté Urbaine de Bordeaux pursuant to article L211-1 of the French *Code de l'urbanisme*, Seller is entitled to freely dispose of the Acquired Real Property and, upon the Closing, Purchaser shall be vested with the same rights and title.

5.6.2. The Acquired Real Property is not subject to any security or other rights in favor of Seller or any Affiliate of Seller.

5.6.3. Seller has taken, or shall have taken at Closing, any and all steps necessary to ensure transfer of legal title to the Acquired Real Property to Purchaser, including without limitation the withdrawal or resigning by any Governmental Authorities, especially the City of Pessac and the Communauté Urbaine de Bordeaux from their preemption right to purchase the Acquired Real Property.

5.7 Intellectual Property rights.

5.7.1. Subject to the provisions of the Transitional Services Agreement, the Acquired IP Rights, together with the Intellectual Property Rights licensed to Purchaser under the GSK Agreements? are sufficient and necessary to conduct the Pessac Business as presently conducted and, to the Sellers' best knowledge, their use does not infringe any rights of third parties.

5.7.2. Seller has obtained, or shall have obtained at Closing, when required, all consents to the assignment of the material IP Rights as listed in **Schedule 5.7.2** (the "Material IP Rights"), to Purchaser. Seller shall hold Purchaser. harmless against the consequences of any claims by third parties that any Acquired IP Rights was transferred without their consent (when such consent was required either by contract or by Law).

5.7.3. Seller is the sole owner of the Acquired IP Rights (other than those that represent IP License Rights) and has good and valid title to the Acquired IP Rights which are free of any rights of third parties, and Seller is entitled to freely assign the Acquired IP Rights (other than those that represent IP License Rights).

5.7.4. Seller has not received any written notice of, nor is he aware of, any infringement or unlawful use of any of the Acquired IP Rights by third parties.

5.7.5. With respect to the Acquired IP Rights all fees have been paid when due and all other measures necessary for the support and maintenance of the Acquired IP Rights have been taken in full and on time, except where failure to do so would not affect the conduct of the Pessac Business.

5.7.6. Other than as contemplated under the Transaction Documents, Seller is not a party to any license agreements regarding the Acquired IP Rights as licensor.

5.8 Contracts.

5.8.1. Seller has obtained, or shall have obtained at Closing, when required, all consents to the assignment of the Material Contracts to Purchaser.

5.8.2. Each Material Contract is in full force and effect and Seller has performed in all material respects, all obligations required to be performed by Seller under the Material Contracts and is not in default under any Contract, nor has Seller been notified by a party to a Material Contract of any default of Seller

5.8.3. None of the Material Contracts has been terminated, nor has Seller been informed by a party to a Material Contract of the intent of such party to terminate any such Material Contract.

5.8.4. **Schedule 5.8.4** sets forth a list of all suppliers to the Pessac Business.

5.8.5. **Schedule 5.8.5** contains a list of all customers of the Pessac Business.

5.8.6. The conclusion or performance of the Transaction Documents will neither result in a termination of any of the Material Contracts nor in any major amendments of the terms and conditions of the Material Contracts, being understood that prior to the Execution date, the GSK Agreements have been amended effective on the Closing Date as agreed between the parties and GSK.

5.8.7. Other than the Material Contracts, there exist no lease or any other agreements regarding the Pessac Business with a term of more than one (1) year which in a single case result in yearly expenses of more than EUR 10,000.

5.8.8. There are no claims of customers for breach of product or service warranties regarding the Pessac Business currently pending.

5.9 Conduct of Business.

5.9.1. Since December 31, 2013, no Material Adverse Change has occurred.

5.9.2. Since January 1, 2014 until the date hereof, Seller has not

(b) sold, transferred or otherwise disposed of, other than in the ordinary course of business, any assets, properties or rights or cancelled any claims relating to and which are material to the Pessac Business,

(c) entered into any agreement with any customer, distributor or representative, or any other transaction, other than any of the Material Contracts, which is material to the Pessac Business, or which does not fall within the ordinary course of the business and is not transferred by Seller to Purchaser under this Agreement;

(d) disposed of or permitted the elapse of any Acquired IP Rights, or disposed of or permitted the elapse of any agreement under which Seller is entitled to any Acquired IP Rights;

(f) made any changes in the warranty or other policies regarding service, support or maintenance of the Acquired Assets or the products manufactured in the Pessac Business;

(g) granted any general increase in the compensation or benefits of officers or employees related to the Pessac Business other than in the ordinary course of business (including any such increase pursuant to any bonus, pension, profit-sharing, severance, other plan or commitment).

5.9.3. Subsidies: With regard to the Acquired Property, Seller has not entered into any agreement that could lead to the repayment or non-payment of a grant or a subsidy or allowance that would have been or that should be paid to Seller. Seller declares and warrants that all allowances or subsidies that have been paid to Seller over the last six years preceding the Closing Date shall not give rise to any repayment or reimbursement by Purchaser.

5.10 Litigation.

5.10.1. There is no action, suit, administrative or other proceeding, arbitration or litigation pending, nor has Seller been informed by any third party of the intent of such third party to bring any such action, suit, administrative or other proceeding, arbitration or litigation, against Seller with respect to the Pessac Business, including without limitation any action alleging that the conduct of the Pessac Business constitutes an infringement of any Intellectual Property Rights of a third party or which seeks to prevent the consummation of any of the Transaction Documents.

5.10.2. No specific guarantee has been given for any products or the Product under the terms of which Purchaser could be liable beyond the limits and duration provided under the Assumed Contracts.

5.10.3. No proceeding regarding the Pessac Business is pending before any court or other Governmental Authority.

5.10.4. There are no claims pending against Seller regarding product liability, non-conformity, hidden defects or defective products resulting from the conduct of the Pessac Business.

5.11 Permits, Licenses, Authorizations.

5.11.1. **Schedule 5.11.1** contains a list of the material permits, licenses and authorizations, which are required for the operation of the Pessac Business according to the Law and issued to Seller by appropriate Governmental Authorities upon appropriate filing with regard to the Pessac Business. Without prejudice to the restrictions and limitations contained in any other provision of this ARTICLE V, Seller is in compliance with each of such permits, licenses and authorizations, except to the extent any such non compliance would not have a material adverse effect on the operation of the Pessac Facility and/or the Pessac Business.

5.11.2. Without prejudice to the restrictions and limitations contained in any other provision of this ARTICLE V (including, but not limited to, those contained in Section 5.13), the Pessac Business as operated by Seller is in compliance in all-material respects with all applicable Laws and, as of the Effective Date, there is no commitment related to the making or financing of any investment in the Pessac Business and/or the Pessac Facility to any Governmental Authority, including without limitation any engagement, undertaking or warranty on the level of employment at the Pessac Facility.

5.12 Employees and Labor Matters.

5.12.1. **Schedule 5.12.1 Part A** is a complete list of all the employees being transferred to Purchaser hereunder (the "Transferred Employees"), setting forth their names, salary, position and date of the beginning of the employment; **Schedule 5.12.1 Part B** lists the additional compensation owed to the Transferred Employees.

5.12.2. All the employees dedicated to the Pessac Business, but subject to **Schedule 5.12.12,** are listed in **Schedule 5.12.1.** There is no other employee or no individual or any Person that may claim for the transfer of his employment agreement to the Purchaser further to the completion of the Transaction.

5.12.3. **Schedule 5.12.3** set forth a complete list of the collective bargaining agreements (*convention collective et accords collectifs*), internal rules (*règlement intérieur*), to the extent applicable in respect of the Transferred Employees.

5.12.4. There are no pension and employee Benefit Plans applicable to the Transferred Employees other than as disclosed in **Schedule 5.12.3** and **Schedule 5.12.1 Part B**.

5.12.5. Seller has complied in all material respects with all pension and employee Benefit Plans applicable to the Transferred Employees.

5.12.6. The Transferred Employees do not benefit from any termination, severance or retirement payment, or any payment for breach of contract, or from retirement or life insurance benefits or schemes, or from any undertakings in this respect, other than as required by applicable Laws, the collective bargaining agreements or as set forth in **Schedule 5.12.1**.

5.12.7. The Pension Liabilities pertaining to the Transferred Employees are set forth in **Schedule 5.12.7**.

5.12.8. Seller has complied in relation to each Transferred Employee in all material respects with all statutes, regulations, collective agreements, terms and conditions of employment, internal rules relating to their working conditions and has complied in relation to each Transferred Employee to all its obligations under the applicable Law in respect of employment and the payment of social security, retirement and unemployment contributions and similar Taxes.

5.12.9. Except as disclosed in **Schedule 5.12.12**, no employment agreement regarding an employment in the Pessac Business commencing on a date following the execution of this Agreement has been concluded.

5.12.10. At the Effective Date, there exists no agreements between Seller and any Transferred Employees that provide either for (i) any additional compensation for the benefit of such Transferred Employee (other than as listed in **Schedule 5.12.1 Part B** or (ii) for the employment of any such Transferred Employee within the Seller's organization after the Closing Date.

5.12.11. The Pessac employees who were granted free shares (*actions gratuites*) of the Seller with a vesting date (*période d'acquisition*) expiring after the Closing Date have been allowed, per a specific Board resolution of Seller, to keep the benefit of such free share allocation despite the transfer of their employment agreement to the Purchaser pending the vesting period; Seller shall hold Purchaser harmless against any claims of any such Transferred Employees in relation to such free shares allocation and the potential consequences that the Closing may have on such allocation or the subsequent holding of the Seller's shares.

5.12.12. Since March 6, 2014, except for the Transferred Employees listed in **Schedule 5.12.12**, no employees of Seller primarily affected to the Venissieux business or of any Seller's Affiliates has been transferred to the Pessac Business and/or Pessac Facility, and no Seller's Employees primarily affected to the Pessac Facility and/or the Pessac Business have been transferred and/or assigned to other jobs and/or duties at Venissieux and/or Seller's Affiliates in view of the completion of the Transaction.

5.13 Environmental Matters.

5.13.1. In respect of the Pessac Business and Pessac Facility (i) Seller is not subject to any outstanding written communication from a Governmental Authority alleging that Seller is not in compliance in any material respect with any Environmental Laws, and (ii) Seller holds and is in compliance in all material respects with all Environmental Permits; in particular and without limiting the foregoing, Seller has complied with the Governmental Authority requirement to build a pH neutralization system on effluent flow in 2014 at the Pessac Facility.

5.13.2. **Schedule 5.13.2** hereto contains (i) a list of material environmental Permits required for the conduct of the Pessac Business as now conducted (the "Environmental Permits"), (ii) a comprehensive description of the waste disposal practices of the Business, (iii) the list of material environmental instructions by Governmental Authorities received by Seller since January 1, 2010, in respect of the Pessac Business and Pessac Facility and (iv) a list of the location of all underground tanks, sumps or pits at the Pessac Facility currently used to contain hazardous materials on a continuous basis.

5.13.3. The use of the Acquired Property in the Pessac Business as currently conducted are in compliance in all material respects with all Environmental Laws.

5.13.4. Seller has always transported waste from Pessac Facility to a place or a destination in accordance with its Environmental Permits and in accordance with Law and that such transportation has not give rise to any enquiries or Claims.

5.13.5. To the best of Seller's knowledge, after having made reasonable inquiry for the purpose of this representation, the operations of Seller on the Pessac Facility have not been the source of any contamination of the soil.

5.14 Tax Matters.

On the Closing Date, there shall not be any encumbrances on any of the Acquired Property in connection with any failure (or alleged failure) by the Seller to pay any Tax pertaining to the Pessac Business and/or the Pessac Facility.

5.15 Insurance.

Schedule 5.15 sets out the details of the Seller's insurance policies covering property damages with respect to the Pessac Facility and product and professional liability with respect to the Pessac Business.

Seller warrants that, up to the Effective Date, (i) all premiums due on the policies in respect of such insurance cover (the Policies) have been paid, (ii) all the other conditions of the Policies have been performed and observed, (iii) none of the Policies has or may become void or voidable as a result of an act or omission of the Seller,

Seller shall indemnify and hold harmless Purchaser for any damages to the Pessac Facility and/or the Pessac Business usually covered under said insurance policies, occurred or discovered after the Closing Date but having its cause prior to the Closing Date.

5.16 Financial information

The Business Plan provided by Seller, as set forth in **Schedule 5.16**, for Purchaser to make its own opinion on the value of the Pessac Business, has been prepared with the care of a prudent business man and was based upon a reasonable estimate of the costs and revenues of the Pessac Business consistent with accepted practices and principles in the pharmaceutical industry and for the period of time referred to in the said Business Plan and with regard to the information available as of the date on which it was last updated.

ARTICLE VI.REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser represents and warrants to the Seller and the Seller as follows:

6.1 Organization and Good Standing.

The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of France and has all requisite corporate power and authority to conduct its business as now being conducted.

6.2 Authorization - No Violations.

6.2.1. The execution and delivery by the Purchaser of this Agreement and the Ancillary Agreements and the performance by it of the Transaction have been (or, in the case of the Ancillary Agreements, will have been at the Closing Date) duly authorized by all necessary corporate action. Assuming valid execution by the other parties thereto, this Agreement and each of the Ancillary Agreements to which the Purchaser is a party hereunder, constitutes (or will constitute when signed) a valid and binding agreement of the Purchaser, enforceable against it in accordance with the terms hereof or thereof, subject to the Enforceability Exception.

6.2.2. The execution, delivery and performance by the Purchaser of this Agreement and the Ancillary Agreements to which it is a party and the consummation of the Transaction will not: (i) violate or conflict with any provision of the certificate of incorporation (or other constitutive documents) or by-laws (or other governing documents) of the Purchaser; (ii) materially breach, violate or constitute a default under or an event which would give rise to any right of termination or cancellation, in accordance with the express terms of any agreement, to which the Purchaser is a party, or by which the Purchaser or any of its properties or assets may be bound; (iii) violate or conflict with any Law applicable to the Purchaser or by which any of its properties or assets may be bound; or (iv) except as expressly envisaged in this Agreement, require any registration or filing by the Purchaser with, or any permit, license, exemption, consent, authorization or approval of, or the giving of any notice by the Purchaser to, any Governmental Authority.

6.3 Availability of Funds

The Purchaser has, as of the Closing Date, available cash to pay the Closing Purchase Price at the Closing Date and to pay any other amounts payable pursuant to this Agreement and to effect the Transaction.

6.4 No Claims or Litigation.

There are no suits, actions, claims, proceedings or investigations pending or, to the Purchaser's knowledge, threatened challenging the validity of this Agreement, any of the Ancillary Agreements to which the Purchaser is or is to become a party, or the Transaction.

6.5 Investigation

Purchaser acknowledges that it is relying on (i) the representations and warranties of the Seller contained in ARTICLE V and (ii) its own investigation and analysis in entering into the transactions contemplated by this Agreement and the Transaction Documents. Purchaser is knowledgeable about the industry in which the Pessac Business operates and is capable of evaluating the merits and risks of the transactions contemplated by this Agreement and the Ancillary Agreements and has reasonably evaluated the economic risk of such investment so far as the information disclosed by the Seller in the frame of the due diligence process are true, correct and relevant. Purchaser has been afforded access to such books, records and DR Documents provided by the Seller in the due diligence process, Pessac Facility and personnel designated by the Seller of the Pessac Facility for purposes of conducting a due diligence investigation and has made its own opinion on the Transaction with regard to the information disclosed by Seller under this due diligence process. For purposes of this paragraph, "DR Documents" means the documents made available to Purchaser and its advisors in the electronic data room opened by the Purchaser during the due diligence process, an index of which is attached as **Schedule 6.5** for practical purpose. The DR Documents have been copied on a CD-rom, two originals of which have been signed by both Parties and remitted to each of the Parties on the date hereof. On the Closing Date, a further CD-rom containing additional documents delivered by the Seller to the Purchaser between the date hereof and the Closing Date, if any, will be exchanged between the Parties. The Information contained in any DR Documents shall operate to qualify the representations made pursuant to this Agreement, except (i) where the contents of any DR Document contradicts the contents of a Schedule, in which case the terms and contents of the Schedules shall prevail and (ii) where any such DR Documents does not disclose the matter in such manner and in such detail as to enable Purchaser to make an informed and accurate assessment of the matter concerned.

6.6 Financial Projections.

As part of the information disclosed to Purchaser prior to the execution of this Agreement, the management, employees or respective advisors of Seller have given Purchaser access to projections, estimates, management analyses, budgets, and forecasts as well as a Business Plan. Purchaser presumes that such information relies on assumptions made by Seller based upon fair and reasonable estimate of the costs and revenues with regard to the information receive as of the Closing Date from any Person and acknowledges that said Business Plan may vary beyond Closing Date further to any non predictable event as of the Closing Date or variation of the general economic conditions..

6.7 No Other Representations.

Neither the Purchaser nor any other person or entity acting on behalf of the Purchaser, makes any representation or warranty, express or implied other than those contained in this ARTICLE VI.

ARTICLE VII. COVENANTS

7.1 Covenants of the Seller.

7.1.1. Conduct the Pessac Business until Closing

The Seller, pending the Closing and except as otherwise agreed to in writing by the Purchaser, covenants and agrees that the Pessac Business shall be conducted by the Seller in the ordinary course and in the same manner as heretofore conducted. In particular:

(a) The Seller shall not sell, transfer, assign nor grant any Liens (other than Permitted Liens granted prior to the date hereof) or the right to use or otherwise dispose of any Acquired Property;

(b) The Seller shall not transfer or appoint any key Transferred Employees to any other positions in Seller's organization or Affiliates and shall not replace any employee resigning from its position or dismissed by Seller before the Closing Date, unless otherwise agreed with Purchaser;

(c) The Seller shall not amend the compensation or otherwise materially alter the terms of employment of any of the Transferred Employees (other than normal recurring increases in the ordinary course of business or pursuant to plans, programs or agreements existing on the Execution Date;

(d) The Seller shall not enter into any agreements with any customer, distributor or representative, or any other transaction which is material to the Pessac Business and which does not fall within the ordinary course of the business;

(e) The Seller shall not enter into, terminate, modify or cancel any contract constituting a Material Contract other than in the ordinary course of business;

(f) The Seller shall not dispose of or permit the elapse of any Intellectual Property Rights which are material to the Pessac Business, or dispose of or permit the elapse of any agreement under which Seller has any right or license which is material to the Pessac Business

(g) The Seller shall maintain and service the Acquired Assets consistent with past practice.

7.1.2. Defense of the Patents after Closing

The Seller shall, at no cost to the Purchaser, pay any and all fees and charges relating to the Flamel Patent Rights in any country where the Flamel Patent Rights have been registered in accordance with the GSK License Agreement. **Schedule 7.1.2** sets forth the list of the Flamel Patents Rights and their country of registration as at the date hereof.

7.1.3. Information Systems and Information Technology ("**ISIT**")

Schedule 7.1.3 Part A lists the systems composing the Information Systems and Information Technology (ISIT) relating to the Pessac Business. Such systems are broken down in two categories: (i) systems that exist at the Pessac Facility and which will not be disrupted by the transfer of the Pessac Business at Closing, as detailed in **Schedule 7.1.3 Part C** (the "Operational Systems") and (ii) systems that are necessary for the operations of the Pessac Business and that will be impacted by the transfer **(**the **"**Migration Systems**")** which are all the ISIT systems identified in **Schedule 7.1.3 Part A** other than the Operational systems**.** The Migration Systems will be subjected to a migration plan to be completed by Seller between Signing and Closing, the details of which has been agreed between the Parties and is detailed in **Schedule 7.1.3 Part B** (the "Initial Migration Plan"**)**.

Seller represents and warrants that the ISIT that shall have been installed at the Pessac Facility at Closing (including Operational Systems and Migration Systems) shall, subject to the services to be rendered by Seller to Purchaser after Closing under the Transitional Services Agreement, operate in substantially the same manner as the ISIT used in the Pessac Business immediately prior to the Closing Date.

Seller further represents that (i) the migration plan in respect of the Migration Systems will be implemented in compliance with the Initial Migration Plan and (ii) the Migration Systems will, upon completion of the relevant MSN (as detailed in **Schedule 7.1.3 Part A** and prior to the Closing Date, be subjected to a non-regression testing process as detailed in **Schedule 7.1.3 Part D**.

In case of any disagreement between the Parties as to whether a specific ISIT system conforms to the relevant MSN (as detailed in **Schedule 7.1.3 Part A**), the Parties will attempt to resolve any such disagreement in good faith.

Each of the Parties shall bear its own internal and external costs and charges incurred in relation to the preparation of the initial migration of information systems activities. The Purchaser agrees to reimburse to Seller the purchase costs related to the software licenses Seller may have to purchase for the initial migration when such licenses were not used by Seller for the Pessac Business and have been purchased for complying with Purchaser's specifications or specific needs, subject to prior agreement of Purchaser on such expenses.

7.1.4. Without prejudice to anything contained in the Ancillary Agreement, Seller hereby covenants to grant to Purchaser the contract manufacturing rights related to the products set out in **Schedule 7.1.4.**

7.2 Covenants of the Purchaser.

7.2.1. Business Receivables. Subject to the provisions of ARTICLE VIII, the Business Receivables (being a Retained Asset) shall be and remain the property of the Seller and the Seller shall be solely entitled to all sums which are comprised within the Business Receivables. The Seller shall be solely entitled to collect for its own account, and to enforce for its own benefit all securities for, the Business Receivables. The Purchaser shall not be entitled to any payment under any of the Business Receivables whether by payment in cash or by any other means (including any set-off of claim caused by Purchaser), unless otherwise provided under the Cut-off Schedule as provided in ARTICLE VIII.

7.2.2. **Change of Site Operator.** Promptly following the Closing, the Purchaser shall notify the *Préfet*, in compliance with Article 34 of Decree n° 77-1133 of September 21, 1977, of a change of site operator and send a copy of such notification to the Seller.

7.2.3. **Insurance Replacement.** Purchaser acknowledges that the insurance that covers the Acquired Property is a group insurance, and that it will as such be terminated as early as at 11:59 p.m. (Central European time) on the Closing Date. At the date hereof, Seller shall provide Purchaser with the detailed description of the Acquired Assets as provided to its own insurance company for covering any damages to the Acquired Properties, in order for Purchaser to subscribe to its insurance company a similar coverage. Purchaser acknowledges that, beyond the Closing Date, the Acquired Properties will no longer be covered under the Seller's insurance policies. Purchaser shall enter into the appropriate insurance policies to cover the Acquired Property and the Acquired Real Property effective as from the Closing Date, and shall provide any documentary evidence reasonably required by the Seller upon first request from the Seller.

7.2.4. **Responsible Pharmacist**. Purchaser acknowledges that the role of responsible pharmacist is currently assumed by an employee of the Seller that is not a Transferred Employee; the Purchaser shall be solely responsible for appointing, effective on the Closing Date, a responsible pharmacist for the Pessac Business, as required under the French *Code de la santé publique*.

7.2.5. **Name Change.**

(a) Subject to subparagraph (b) below, within sixty (60) calendar days following the Closing, Purchaser shall remove from the buildings at the Pessac Facility the panels and signs Seller may have leave and could be seen from the outside boundaries of the Pessac Facility encompassing reference to Seller's name or any other trade name not acquired by Purchaser pursuant to this Agreement or any name not licensed to Purchaser pursuant to the any of the Ancillary Agreements. Subject to subparagraph b) hereinafter, the Purchaser agrees that from and after the Closing Date, Purchaser shall cease to use any items and written materials including labels, packing materials, letterhead, marketing materials and other materials, in each case which include the words "FLAMEL". The Purchaser acknowledges and agrees that, Subject to subparagraph b) hereinafter nothing in this Agreement can be interpreted as Purchaser having purchased any right of use on the trade name "FLAMEL". Within sixty (60) calendar days after the Closing Date, the Purchaser shall file in all jurisdictions in which is qualified to do business any documents necessary to reflect such change of name or terminate its qualifications therein. and shall provide any documentary evidence reasonably required by the Seller upon first request from the Seller that any measures required to be taken by Purchaser under this paragraph have been taken.

(b) However, unless otherwise provided in any Ancillary Agreements for a longer time period, the Purchaser shall be allowed, for a period of six (6) months after Closing:

- to use the stock of labels, technical and commercial documentation and movable assets held at the Pessac Facility as existing at the Closing Date and bearing the "FLAMEL" names, trademarks or logos in connection with the Pessac Business, and

- to market and sell directly or through its distributors the finished goods included in the Acquired Inventory marked with "FLAMEL" names, trademarks or logos as at the Closing Date;

, it being understood that the consideration for such use shall be deemed to be included in the consideration paid by the Purchaser pursuant to Section 2.1 hereof.

(c) Notwithstanding the forgoing, Purchaser shall be authorized to use until necessary replacement any and all materials and/or equipment, including clothes, provided by any suppliers under any Assumed Contract, which are supporting or making reference to the FLAMEL name.

7.2.6. Differentiation of Product. From and after the Closing, and as promptly as commercially, legally and technically practicable, Purchaser shall institute appropriate procedures to ensure that products and goods, including Product, of the Pessac Business manufactured, finished or sold by, or on behalf of, Purchaser can be distinguished from products and goods, including Product, of the Pessac Business manufactured, finished or sold by, or on behalf of, Seller or its Affiliates. For example, such differentiation and distinction shall be made by adding different batch numbers and manufacturing date to such goods and products.

7.2.7. Tax Credit (*Credit Impôt Recherche*).

(a) Purchaser shall take prompt, appropriate and effective steps so as to provide that the Purchaser shall obtain the approval from the French competent Governmental Authorities to be recognized as a “research center” (*organisme de recherche agréé*) effective on January 1st, 2015 and if, and when obtained, maintain such approval throughout the term of the Services Agreement, including any extensions of that Agreement, in order to allow Seller to be entitled to the research tax credit with respect to the research services outsourced to Purchaser under the Service Agreement (subject to the related expenses being eligible for the *research tax credit*). Seller hereby agrees and acknowledges that obtaining the relevant status of “research center” shall be mainly subject to the valuation by the relevant Governmental Authority of the quality of the information provided by Seller with regard to the research and development programs implemented at Pessac Facility prior to the Closing Date and the quality of the Transferred Employees.

The Parties shall therefore fully cooperate with one another for the purposes of preparing the application file to be filed with the *Direction Générale de la Recherche et de l'Innovation* of the French Ministry for Education and Research and the follow-up of the matter through the final decision of the competent Governmental Authority to grant of the approval (or to refuse such grant), as well as for its renewal. For the avoidance of doubt, Purchaser, provided it fully cooperates, and procures that its Designated Employees (as defined below) fully cooperate for the purpose of the preparation and follow-up of the application file, shall not be liable to Seller in case the approval is not granted on the basis that the research and development projects referred to in the application file do not fulfill the eligibility criteria set forth by the French competent Governmental Authority.

To that effect, the Parties agree as follows:

- The research and development project that shall be described for the purposes of the a*pplication form for the research tax credit shall be* agreed upon between the Parties, upon Seller's proposal, within 45 calendar days from the Closing; it being understood that the choice of the project shall be made with a view to identify the project that is the most likely to correspond to the criteria utilized by the competent Governmental Authority for assessing the merits of applications of this kind (the '**Project**"); Seller shall disclose to Purchaser to this aim such completed projects implemented prior to Closing at Pessac Facility by the Transferred Employees in order to support the skill and qualification of said Transferred Employees;

- The completed application form and its attachments (including the description of the research and development project) shall be prepared by the Purchaser with close cooperation of the Seller who shall appoint one of its employees and/or consultant as representative to the Purchaser to this aim. Purchaser shall also appoint one of its employees and/or consultant as representative to the Seller to this aim. Seller shall designate to the Purchaser (without assuming or incurring any kind of liability to Purchaser or any Person therefore) such of the Transferred Employees who, in its opinion, are the most qualified to handle the preparation of the application form for Purchaser (the "Designated Employees"). Purchaser agrees and undertakes to consider and encompass in the application all Sellers' comments and/or requests for the drawing up of the application, unless, in the reasonable opinion of Purchaser, such comments or requests would weaken the content and/or structure of the application.

- Each Party shall make its best commercial efforts with the other to reach an agreement on the content and structure of the application form to file no later than on March 31, 2015. Purchaser shall file the application form upon evidence of this written agreement of Seller by April 30, 2015 at the latest, unless otherwise agreed in writing between the Parties.

- In case of any difficulty in completing the application file, the Parties will use the services of a common external consultant having reputable expertise in such matters to assist them completing the file within the legal timeframe, at Purchaser costs.

- Conduct during the instruction of the application by the competent Governmental Authority: the Parties shall fully cooperate in order to answer all questions from the competent Governmental Authority, if any, in a timely and effective manner. Purchaser shall forward any questions of the competent Governmental Authority in a timely manner to Seller so as to enable Seller to assist in preparing the answers to be provided to said Governmental Authority, and shall fully cooperate with Seller for the preparation of such answers and take Seller's comments into account.

(b) The procedure and timing described above shall, *mutatis mutandis* be applied for the purposes of the renewal of the approval (to the extent it was granted initially).

(c) Should Purchaser fail to be approved as a research center effective as of January 1st, 2015 for reasons attributable to Purchaser during the implementation of the procedure described above, then Purchaser shall indemnify Seller for Losses incurred by Seller in relation to Seller not being able to benefit from the tax credit with respect to the research services outsourced to Purchaser under the Service Agreement during the year 2015 (if any with regard to the then applicable Law) to the extent and in the proportion such failure is attributable to Purchaser action or omission and up to the amount of said tax credit.

The provisions of this sub-paragraph (c) shall apply, mutatis mutandis, in case Purchaser fails to obtain the renewal of its approval (to the extent such approval had been obtained initially).

(d) In case no approval (or renewal of approval) has been obtained for 2015 (or any renewal period), Purchaser shall, by June 30, 2016 and each subsequent year throughout the term of the Service Agreement, provide appropriate unqualified certificate from its Corporate Auditor (*Commissaire aux Comptes*) that it does not benefit from any research tax credit in relation to the services supplied by Purchaser to Seller under the Services Agreement.

Should Purchaser have benefited from any research tax credit in relation to the said services during a certain year (or should Purchaser fail to timely provide the required certificate from its Corporate Auditor (*Commissaire aux Comptes*) as provided above), then Purchaser shall reimburse to Seller the Tax Credit amount corresponding to the services supplied by Purchaser to Seller under the Services Agreement during the related year within 30 days from the date of filing of the Cerfa form 2069A by Purchaser relating to the relevant tax credit, together with related interest at the EURIBOR 1 month rate related to the period from the day payment was due as set forth above up to the actual payment date increased by one (1) percentage point.

Once a year, Seller, with persons duly designated by Seller with indication of their employer and position to be bound by non-disclosure obligations with regard to any information proprietary to the Purchaser, may, at its sole expense, at any time and during normal business hours and on giving the Purchaser 30 business days' prior notice in writing, conduct an audit of the Purchaser's premises where it keeps its books and records, to verify that the Purchaser does not benefit from any research tax credit in relation to the services supplied by Purchaser to Seller under the Services Agreement. The Purchaser undertakes to give Seller reasonable access to said premises, as well as to all information and documents in connection with tax credit filing and correspondence. The Purchaser also agrees to provide Seller with all reasonable assistance for any such inspection. All such audits shall be performed so as not to detrimentally affect or delay performance of its activities by the Purchaser or its Affiliates.

7.2.8. Guaranteed Payment Obligations

Purchaser agrees and undertakes to promptly pay to Seller any amount owed to Seller under this Agreement upon agreement of the Parties on the amount due and the due date of payment or, in the absence of agreement thereon between the Parties, upon a final award issued by an arbitral tribunal pursuant to Section 12.12 below.

As security for the payment of the sums owed to Seller under the Guaranteed Payment Obligations, it is agreed that in case of default by Purchaser to pay off the due amount under any of the Guaranteed Payment Obligations at the due date as provided above, any such amount shall be deducted from the total purchases obligations of Seller under Article 5 of the Master Services Agreement and as determined in Section 5.9 of said Master Services Agreement.

For the purpose of this Section, "**Guaranteed Payment Obligations**" means the payment obligations of Purchaser under the following Sections of this Agreement: Section 8.3 (Cut-off principles – Balancing Payment), (ii) Section 7.2.7 (Tax Credit) and (iii) the Purchaser Indemnification under Section 9.1 and (iv) the Acquired Inventory Purchase Price.

7.3 Mutual Covenants.

7.3.1. Assumed Contracts. The transfer of the Assumed Contracts shall be effected as follows:

(a) Any Assumed Contract which can be assigned by the Seller to the Purchaser without the consent of the relevant counter-party the ("Counterparty") shall be transferred by the Seller to the Purchaser on the Closing Date. The Parties shall inform the Counterparty, as necessary, of such assignment.

(b) The Purchaser shall, where required under the terms of the relevant Assumed Contract to perfect the assignment of such Assumed Contract, enter into a direct covenant with the Counterparty to carry out, perform and discharge the obligations referred to in Section 1.2..

(c) Except for the GSK Agreements and the Servier Agreements**,** if and insofar as the benefit of any Assumed Contract cannot be transferred by the Seller to the Purchaser at Closing without the agreement or consent of any Counterparty or the novation of the relevant Assumed Contract (or where such transfer or purported transfer would constitute a breach of such Assumed Contract or give rise to a right to terminate such Assumed Contract):

- This Agreement shall not constitute an assignment or attempted assignment of any such Assumed Contract;

- Beginning on the date hereof, the Purchaser and the Seller shall use all reasonable endeavors (but without being required to incur unreasonable costs or make any payments to any Counterparty) to obtain such consent or to procure that such Assumed Contract is assigned or novated as soon as possible after Closing;

- If before the Closing Date no consent can be obtained for the transfer of certain Assumed Contracts (x) the Parties shall continue to use their reasonable commercial efforts to obtain such consent as promptly as possible after the Closing Date, and (y) with respect to such contract under the list of Assumed Contracts for which the appropriate consents have not been obtained prior to the Closing Date, and until such consents are obtained, the Seller shall, to the extent permissible and lawful under the relevant contract, continue the performance of such contracts on behalf of the Purchaser, in which case the Purchaser shall hold the Seller harmless from all claims made by the Counterparty(ies) concerned against the Seller with regard to such contracts, provided, however, that such claims do not arise out of a breach by the Seller of the terms and conditions of such Contracts, in which case the Seller shall then hold the Purchaser harmless from all claims made against the Purchaser by the Counterparty(ies) concerned by such breach, and (z) once the consent is obtained, the Seller shall transfer such contracts and the related revenues and charges from the Closing date to the Purchaser, and the Parties shall notify the Counterparty concerned the effectiveness of such assignment;

- If a Counterparty shall give the Seller or the Purchaser notice that it will not consent to the assignment or novation of the relevant contract or will only give such consent subject to terms which are not satisfactory to the Purchaser or terminate such contract or shall make any other claim on the grounds that the purported transfer of such contract constitutes a breach of, or entitles the Counterparty to terminate, that contract, then the Seller and the Purchaser shall treat the contract as excluded from the sale and purchase of the Pessac Business., and neither the Seller nor the Purchaser shall have any further obligation to the other with regard to the transfer to the Purchaser of that contract

7.3.2. Confidentiality.

(a) Without prejudice to any rights accrued hereunder, with effect from Closing the Confidentiality Agreement shall be terminated and shall be of no further force and effect.

(b) Each of the Parties shall treat as strictly confidential and not disclose or use any information received or obtained as a result of entering into this Agreement (or any agreement entered into pursuant to this Agreement, in particular any Transaction Documents) which relates to (the "Confidential Information") :

- the provisions of this Agreement and any agreement entered into pursuant to this Agreement (in particular the Transaction Documents);
- the information provided in the course of the discussions between the Parties;
- the negotiations relating to the Letter of Intent, this Agreement and/or to the Transaction Documents.

Seller shall treat as strictly confidential and not disclose or use any information relating to the Transaction following Closing Date.

The foregoing shall not prohibit disclosure or use of any information if and to the extent that the disclosure or use is required by law, any Governmental Authorities, or any recognized stock exchange on which the shares of any party are listed;

(i) the disclosure or use is required to vest the full benefit of this Agreement in any Party;

(ii) the disclosure or use is required for the purpose of any legal Proceedings arising out of this Agreement or any other agreement entered into under or pursuant to this Agreement or the disclosure is made to a Tax authority in connection with the tax affairs of the disclosing party;

(iii) the disclosure is made to professional advisers of any party on terms that such professional advisers undertake to comply with the provisions of this Section 7.3.2 in respect of such information as if they were a party to this Agreement;

(iv) the information is or becomes publicly available (other than by breach of the confidentiality undertaking set forth in this Section 7.3.2);

(v) Purchaser and Seller have given prior written approval to the disclosure or use; or

(vi) the information is independently developed after Closing by employees who did not have access to the Confidential Information of the disclosing Party,

provided that prior to disclosure or use of any information pursuant to paragraphs (i), (ii) or (iii) above, the Party concerned shall promptly notify the other Party of such requirement with a view to providing the other Party with the opportunity to contest such disclosure or use or otherwise to agree the timing and content of such disclosure or us.

7.3.3. **Press Releases.** Upon execution of this Agreement, each Party will issue a public release in the form of the documents attached in **Schedule 7.3.3**. No further public release, disclosure or announcement concerning the Transaction shall be issued by either Party or any of their Affiliates, or any of the officers, directors or employees thereof, without the prior written consent of the other Party (which consent shall not be unreasonably withheld), except as such release or announcement may be required by any applicable law, rule or regulation (in particular those of any national or international stock exchange), in which case the party required to make the release or announcement shall allow the other party reasonable time to comment on such release or announcement in advance of such issuance; provided, however, that the Seller may make internal announcements to its respective employees and competent works council (and, in the case of the Seller, to the Transferred Employees) to the extent required by applicable Law.

7.3.4. **Additional Schedules**. From time to time prior to the Closing, the Seller may supplement or amend the Disclosure Schedules with respect to any matter arising after the date hereof that, if existing at, or occurring on, or known on the date of this Agreement, would have been required to be set forth or described in the Disclosure Schedules. No such supplement to or amendment of the Disclosure Schedules made after the execution hereof and notified to the Purchaser with ten (10) Business Days prior notice shall be deemed to cure any breach of any representation or warranty made pursuant to this Agreement, except:

(a) subject to the provisions of paragraphs (b) and (c) below, for purposes of the Certificate of Seller required to be delivered pursuant to Section 4.2.1 with respect to the reiteration of the Seller's representations and warranties referred to in ARTICLE V,

(b) for purposes of the indemnification provisions set forth in ARTICLE IX and then only if the matter giving rise to a supplemental or amended disclosure has arisen in the ordinary conduct of the Pessac Business as defined in Section 7.1.1, provided that such additional disclosure shall not be considered as additional Disclosure Schedule if to cure an event having a financial effect on the Business Plan greater than one hundred thousand Euros (100,000€);

(c) for all purposes if it constitutes disclosure with respect to a Retained Liability, it being understood that any disclosure in relation therewith shall be for information purposes only and may not limit in any way the rights of Purchaser under this Agreement in relation with indemnification for Retained Liabilities.

7.3.5. Books and Records; Access

a) Seller agrees to deliver, or cause to be delivered, to the Purchaser as soon as practicable after the Closing, subject to applicable Laws, (i) all material books, records, files, supplier invoices and other documents of Seller to the extent solely related to the Pessac Business (save where Seller is required to keep originals pursuant to applicable Law), as the same shall exist as of the Closing Date; and (ii) copies of all other material books, records and other documents related to the Pessac Business, as the Purchaser may reasonably request; provided that (1) any portions thereof that do not relate to the Pessac Business may be redacted from the copies delivered to the Purchaser; and (2) with respect to any such material books, records and other documents recorded in an electronic form, Seller may elect to provide either hard copies or electronic copies. Seller shall ensure that the books and records provided hereunder are a true and accurate description in all material respects of the events in respect of the Pessac Business recorded therein.

b) From and after the Closing Date and for a period of five (5) years, Seller shall provide to the Purchaser, as soon as practicable upon request, such missing information relating to the Business as is reasonably requested by the Purchaser and which has not already been provided by Seller to the Purchaser pursuant to subparagraph (a) above.

c) From and after the Closing Date, Purchaser shall maintain copies of all Pessac Records transferred to it in accordance with this Agreement for a period of five (5) years as from the Closing Date. From and after the Closing Date and for a period of five (5) years, and upon seven (7) days' prior notice, the Purchaser will permit Seller and its duly authorized representatives access, during normal business hours and upon reasonable request (notably for financial reporting and accounting matters, the preparation of any filing or other submission required by Law, or for other purposes envisaged by this Agreement, including without limitation the conduct of defense of Direct Claims and Third Party Claims as set forth in ARTICLE IX, or the preparation of Purchaser's application for the French research tax credit as set forth in Section 7.2.7), to all books and records and other documents related to the Pessac Business, which were delivered to the Purchaser on or after the Closing Date. The Parties shall use their best efforts to ensure that such access shall be performed at times and in a manner so as not to disturb or delay operation of the Pessac Business.

7.3.6. Further Actions. Subject to the terms and conditions herein provided, each of the parties will use its commercially reasonable efforts to take or cause to be taken all actions (and provide all documents) necessary to consummate the Transaction contemplated by this Agreement.

If at any time after the Closing a Party reasonably considers or is reasonably advised that any further actions or deeds are necessary to transfer the ownership of the Acquired Property or otherwise to carry out this Agreement, the other party shall execute all such further actions, or cause its officers or directors to execute all such further actions, and deliver all such deeds and take and do all such other actions and things as may be reasonably requested by the requesting party to confirm any and all right, title and interest in, to such Acquired Property or otherwise to carry out this Agreement.

7.3.7. Registration

For purposes of Articles L. 141-12 and L. 141-13 of the French Commercial Code and filing with the French tax authorities, the Parties shall execute on the Closing Date a French language short-form agreement in the form attached in **Schedule 4.2.1 (i) (f)** (the "Short Form Agreement") and Purchaser shall cause the same to be registered or recorded within fifteen (15) calendar days of its signature in accordance with the abovementioned provisions. In case of any conflict between the terms of this Agreement and those of the Short Form Agreement, this Agreement shall prevail.

7.3.8. Limited license rights.

Each Party agrees and undertakes to enter into good faith negotiation, promptly following the Closing date, on the terms and conditions of a license agreement whereby Purchaser would be granted with the rights to use the Intellectual Property Rights pertaining to the FLAMEL Drug Delivery Platforms, as defined in the preamble of this Agreement, for manufacturing, distributing, selling and marketing such products and supply such services encompassing such Intellectual Property Rights. Each Party shall make reasonable commercial efforts to have said license agreement effective within ninety (90) calendar days from the Closing Date at the latest and for a period ending when all the related patents have expired.

7.3.9. Negotiation of Real Estate Transfer Deed.

The Parties shall negotiate in good faith the terms of a real estate transfer deed pursuant to which Seller shall assign, effective on the Closing Date, to Purchaser, and Purchaser shall purchase from Seller, the Acquired Real Property (the "Real Estate Transfer Deed"); the Real Estate Transfer Deed shall contain customary provisions for the sale of such a real estate asset; provided that it shall not contain any additional representations, guarantees or covenants of the Seller above and beyond those contained in this Asset Purchase Agreement.

For the purposes of this Agreement, "Acquired Real Property" means all volumes, buildings, easements, improvements and fixtures owned as of the Closing Date by Seller and located in Pessac, France, rue Archimède and 11, avenue Gustave Eiffel, and all appurtenances thereto, as further described in **Schedule 7.3.9**.

ARTICLE VIII.CUT OFF PRINCIPLES AND OTHER COVENANTS

8.1 General Cut-Off Principles.

8.1.1. Apportionment Principles.

General principle. Any outgoings, expenses or liabilities paid or incurred, or any payments or other benefits received or to be received, in respect of the Pessac Business, the GSK Agreements or any of the Acquired Property are of a periodic nature and/or relate or are otherwise attributable to a period of time commencing before but ending after the Closing Date, such amount shall be apportioned between the Parties on a time apportionment basis; meaning that the Seller's portion shall be equal to the amount which would be payable if the relevant period ended at the end of the day of the Closing Date, whereas the Purchaser's portion shall be equal to the amount which would be payable if the relevant period started at the beginning of the day following the Closing Date. It is understood that any such amount chargeable or payable by reference to the extent of the use of any properties or rights shall be apportioned according to the extent of such use.

8.1.2. Tax Matters. The Seller shall be liable for all Taxes, including income Taxes, and all Tax Claims, including any and all reassessment of any Taxes or charges with respect to the operation and/or the ownership of the Pessac Business and/or the Pessac Facility (i) in connection with any Tax period ending on or before the Closing Date or, (ii) with respect to any Tax period beginning before and ending after the Closing Date in connection with the portion of such Tax period ending on the Closing Date ("Pre-Closing Taxes"). The Purchaser shall be liable for the Taxes imposed directly on the Purchaser with respect to the Pessac Business and Pessac Facility (i) in connection with any Tax period beginning after the Closing Date, and (ii) with respect to any Tax period beginning before and ending after the Closing Date in connection with the portion of such Tax period beginning on the Closing Date ("Post-Closing Taxes").

8.1.3. Employee Matters.

(a) **General principle.** Subject to the provision of this subsection 8.1.3, the employment contracts of the Transferred Employees shall be transferred from the Seller to the Purchaser at Closing (together with their title, seniority, payroll, allowances and fringe benefits), if any, pursuant to the statutory provisions applicable to their employment agreements as of the Closing Date. The Seller shall be responsible for and shall pay to the Purchaser all wages, benefits, salaries, deferred compensation, bonuses and premiums (such as *thirteen month*, seniority and vacation premiums, and including premiums linked to profit sharing and incentive), commissions, vacation entitlement, overtime hours payments, accrued unused vacations (including compensatory rest and days off for reduction of working time), and any other benefits (including any incentive payment, transaction bonuses or other payment which may be due to any Transferred Employees as a result of the Transaction), as well as for all payroll taxes and social contributions and/or charges due or accrued in connection therewith ("Payroll Benefits"), due by the Seller to the employees so transferred or accrued up to or relating to any period prior to Closing but not yet paid on such date (the "Pre-Closing Accrued Employee Liabilities"). The Purchaser shall be responsible for the Payroll Benefits accrued following the Closing Date and relating to the employment after the Closing of the Transferred Employees (the "Post-Closing Accrued Employee Liabilities"). For the avoidance of doubt, the Seller shall not be liable to pay to Purchaser any retirement benefits, pensions or accruals owed to any Transferred Employees retiring after the Closing Date, other than such amount provided in Section 4.2.2 (ii) which has been deducted from the payment by Purchaser of the Closing Purchase Price.

(b) **Bonus payments**. Profit sharing agreement ("*accord d'intéressement*" or "*participation*") or bonuses linked to objectives will be borne prorata temporis based on the number of days from the start of the then-current calendar year to the Closing Date by Seller. For the avoidance of doubt, Seller will pay its prorata share of Transferred Employees bonuses only to the extent actually owed to the relevant employees in light of performance recorded at the end of the relevant reference period or pursuant to any agreement made by Seller prior to the Closing Date with any relevant employee representative bodies. Further, the Seller's share of the bonus shall be calculated on the basis of the bonus amount defined by Seller prior to Closing – i.e. Seller shall not be liable to pay any amount attributable to any decision by Purchaser to amend the bonus amount or the targets to be achieved by employee in order to obtain such bonus.

8.2 Cut-Off Schedule.

8.2.1. The Seller shall prepare and deliver to the Purchaser within 60 days after the Closing Date, in the frame of Transitional Services Agreement and free of charge to Purchaser, a schedule (the "Cut-off Schedule") apportioning all outgoings, expenses, liabilities and receipts in respect of the Pessac Business and Acquired Property, in accordance with the principles set forth under Section 8.1. The Cut-Off Schedule shall show the net amount owing (if any) from either party (the "Balancing Payment").

8.2.2. The Purchaser shall give and shall procure that the Seller is given all co-operation necessary to enable the Seller to prepare the Cut-Off Schedule. The Seller and the Purchaser shall use their respective reasonable endeavors to agree the Cut-Off Schedule and the amount of the Balancing Payment (if any) within thirty (30) Business Days after the delivery of the Cut-Off Schedule to the Seller in accordance with subsection 8.2.1.

8.2.3. If the Cut-Off Schedule and/or any of the items shown in it are not agreed by the parties within thirty (30) Business Days after the delivery of the Cut-Off Schedule to the Seller in accordance with subsection 8.2.1, then either party may require such item or items (but no other items) to be referred by the Purchaser and the Seller jointly to the Independent Accountants for determination on the following basis:

(a) the Independent Accountants shall be instructed to notify the Seller and the Purchaser of their determination of any such item within thirty (30) Business Days of such referral;

(b) the Seller and the Purchaser shall be entitled to make written submissions to the Independent Accountants, but subject thereto the Independent Accountants shall have power to determine the procedure to be followed in relation to their determination;

(c) any submissions to and the determination of the Independent Accountants shall be in the English language;

(d) in making such submissions the Seller and the Purchaser shall state their respective best estimates of monetary amounts of the items referred for determination;

(e) in making their determination the Independent Accountants shall act as experts and not as arbitrators; and

(f) the fees and expenses of the Independent Accountants shall be borne and paid by the Seller and the Purchaser equally.

(g) The Seller and the Purchaser shall use their respective reasonable endeavors to procure that the Independent Accountants comply with the requirements placed upon them under this Section (including, without limitation, the provisions relating to timing).

8.3 Balancing Payment.

Any Balancing Payment as shown in the Cut-Off Schedule shall be paid by the Purchaser to the Seller or by the Seller to the Purchaser (as the case may be):

(a) within thirty (30) Business Days after the date of determination of the Balancing Payment in accordance with Section 8.2,

(b) in Euros by wire transfer of immediately available funds to the account of Seller or Purchaser (as appropriate), such account to be designated at least three (3) Business Days prior to the date of payment.

ARTICLE IX. INDEMNIFICATION

9.1 Indemnification by Purchaser

Subject to the terms and conditions of this Agreement, from and after the Closing Date, Purchaser ("Purchaser Indemnifying Party") shall indemnify, defend and hold Seller ("Seller Indemnified Party") harmless from and against any and all Loss incurred by such Seller Indemnified Party resulting or arising from or related to, or incurred in connection with:

9.1.1. Subject to the provisions of the initial paragraph of ARTICLE V, any breach of any representation or warranty of Purchaser contained herein as if such representation or warranty were made on and as of the Closing Date (except for any such representations and warranties that are made at a specific date), to the extent not otherwise giving rise to indemnification pursuant to subsection 9.1.2, 9.1.3 or 9.1.4; or

9.1.2. Any Assumed Liability after the Closing Date, provided that Loss is not due to the action or inaction of Seller or any breach of any Seller's representations, warranties and/or covenants under this Agreement or any Ancillary Agreement:

9.1.3. Any breach of any covenant, agreement or other undertaking of Purchaser contained therein;

9.1.4. The ownership and operation of the Pessac Business and Acquired Assets after the Closing provided that Loss is not due to the action or inaction of Seller or any breach of any Seller's representations, warranties and/or covenants under this Agreement or any Ancillary Agreement; and

9.1.5. Any Loss relating to Product sold by Purchaser under the Assumed Contracts (including the GSK Agreements), from and after the Closing except for any Product included in the Acquired Inventory, including, any product recalls and product liability claims, relating to adverse events or otherwise.

9.2 Indemnification by Seller

Subject to the terms and conditions of this Agreement, from and after the Closing Date, Seller ("Seller Indemnifying Party") shall indemnify, defend and hold Purchaser ("Purchaser Indemnified Party") harmless from and against any and all Losses incurred by Purchaser Indemnified Party resulting or arising from or related to, or incurred in connection with:

9.2.1. Subject to the provisions of the initial paragraph of ARTICLE V, any breach of any representation or warranty of Seller contained herein as if such representation, or warranty were made on and as of the Closing Date (except for any such representations, covenant and warranties that are made at a specific date);

9.2.2. Any Retained Liability;

9.2.3. Any breach of any covenant, agreement or other undertaking of Seller contained therein.

9.3 Payments

The Party making a claim for indemnification is, for the purposes of this Agreement, referred to as the "lndemnified Party" and the Party against whom such claim is asserted is, for the purposes of this Agreement, referred to as the "lndemnifying Party". Indemnification under this ARTICLE IX with respect to any claim concerning any Loss shall be due and payable upon the earliest of:

(a) the date determined by mutual agreement between the Indemnified Party and the Indemnifying Party or the date of issuance of a final award issued by an arbitral tribunal pursuant to Section 12.12 (or, if later, the date for payment set forth in such award);

(b) in the case of a Third Party Claim, the date on which payment must be made to the relevant third party after issuance of a definitive order issued by a Governmental Authority or a final judgment, award, order or other ruling issued by a court or arbitral tribunal having jurisdiction over the subject matter of such Third Party Claim (and in each such case, which (x) is not subject to appeal or with respect to which the time for appeal has elapsed, or (y) if subject to appeal, requires the relevant party to make payment pending such appeal (provided that any such payment made pending appeal shall be promptly repaid by the Indemnified Party to the Indemnifying Party upon any reversal of the final judgment, award, order or other ruling having required such payment to be made pending appeal).

9.4 Notice of Claim; Right to Participate in and Defend Third Party Claims

9.4.1. Claim Notice. If, after the Closing, an Indemnified Party (a) receives written notice of the assertion of any claim, the commencement of any suit, action, investigation or proceeding, or the imposition of any penalty or assessment by a third party (including a Governmental Authority) in respect of which indemnity may be sought under Section 9.1 or Section 9.2 (a "Third Party Claim"), or (b) shall have a claim for indemnification under Section 9.1 or Section 9.2 which does not relate to a Third Party Claim (a "Direct Claim"), it shall provide written notice thereof to the Indemnifying Party in accordance with Section 12.3 (a "Claim Notice"). A Claim Notice shall provide a description in reasonable detail of the nature of the Direct Claim or Third Party Claim, indicate the sections of this Agreement which form the basis for indemnification, be accompanied by copies of all supporting documentary evidence in connection therewith (including court papers) (or provide access to the same) and indicate the estimated amount of related Loss (to the extent such amount is known or can reasonably be determined). A Claim Notice shall be made (x) in the case of a Third Party Claim, within thirty (30) Business Days following the date of receipt by the Indemnified Party of the written notice of assertion of the Third Party Claim (provided that such time period shall be reduced to ten (10) Business Days in the case of a Third Party Claim relating primarily to Taxes) or such shorter period as may be required in the event of emergency proceedings or where a response to a notification must be given within a time period to avoid a forfeiture of rights, and (y) in the case of a Direct Claim, with reasonable promptness in view of the circumstances (and in any event within (60) sixty Business Days of its becoming aware of the related Loss). Failure by the Indemnified Party to comply with such notice periods shall have no consequences on its right to make a claim for indemnification under this Agreement; provided, however, that any such failure shall relieve the Indemnifying Party from any liability that it may have to the Indemnified Party to the extent of any increase of the Loss resulting from such failure.

9.4.2. Defense of Third Party Claims

(a) The Indemnifying Party shall have fifteen (15) Business Days from the receipt of the relevant Claim Notice or, in the event of a Direct Claim and if the amount of the claim has not been determined at the time of the Claim Notice, the date on which the amount of the Direct Claim has been notified by the Indemnified Party (the "Notice Period") to notify the Indemnified Party whether or not it disputes its liability to the Indemnified Party hereunder with respect to such claim or demand. If the Parties agree, on or prior to the expiration of the Notice Period, upon the validity and amount of such claim, the Indemnifying Party shall pay to the Indemnified Party, within twenty (20) Business Days following the date of such agreement, the full agreed amount of the indemnification due on such claim. If the parties are unable to reach agreement on or prior to the expiration of the Claim Notice or if the Indemnifying Party dispute their liability with respect to such claim or demand or the amount thereof, such dispute shall be resolved in accordance with Section 12.12 hereof.

(b) In the event that the Indemnifying Party notifies the Indemnified Party within the Notice Period that it desires to defend a Third Party Claim then, except as hereinafter provided, the Indemnifying Party shall have the right to defend the Third Party Claim by appropriate proceedings, including counsel of its choice, reasonably acceptable to the Indemnified Party, which proceedings shall be promptly settled or prosecuted by it to a final conclusion in such a manner as to avoid any risk of the Indemnified Party becoming subject to liability for any other matter and shall pay all fees and disbursements incurred in connection with such proceedings; provided however, that the Indemnifying Party shall not, without the prior written consent of the Indemnified Party (i) consent to the entry of any judgment against the Indemnified Party, (ii) enter into any settlement or compromise of any claim or demand for other than monetary damages, or (iii) enter into any settlement or compromise or any claim or demand for monetary damages which does not include, as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release, in form and substance satisfactory to the Indemnified Party. The Indemnified Party shall have the right to participate in the defense assumed by the Indemnifying Party and to employ counsel of its choice, reasonably acceptable to the Indemnifying Party, at its own expense, separate from the counsel employed by the Indemnifying Party (it being understood that the Indemnifying Party shall control such defense). If requested by the Indemnifying Party, the Indemnified Party agrees to cooperate with the Indemnifying Party and its counsel (at the cost of the Indemnifying Party) in contesting any such Third Party Claim and to refrain from taking any action, which jeopardize or interfere with the defense of such claims. The Indemnifying Party shall keep the Indemnified Party fully informed of the progress of any Third Party Claim and its defense in the event the Indemnified Party did not elect to participate in the defense against such Third Party Claim.

9.5 General Exclusions and Limitations.

9.5.1. The Indemnifying Party shall have no liability to the Indemnified Party under any provision of this Agreement:

(a) for any Loss which arises as a result of the passing of, or any change in, after the Closing Date, any Law in effect on the Closing Date, or any imposition of any Tax not in effect on the Closing Date, even if such Law or Tax imposition has retroactive effect;

(b) to the extent that the facts giving rise to the relevant Losses were contained in a Disclosure Schedule as provided in this Agreement and to the extent of such content;

(c) to the extent that the relevant Loss is due to the Indemnified Party's willful misconduct, gross negligence or bad faith;

(d) if and to the extent that (in the event that the relevant breach can be cured) the Indemnifying Party has, within thirty (30) days following receipt by Indemnifying Party of Indemnified Party's notice, completed all and any action to cure such breach and eliminate the related Loss;

(e) if and to the extent that the Indemnified Party is entitled to receive or has received recovery for the relevant Loss from any other Person (including under any insurance policy) or, in the case described above, if and to the extent that non recovery from any other Person is due to the failure of the Indemnified Party to use its or their reasonable efforts to obtain such recovery;

9.5.2. **Limitation on quantum**. The Indemnifying Party shall not be liable in respect of any Direct Claim or Third Party Claim unless and until:

(a) the amount of each such claim exceeds Five Thousand Euros (€5,000) (the "Claim Threshold"), and

(b) the aggregate amount of all such claims exceeds fifty thousand Euros (€50,000) (the "Indemnity Threshold"), in which case the Indemnifying Party shall only be liable for the amount in excess of, but excluding, the Indemnity Threshold; it being understood that only claims exceeding the Claim Threshold shall be included in calculating the Indemnity Threshold,

Provided that the aggregate liability of the Indemnifying Party for all claims by the Indemnified Party under this Agreement shall not exceed the amount of **THREE MILLION EUROS** (€3 000 000) (the "**Indemnity Cap**").

9.5.3. Effective nature of Losses.

(a) Any liability for indemnification pursuant to this Agreement shall be determined without duplication of recovery. In the event that the Indemnified Party is indemnified for a Loss pursuant to one provision of this Agreement, the Indemnified Party shall not be entitled to indemnification again form the same Loss in the event another provision or provisions of this Agreement are also breached.

(b) A Loss shall be eligible for indemnification by the Indemnifying Party to the extent and only to the extent such Loss has effectively been sustained by the Indemnified Party.

(c) Any deficiency assessed by the Tax authorities whose sole effect is to shift a Tax liability from one fiscal period to another shall give rise to indemnification by the Indemnifying Party only insofar as the Indemnified Party is required to pay a penalty or interest charge in relation thereto.

(d) Any deficiency assessed with regard to a Tax, such as a value-added Tax, which is recoverable shall give rise to indemnification by the Indemnifying Party only insofar as the Indemnified Party is required to pay a penalty or interest charge in relation thereto.

(e) If a claim is based upon a liability which is contingent only, no indemnification shall be due unless and until such liability becomes due and payable.

(f) In the event that the Indemnified Party is required to make a payment in connection with a Third-Party Claim, the Indemnifying Party shall not be required to make any indemnification payment in connection thereto before such payment has actually been made by the Indemnified Party to such third party.

9.6 Survival of Representations and Warranties.

a) Subject to subparagraph b) hereunder, the indemnification obligations under this ARTICLE IX shall survive eighteen (18) months following the Closing Date, save for Tax Claims and for all payroll taxes and social contributions and/or charges, which shall survive until the expiration of the applicable statute of limitations plus 90 days. No indemnification claim for the recovery of any Loss may be asserted by the Indemnified Party after the expiration of the applicable indemnification period; provided, however, that indemnification claims made in writing by the Indemnified Party in good faith and with reasonable specificity prior to the expiration of the applicable indemnification period shall not thereafter be barred by the expiration of the applicable indemnification period.

b) Notwithstanding subparagraph a) above, Seller's indemnification obligations in connection with any Direct Claim or Third Party Claim related to Retained Assets and/or Retained Liabilities shall be unlimited in time and monetary respect. No monetary limitation, threshold amount, or any other condition shall apply to such claims. Seller shall be required to fully indemnify, defend and hold Purchaser harmless from and against any Loss related to Retained Assets and/or Retained Liabilities and shall be obligated to fully indemnify with respect to the full amounts.

9.7 Tax Effect of Indemnification Payments.

All indemnity payments made by the Indemnifying Party to the Indemnified Party pursuant to this Agreement shall be treated for all Tax purposes as adjustments to the Closing Purchase Price, unless otherwise agreed between the Parties.

9.8 Efforts to Mitigate Damages.

Both Parties shall use their best commercial efforts to mitigate any indemnifiable damages caused by a breach by any representation, warranty or covenant as set forth in this Agreement.

ARTICLE X.POST-CLOSING COVENANTS

10.1 Non Solicitation of Employees.

Until the second anniversary of the Closing Date, (a) Seller and its Affiliates will not solicit, offer employment to, or employ any Transferred Employee who is then an employee of the Purchaser, or who has left such employment within one hundred eighty (180) days preceding such solicitation, offer, or employment, or encourage any Transferred Employee to leave the employ of the Purchaser and (b) the Purchaser will not directly or indirectly solicit, offer employment to, or employ any person who after the Closing Date is then an employee of the Seller, or who has left such employment within one hundred eighty (180) days preceding such solicitation, offer or employment.

10.2 **Non-Competition / Non Solicitation of Clients.**

10.2.1. Non-Competition by Seller. The Seller agrees that upon Closing and for a period of three (3) years after the expiration of the Supply Agreement, it shall not directly or indirectly, (i) engage in the development, production, processing, sale, marketing or distribution of drug products that compete with the Product; or (ii) engage in providing contract development and manufacturing services for any third party to the extent that such activities pertain to a product that competes with the Product ((i) and (ii), collectively, the "Purchaser Competing Activities"); or (iii) own, manage, operate, control or participate in the ownership, management, operation or control of any other person whose activities constitute or include Purchaser Competing Activities, or (iv) solicit, any business entity which is a client of the Pessac Business under any of the Assumed Contracts for purposes of offering or selling products or services which compete with the Product; provided, however, that nothing herein shall prohibit the Seller or its Affiliates from (a) engaging in the development, production, processing, sale, marketing or distribution of drug products other than the Product, or (b) offering research and development services using FLAMEL Drug Delivery Platforms, or (c) acquiring an interest of less than 5 % of the shares capital and voting rights of publicly listed companies having activities that constitute or include Purchaser Competing Activities, or (d) owning, managing, operating, controlling or participating in the ownership, management, operation or control of any entity in which less than 5 % of the revenues arise from a business that constitute or include Purchaser Competing Activities.

10.2.2. **Non-Competition by Purchaser**. Purchaser agrees that for a period of three (3) years after the Closing Date, no entity of the Purchaser Group shall, directly or indirectly, (i) engage in any activities competing with the activities of the Seller or any of its Affiliates using FLAMEL Drug Delivery Platforms (the "Seller Competing Activities"); or (ii) own, manage, operate or control, or participate in the ownership, management, operation or control of, any other Person whose activities constitute or include Seller Competing Activities; provided, however, that nothing herein shall prohibit the Purchaser or its Affiliates from (x) acquiring an interest of less than 5 % of the shares capital and voting rights of publicly listed companies having activities that constitute or include Seller Competing Activities, nor (y) owning, managing, operating, controlling or participating in the ownership, management, operation or control of any entity in which less than 5 % of the revenues arise from a business that constitute or include Seller Competing Activities.

10.3 **Invalidity or Non-enforceability.**

The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction..

ARTICLE XI.TERMINATION

11.1 **Termination.**

This Agreement may be terminated by written notice of termination at any time before the Closing Date only as follows:

(a) by mutual consent of the Seller and the Purchaser;

(b) by the Purchaser, upon written notice to the Seller given at any time after a period of 90 days following the Execution Date or such later date as shall have been specified in a written instrument signed by the Seller and the Purchaser) if all of the conditions precedent set forth in Section 3.2 hereof have not been met;

(c) by the Seller, upon written notice to the Purchaser given at any time after a period of 90 days following the Execution Date (or such later date as shall have been specified in a written instrument signed by the Seller and the Purchaser) if all of the conditions precedent set forth in Section 3.3 hereof have not been met;

(d) by the Purchaser or the Seller if any Governmental Authority shall have issued an order, decree or ruling or taken any other action (which order, decree, ruling or other action the parties hereto shall use their best commercial efforts to lift) which restrains, enjoins or otherwise prohibits the acquisition by the Purchaser of all or a material portion of the Pessac Business and/or Pessac Facility.

11.2 Consequences.

In the event of the termination hereof pursuant to the provisions of Section 11.1, and, except the termination was the result of a breach by a party of any representation, warranty or covenant hereunder in which event the party whose representation, warranty or covenant was breached shall be liable to the other, none of the Parties shall be liable to the other for such termination, whatever the consequences are for any Party.

ARTICLE XII.MISCELLANEOUS PROVISIONS

12.1 Amendment.

This Agreement may not be amended except by a written instrument signed by each of the parties hereto.

12.2 Waivers.

Except as otherwise provided in this Agreement, any failure of any of the Parties to comply with any obligation, covenant or agreement contained herein may be waived only by a written notice from the Party entitled to the benefits thereof. No failure by any Party hereto to exercise, and no delay in exercising, any right hereunder, shall operate as a waiver thereof; nor shall any single or partial exercise of any rights hereunder preclude any other or future exercise of that right by that Party.

12.3 Appointment of the Seller's Agent - Notices.

12.3.1. Election of domicile

(a) Any objection shall be made at the Seller’s address, which shall be the elected domicile (domicile élu) for purposes of article L. 141-14 of the French Code of Commerce, as follows:

FLAMEL TECHNOLOGIES
Parc Club du Moulin à Vent
33 avenue du Docteur Georges Lévy
Venissieux Cedex France 69693
A l’attention du Directeur Général

(b) For purposes of Article L. 141-19 of the French Commercial Code, during the twenty days following publication of this Agreement in the Official Bulletin of Civil and Commercial Notices, Purchaser shall hold an original of this Agreement at its registered address to facilitate consultation thereof by any objecting or registered creditor.

12.3.2. Subject to notice provisions expressly specified elsewhere in this Agreement, all notices and other communications hereunder shall be deemed sufficiently given to a person if given in writing and shall become effective when delivered by hand, by overnight service, special courier which requires a delivery receipt therefore, by facsimile transmission with confirmation of receipt, by email transmission provided a confirmation of delivery or of reading is delivered by the server of destination, by registered or certified mail (return receipt requested), postage fees prepaid, at such person's address set forth below (or at such other address as may from time to time be designated by such party to the other in accordance with this Section 12.3.1):

If to the Seller, to:

FLAMEL TECHNOLOGIES

Address: Parc Club du Moulin à Vent
33 avenue du Docteur Georges Lévy
Venissieux Cedex France 69693
Marked for the attention of the CEO

Email: anderson@flamel.com

with copies to: FIDAL
Direction Paris
Tour Prisma | 4-6, avenue d'Alsace | 92982 PARIS LA DEFENSE CEDEX | France
Marked for the attention of: Anne Fréchette-Kerbrat

Email : anne.frechette-kerbrat@fidal.com

If to the Purchaser, to:

RECIPHARM PESSAC

Address: Rue Archimède, 33600 Pessac, France
Facsimile: + 33 5 56 36 58 91
Marked for the attention of: General Manager
Email: stephane.guisado@recipharm.com

with copies to: RAMBAUD – LE GOATER, Avocats
50 rue Rambuteau, 75003 Paris, France
+33 1 48 87 10 62
Marked for the attention of: Bernard Le Goater
Email : bernard.legoater@rambaudlegoater.com

12.4 Assignment.

Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the Parties hereto without the prior written consent of the other Party, provided, however, that without such prior consent the Purchaser may at any time prior to the Closing Date, assign, in its sole discretion, all or any part of its rights and interests hereunder to any wholly owned Affiliate of the Purchaser; provided, however, that the Purchaser shall remain jointly and severally liable for the performance of all obligations so assigned and that the assignee shall remain a wholly owned Affiliate of the Purchaser.

12.5 No Third Party Beneficiaries.

Subject to the provisions of Section 12.4, neither this Agreement or any provision hereof, nor any Schedule, certificate or other instrument delivered pursuant hereto, nor any agreement to be entered into pursuant hereto or any provision hereof, is intended to create any right, claim or remedy in favor of any person or entity, other than the parties hereto and their respective successors and permitted assigns.

12.6 No Set-off.

All payments to be made by either Party under this Agreement or any of the Ancillary Agreements shall be made in full without any set-off, restriction or condition and without any deduction for or on account of any counterclaim.

12.7 Expenses.

Each Party shall pay its own fees and expenses incurred by it in connection with this Agreement and other documents to be delivered hereunder or thereunder, except as specifically provided to the contrary in this Agreement.

12.8 Counterparts.

This Agreement may be executed in any number of counterparts and any Party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument.

12.9 Headings, etc.

The article and section headings contained in this Agreement are solely for convenience of reference, are not part of the agreement of the Parties and shall not be used in construing this Agreement or in any way affect the meaning or interpretation of this Agreement.

12.10 Entire Agreement; Severability.

This Agreement and the Schedules and Exhibits, the Ancillary Agreements, the certificates and other instruments and documents delivered pursuant hereto embody the entire agreement of the parties hereto in respect of, and there are no other agreements or understandings, written or oral, among the parties relating to, the subject matter hereof. This Agreement supersedes all prior agreements and understandings, written or oral, between the parties with respect to the subject matter hereof, including the LOI of March 6, 2014.

12.11 Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of France.

12.12 Dispute Resolution

12.12.1. The Parties shall do their best effort to settle amicably any dispute, controversy or claim arising out of or in connection with this Agreement or the breach, termination or validity thereof (a "Dispute") within 30 Business Days following the notification by one of the Party to the other of such Dispute.

12.12.2. Should the Parties fail to reach such settlement, the Parties shall then refer the dispute to proceedings under the ICC Mediation Rules. If the dispute has not been settled pursuant to the said Rules within sixty (60) Business Days following the filing of a Request for Mediation or within such other period as the Parties may agree in writing, such dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("ICC") (the "Rules"), which Rules are deemed to be incorporated by reference into this clause except as expressly modified herein. The seat of the arbitration shall be Paris (France). The arbitration proceedings shall be conducted in English and documentary exhibits may be admissible in English or in any other language so long as a certified English translation is provided. The arbitral tribunal shall consist of three arbitrators and shall not have the power of *ex aequo et bono.*

12.12.3. The Parties hereby waive any rights of application or appeal to any other court having jurisdiction to the fullest extent permitted by law in connection with any question of law arising in the course of the arbitration or with respect to any award made, except for actions to enforce an arbitral award and actions seeking interim, interlocutory or other provisional relief in any court of competent jurisdiction.

12.12.4. The award shall be final and binding upon the Parties, and shall be the sole and exclusive remedy between the Parties regarding any claims, counterclaims, issues, or accounting presented to the arbitral tribunal. Judgment upon any award may be entered in any court having jurisdiction.

12.12.5. The Parties shall each bear their own costs and expenses and an equal share of the arbitrators' fees and expenses and administrative fees of the arbitration.

12.12.6. Any monetary award shall be made and promptly payable in Euro and the arbitral tribunal shall be authorized in its discretion to grant pre-award and post-award interest at commercial rates. Any costs, fees, or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting such enforcement.

12.12.7. This Agreement and the rights and obligations of the Parties shall remain in full force and effect pending the award in any arbitration proceeding hereunder.

12.12.8. All notices by one Party to another party in connection with the arbitration shall be in accordance with the provisions of Section 12.3 except that no notice may be transmitted solely by facsimile.

12.12.9. This Agreement to arbitrate shall be binding upon the successors and assigns of each Party.

12.13 Exhibits and Schedules.

All Exhibits and Schedules hereto are hereby incorporated by reference into this Agreement and are hereby made a part hereof.

12.14 Interpretation.

12.14.1. When a reference is made in this Agreement to a section or article, such reference shall be to a section or article of this Agreement unless otherwise clearly indicated to the contrary.

12.14.2. A reference to any Party to this Agreement or any other agreement or document shall include such Party's successors and permitted assigns.

12.14.3. A reference to any legislation or to any provision of any legislation shall include any amendment to, and any modification or re-enactment thereof, any legislative provision substituted therefore and all regulations and statutory instruments issued thereunder or pursuant thereto.

12.15 Conflict.

In the event of any conflict between the provisions of the Ancillary Agreements (including the Real Estate Transfer Deed), on the one hand, and the provisions of this Agreement, on the other hand, then, the provisions of this Agreement shall prevail as between the parties. The Parties acknowledge and agree that the execution of the Ancillary Agreements (including the Real Estate Transfer Deed) contemplated in this Transaction, will not represent a novation nor an amendment to this Agreement.

Nothing contained in the Ancillary Agreements (including the Real Estate Transfer Deed), shall be construed to expand nor to restrict the representations, warranties and covenants of the Parties set forth in this Agreement.

12.16 VAT exemption regime

As the transfer contemplated in this Agreement is a transfer in return for payment concerning a complete set of assets, within the meaning of such term under the tax regulations (especially the BOI-TVA-CHAMP-10-10-50-10-20121001), on the one hand, and the Seller and Purchaser being subject to VAT, on the other hand, the Parties agree to take advantage of the exemption from VAT provided by Section 257 bis of the French Tax Code applicable to deliveries of goods, provision of services and transactions, carried out between persons liable for value added tax under conditions; for this purpose, the Purchaser undertakes to make subsequent sales of such assets subject to VAT and, if applicable, to make the adjustments provided for in Section 207 of Appendix II the French Tax Code.

In accordance with the provisions of Section 287-5, c) of the French Tax Code, the Parties shall mention the total amount exclusive of tax of the assets thus transferred on their VAT return entered into for the period during which this Transfer is carried out.

In the event of any difficulty due to the application of this provision, the Purchaser undertakes to personally arrange for the payment of the VAT due pursuant to this Agreement. The Seller shall then issue an invoice in accordance with the provisions of French law, which includes inter alia, an indication of the amount of VAT.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date first above written in Paris.

/s/ Michael S. Anderson
FLAMEL TECHNOLOGIES
By: Michael S ANDERSON
Chief Executive Officer

/s/ Mark Quick
RECIPHARM PESSAC
By: Mark QUICK
Executive Vice President Corporate Development of RECIPHARM AB
Duly authorized to sign on behalf of RECIPHARM PESSAC

Schedule A
Definitions

"**Acquired Assets**" has the meaning set forth in Section 1.1.1.

"**Assumed Contracts**" has the meaning set forth in Section 1.2.

"**Acquired Inventory**" has the meaning set forth in Section 1.1.4.

"**Acquired IP Rights**" has the meaning set forth in Section 1.1.1 (c).

"Acquired Real Property" has the meaning set forth in Section 7.3.9.

"Acquired Property" means, collectively, the Acquired Assets, the Acquired Real Property, the Assumed Contracts and the Acquired Inventory.

"Assumed Contracts" has the meaning set forth in Section 1.2.

"Assumed Liabilities" has the meaning set forth in Section 1.3.

"**Affiliate**" of any corporate person means any other person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the first mentioned Person. A person shall be deemed to control another person if such first mentioned persons owns, directly or indirectly, 50 % or more of the voting rights of the second mentioned person.

"**Affiliated Companies**" means the entities in which the relevant party owns, directly or indirectly, more than 50 % of the outstanding equity interest and voting rights.

"**Agreement**" has the meaning set forth in the Recitals.

"**Ancillary Agreements**" means the Quality Agreement, the Master Services Agreement, the Supply Agreement, the Services Agreement, the Transitional Services Agreement and the Short-Form Agreement, as all included in **Schedule 4.2.1 (i) (a) to (f)**, as well as the Real Estate Transfer Deed.

"**Business Assets**" means the tangible assets described in Section 1.1.1 (a)

"**Business Day(s)**" means days on which banks in France, Sweden and in the United States are open for business, not being a Saturday or a Sunday or a public/bank holiday.

"Business Plan" means the financial projections provided by Seller, as set forth in **Schedule 5.16**.

"Business Receivables" means all amounts receivable by or owing to the Seller as at the Closing Date (whether or not any such amounts are then due and payable) for goods and/or services supplied by the Seller or otherwise receivable by or owing to the Seller in connection with the Pessac Business.

"**Claim Notice**" has the meaning set forth in Section 9.4.1.

“**Closing**” means the time at which the Seller consummates the sale, assignment, transfer and delivery of the Acquired Property and the Acquired Real Property to Purchaser, and Purchaser assumes the Assumed Liabilities and the Assumed Contracts, as provided herein, by the execution and delivery by the Seller of the documents and instruments referred to in Section 4.2.1 against delivery by Purchaser of the documents, instruments and payments referred to in Section 4.2.2

"**Closing Date**" has the meaning set forth in Section 4.1.

"**Closing Purchase Price**" has the meaning set forth in Section 2.1.3.

"**Direct Claim**" has the meaning set forth in Section 9.4.1.

“**Disclosure Schedules**" has the meaning set forth in ARTICLE V.

"**Dispute**" has the meaning set forth in Section 12.12.1.

“**DR Documents**" has the meaning set forth in Section 6.5.

"**Effective Date**" has the meaning set forth in the first paragraph of ARTICLE V.

"**Execution Date**" means the date of execution of this Agreement.

"**Encumbrances**" means any liens, charges, pledges or other security interests or encumbrances or other third party rights.

"**Enforceability Exception**" means any limit to enforceability of a contract under bankruptcy, reorganization and similar losses affecting enforcement of creditors' rights generally.

"**Environmental Law**" mean any Law governing pollution, the protection of the environment and health and safety matters as well as waste and resource consumption regulations.

"**Environmental Permits**" has the meaning set forth in Section 5.13.2.

"**Governmental Approval**" means any approvals, consents, permits, rulings, waivers, exemptions or other authorizations issued, granted, given or otherwise made available by or under the authority of any Governmental Authority.

"**Governmental Authority**" means a court, arbitral tribunal, administration agency or other regulatory authority, including social security and tax authorities.

"**GSK Agreements**" means (i) the following agreements entered into by and between Seller and SmithKline Beecham (Cork) Limited, a company organized under the laws of the country of Ireland with a place of business at Curraghbinny, Carrigaline, Country Cork, Ireland, and or its Affiliates **("GSK"):** the Supply Agreement for Commercial Manufacturing, dated effective January 1, 2011 and the First Amendment to Supply Agreement for Commercial Supply dated effective as of the Closing Date; the Side Agreement dated December 3, 2004 as amended by letter agreement dated November 10, 2005; the Letter Agreement dated July 28, 2006 ; the Second Amendment to Side Agreement relating to Coreg CR dated effective as of the Closing Date; the equipment Letter Agreement dated effective as of the Closing Date and (ii) the Consent to Assignment of Supply and Other Arrangements entered into by and between Seller, GSK and Purchaser and dated effective as of the Closing Date.

"**GSK Inventory**" means the API belonging to GSK and delivered at the Pessac Facility under the GSK Agreements.

"**GSK License Agreement**" means the license agreement entered into by and between Seller and SB Pharmco Puerto Rico, Inc., a GlaxoSmithKline company, dated March 26, 2003, as amended effective on 18th October 2004, 16th March 2007 and 17th September 2012 and by the Letter Amendment dated April 26, 2013, and as further amended from time to time..…

"**ICC**" has the meaning set forth in Section 12.12.2.

"**Indemnifying Party**" has the meaning set forth in Section 9.3.

"Independent Accountants" means any first rank independent accounting firm appointed by mutual agreement of the Seller and Purchaser, or, in the absence of agreement, any first rank independent accounting firm appointed by the President of the Paris Commercial Court.

"**Intellectual Property Rights**" shall mean (i) all French, European, international and foreign patents and applications therefore and all reexaminations, reissues, divisions, renewals, extensions, provisionals, continuations and continuations-in-part thereof; (ii) Know-How (including for the avoidance of doubt, the Pessac Know-How); (iii) all copyrights, copyrights registrations and applications therefore, and all other rights corresponding thereto throughout the world; (iv) all domain names, uniform resource locators ("URLs") and other names and locators associated with the Internet; (v) rights in computer softwares, including, without limitation, all source code, object code, and firmware; and (vi) all trade names, logos, common law trademarks and service marks, trademark and service mark registrations and applications therefore throughout the world.

"**Know-How**" means undisclosed or confidential information (such as know-how, trade secrets and inventions (whether patentable or not)) and proprietary information (including plans, specifications and drawings).

"**Law**" means any statute, rule, regulation, ordinance, code, judgment, order, writ, injunction, decree or other requirement of any court or of any governmental body, agency or administration, including European Union's Regulations and directives, including any mandatory provisions under any regulations applicable to the pharmaceutical industry.

"**Liability**" means any indebtedness, liability, duty or obligation of any kind, whether deriving from contract, statute or otherwise, whether present or future, actual or contingent, ascertained or unascertained, and whether owed or incurred severally or jointly or as principal or surety.

"Loss" means damages, losses, deficiencies, liabilities, costs and expenses (including reasonable attorney's fees), to the exclusion of consequential, incidental or indirect damages, lost profits or punitive, special or exemplary damages; in particular, no "multiple of profits" or "multiple of cash flow" or similar valuation methodology shall be used in calculating the amount of any Loss.

"**Material Adverse Change**" shall mean the occurrence of any event, fact or circumstance, which :

- is outside the control of the Parties, directly and specifically adversely affects the Pessac Business or the Pessac Facility in a material manner, and has a lasting (*durable*) material effect, or can reasonably be expected to have a lasting (*durable*) material adverse effect, on the value of the Acquired Properties and/or the sustainability of the Pessac Business; and

- is not caused by (x) general financial, economic, market or political conditions or economic or business conditions affecting the pharmaceutical business generally (including as a result of a change in the price of raw materials), (y) any act by Purchaser or any of its Affiliates, (z) the announcement or pendency of the Transaction;

- if capable of remedy, shall not have been cured by Seller prior to the Closing Date.

"**Material Contract"** has the meaning set forth Section 1.2.

"**Permits**" means all consents, licenses, permits or authorizations granted or required for the conduct of the Pessac Business.

"**Permitted Liens**" means encumbrances for current taxes or assessments, not delinquent, *clause de reserve de propriété*, and all encumbrances arising and continuing in the ordinary course of business, for obligations which are not delinquent, and which do not materially affect the value of the assets of the Pessac Business or the Purchaser, as the case may be.

"**Permitted Real Property Encumbrances**" means any Permitted Lien related to any real property and any easement, right of use or other third party adverse right which does not materially affect the conduct of the Pessac Business as conducted as of the date hereof.

"**Person**" means any natural person, partnership, corporation, limited liability company, business trust, joint stock company, unincorporated association, joint venture, Governmental Authority or other entity or organization.

"**Pessac Business**" has the meaning set forth in the Recitals.

“**Pessac Facility**” has the meaning set forth in the recitals.

“Pessac Know-How” means the Know-How relating to the Pessac Business, including the Know-How relating to the manufacturing by spray-coating, wet-granulation or extrusion-spheronization but excluding any Know-How related to the Flamel Drug Delivery Platforms.

“**Pessac Records**” has the meaning set forth in Section 1.1.1 (c).

"**Post-Closing Taxes**" has the meaning set forth in Section 8.1.2.

"**Pre-Closing Taxes**" has the meaning set forth in Section 8.1.2.

"**Product**" means Coreg CR microparticles as manufactured by Seller at the date hereof under a supply contract with SmithKline Beecham (Cork) Limited dated on 30 September 2011.

"**Purchaser Group**" shall mean the Purchaser and each of its Affiliated Companies specifically operating in the field of the Pessac Business.

"**Purchaser**" has the meaning set forth in the Recitals

“Quality Agreement" means the quality agreement to be executed on the Closing Date substantially in the form attached in **Schedule 4.2.1 (i) (a).**

“Real Estate Transfer Deed” has the meaning set forth in Section 7.3.9.

"Real Property Encumbrances" means any encumbrance of any kind (meaning any pledge, mortgage, seizure, privilege, lien, usufruct, right of pre-emption, enjoyment or claim, easement, right of first refusal or any third party option right or any other encumbrance or security interest of any kind).

“**Required Assets**” has the meaning set forth in Section 5.5.2.

"**Retained Liabilities**" has the meaning set forth in Section 1.3.2.

"Seller" means FLAMEL TECHNOLOGIES.

"Seller Group" means the Seller and its Affiliates..

"**Service Agreement**" means the services agreement to be executed on the Closing Date substantially in the form attached in **Schedule 4.2.1 (i) (d).**

"**Servier Agreements**” has the meaning set forth in Section **4.2.1 (iii)**.

“**Short-Form Agreement**” has the meaning set forth in Section 7.3.7.

"**Supply Agreement**" means the supply agreement to be executed on the Closing Date substantially in the form attached in **Schedule 4.2.1 (i) (c)**

"**Tax Claims**" means any and all actions, suits, claims or legal administrative, arbitration, governmental or other proceeding or investigations in connection with Pre-Closing Taxes imposed upon the Purchaser Group.

"**Tax Returns**" means any return, declaration, report, claim for refund, or information return or statement relating to Taxes, including any such document prepared on a consolidated, combined or unitary basis and also including any schedule or attachment thereto, and including any amendment thereof.

"**Taxes**" shall mean any taxes and more generally any mandatory levies (including their principal amount and, as the case may be, penalties, surcharges and interest thereon). Taxes include, without limitation, (i) any tax (governmental, departmental or local), governmental fee or other like assessment or charge of any kind whatsoever (including any net income, alternative or add-on minimum tax, gross income, gross receipts, sales, use, ad valorem, value added, transfer, franchise, profits, license, withholding tax on amounts paid, payroll, employment, excise, severance, registration, stamp, capital stock, occupation, property, environmental or windfall profit tax, premium, custom, duty or other tax), together with any interest, penalty, addition to tax or additional amount due, imposed by any Governmental Authority (French or foreign) responsible for the imposition of any such tax, (ii) any liability for the payment of any amount of the type described in clause (i) above as a result of a party to this Agreement being a member of an affiliated, consolidated or combined group with any other corporation at any time prior to the Closing Date.

"**Transfer Taxes**" shall mean any Taxes triggered by the sale of the Acquired Assets and the Acquired Real Property under this Agreement.

"**Third Party Claim**" has the meaning set forth in Section 9.4.1.

"**Third Party**" means any Person other than the parties hereto and their respective Affiliates.

"**Transaction**" means all the transactions provided for or contemplated in this Agreement and the Ancillary Agreements.

"**Transaction Documents**" has the meaning set forth in Section 5.1.

"Transitional Services Agreement" means the transitional services agreement to be executed on the Closing Date substantially in the form attached in **Schedule 4.2.1 (i) (e).**

"**Transferred Employees**" has the meaning set forth in Section 5.12.1.

"**Subsidies**" means any monetary grants made to the Seller for the Pessac Business or the Pessac Facility by a Governmental Authority for any purposes.

MASTER AGREEMENT ON SUPPLY OF SERVICES AND PRODUCTS

THIS AGREEMENT (the **"Agreement"**) is made and effective on this December 1st, 2014 (the **"Effective Date"**) by and between:

(1) **RECIPHARM PESSAC**, a French *Société par Actions Simplifiée* under the registration process with the commercial court of Bordeaux and having its principal place of business at rue Archimède, 33600 PESSAC France ("**RPC**").

(2) **FLAMEL TECHNOLOGIES SA,** a French *Société Anonyme* with the registered number 379 001 530 and having its principal office at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX ("**FLAMEL**").

A. The Parties entered into the APA, where the transaction provided under said APA and the ancillary agreements attached to the APA are entering into force at the Effective Date;

B. The Parties agreed in that frame, to have RPC providing various services to FLAMEL in the domain of (i) the research and the development of pharmaceutical products and (ii) the manufacture of finished pharmaceutical products;

C. The Parties have agreed that any part of these services could be assigned by RPC to any of its Affiliates, upon RPC decision with regard to the nature of the services in question or upon special request from FLAMEL; and

D. The Parties have agreed as one of the essential and decisive conditions for RPC to entering into the APA, on a minimum volume of Services to be paid by FLAMEL to RPC each year for the five-year period from the completion of the transactions under the APA.

NOW, THEREFORE, the Parties agree as follows.

1. DEFINITIONS AND INTERPRETATION

All capitalized terms shall have the following meanings. Such definitions constitute an integral part of this Agreement and words importing the singular shall include the plural and vice versa.

1.1 **'Affiliate(s)'** means, with respect to any specified Person, any other Person that, directly or indirectly, through one or more intermediaries, Controls, is Controlled by or is under common Control with, such specified Person;

1.2 **'APA'** means the Assets Purchase Agreement entered into by and between the Parties for the purchase by RPC and the sale by FLAMEL of the assets as defined and described in such APA and related to the pharmaceutical plant of Pessac in France and the business attached to said plant .

1.3 **'CIR'** means the French tax credit system named "*Crédit d'Impôt Recherche*" where a French Person is entitled to deduct from its yearly corporation tax a part of its own research and development costs and such costs invoiced to said French Person by a registered Person;

1.4 **"Control"** means, as a noun or as a verb with respect to the relationship between or among two or more Persons, (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person.

1.5 **'Effective Date'** is defined in the preamble;

1.6 **"External Costs"** are defined in clause 5.2 herein;

1.7 **'Initial term'** means the sixty (60) month period following the Effective Date as provided in clause 2.1 of this Agreement;

1.8 **"Internal Costs"** are defined in clause 5.2 herein;

1.9 **"Minimum Yearly Volume"** is defined in clause 5.4 herein;

1.10 **'Parties'** means FLAMEL and RPC collectively;

1.11 **'Party'** means either FLAMEL or RPC as appropriate;

1.12 **'Person'** means any individual, partnership, firm, corporation, company, association, trust, unincorporated or incorporated organization, or other entities;

1.13 **'Product'** means the finished product to be supplied pursuant to the implementation of the appropriate Supply Services under the Supply Agreement and the related Product Schedule;

1.14 **'Project'** means the description in a Project Schedule of a request from FLAMEL to RPC to procure any works and duties to be implemented under a Service Agreement with the view for pharmaceuticals or materials, without limitation to (i) develop, experiment, and test on a laboratory scale (ii) manufacture said pharmaceuticals or process such materials and/or store the same for any purpose, including without limitation preclinical and clinical studies, stability studies;

1.15 **'Project Agreement'** means the document in the form set out as Appendix 1 to the Service Agreement where the Parties shall describe the Project Services with all scheduling details, to be provided by RPC or such RPC Affiliate designated in accordance with the terms of Article 4 herein, for implementing a Project;

1.16 **"Project Services"** all works and duties related to a Project and described in a Project Agreement;

1.17 **'Product Schedule'** means the document in the form set out as Appendix 1 to the Supply Agreement where the Parties shall describe the tasks and duties of RPC or the RPC Affiliate designated in accordance with the terms of Article 4 herein, for supplying Products;

1.18 **'Services'** means the Project Services and the Supply Services;

1.19 **"Service Agreement"** means the document attached hereto as appendix 1 and setting forth the terms and conditions of the implementation of the Project Services.

1.20 **"Supply Agreement"** means the document attached hereto as appendix 2 and setting forth the terms and conditions of the implementation of the Supply Services.

1.21 **'Supply Services'** means all works and duties requested from a pharmaceutical manufacturer to Process and supply Products in accordance with the terms and conditions of the Supply Agreement and the related Product Schedule;

1.22 **"Year"** means a twelve (12) calendar month period.

2 Duration of the Agreement

2.1 This Agreement shall come into force on the Effective Date for the Initial Term (i.e. a firm and non-cancellable period of **SIXTY** (**60**) calendar months, plus such period of time limited to one (1) Year which should be necessary for FLAMEL to take from RPC or its designated Affiliates such volume of Services meeting the total amount of €18 500 000 as referred to in clause 5.9 of this Agreement.

2.2 Beyond the Initial Term, and subject to clause 2.3 below, this Agreement shall continue for an evergreen period provided that the rights and obligations under clauses 5 (Pricing and Minimum Yearly Volume) and 6 (Effect of termination during the Initial Period) shall be deleted with no force or effect beyond expiration of the Initial Period, but subject to survival of clause 5.5 for final report and payment purpose.

2.3 Beyond the Initial Term, this Agreement may be terminated by either Party subject to a prior written notice to the other at least equal to such notice period either Party is entitled to terminate any Project Agreement under the Service Agreement or any Product Schedule under the Supply Agreement which shall exist and be in force at the date the termination of this Agreement is notified to the other Party.

3 Implementation of the Services

The Parties hereby agree that all the Services to be provided by RPC or such RPC Affiliate designated in accordance with the terms of Article 4 herein, to FLAMEL in the frame of their respective rights and obligations agreed upon in or further to the APA, shall be provided under this Agreement and as follows:

3.1 Any Services to be provided to FLAMEL under this Agreement shall be requested by FLAMEL to RPC.

3.2 Project Services shall be rendered by RPC in accordance with the terms and conditions of the Service Agreement attached hereto and the related Project Agreement to be entered into by and between the Parties at the time said Parties shall have agreed on the definition of the related R&D Services, the compensation of RPC and the schedule of the implementation of said R&D Services.

3.3 Supply Services shall be rendered by RPC in accordance with the terms and conditions of the Supply Agreement attached hereto and the related Product Schedule to be entered into by and between the Parties at the time said Parties shall have agreed on the definition of the related Supply Services for the related Product and the compensation of RPC for such Supply Services.

4 Assignment of the implementation of the Services

4.1 RPC shall provide the Services requested by FLAMEL either with its own means and resources or RPC shall designate upon its sole decision one of its Affiliates to provide such requested Services, especially, without limiting the foregoing, when RPC shall have not sufficient resources to deliver the Services requested.

4.2 FLAMEL may request RPC to designate one of the RPC's Affiliates to provide the Services, for sensitive commercial or regulatory reason only and so long that RPC shall not materially suffer from such loss of compensation with regard to the nature of the Services requested from the RPC's Affiliates. Nothing herein shall prevent the RPC's Affiliates to subcontract such requested Services to RPC. Any dispute between FLAMEL and RPC thereon shall be settled under the provision of clause 8.1 herein.

4.3 When the Services requested by FLAMEL shall be provided by a RPC Affiliate, FLAMEL, and said RPC Affiliate shall enter into the related Project Agreement and/or the Product Schedule. Then, any reference to RPC in the Services Agreement and/or the Supply Agreement shall be deemed to referring and naming the said RPC's Affiliate.

4.4 The implementation by any RPC Affiliate of any Services for FLAMEL under this Agreement shall be implemented by said RPC Affiliate under its own and sole responsibility without any recourse from FLAMEL against RPC as to the results and/or quality of the related Services or any interpretation of any Applicable Laws and Regulations with regard to assignment and/or subcontracting of the related Services.

4.5 Notwithstanding anything contained in this Agreement, the Supply Agreement and the Service Agreement and with regard to the Minimum Yearly Volume and the monthly instalments as referred to in clauses 5.4 and 5.5 hereunder, all the Services RPC's Affiliates shall provide to FLAMEL further to this article 4, shall be invoiced by RPC to FLAMEL and paid by FLAMEL to RPC exclusively. RPC shall arrange under its sole responsibility the payment to its Affiliates of the Services supplied by said Affiliate under the related Project Agreements and Product Schedules.

5 Pricing and Minimum Yearly Volume

5.1 The Parties confirm herein that, during the Initial Term, any Services to be provided to FLAMEL by RPC or any of its Affiliates under this Agreement, shall be quoted, agreed, and paid on the basis of RPC's or the related Affiliate's, Internal and External Costs of the Services plus twenty percent (20%) fees ("Total Cost").

5.2 The related costs calculation shall include (i) fully allocated cost of a full time equivalent ("FTE") or fully allocated cost of manufacturing the product, such fully allocated costs comprises direct costs incurred directly for the provision of the Services by RPC or the RPC Affiliate (including but not limited to labour, materials, goods and supplies) and indirect costs specifically allocable to the provision of Services by RPC or the RPC Affiliate (including but not limited to administrative labour costs, maintenance, insurance the part of depreciation allocated to assets used in the provision of the related Services) ; such calculation being based upon accepted contract manufacturing industry standards and generally accepted accounting principles ("**Internal Costs**") and (ii) the amount paid by RPC or the RPC Affiliate for any project or product specific materials, goods, supplies, and equipment of any nature for rendering the related Services when RPC or the related RPC Affiliate shall have not the resources, capacity or ability to provide such part of the Services whatever this Person is deemed to be a subcontractor or not, and any tax to be invoiced to FLAMEL under Applicable Laws and Regulations ("**External Costs**").

For the avoidance of doubt, all amounts paid by RPC to its designated Affiliate as per article 4 hereinabove, whatever the costs of the said Affiliates are Internal Costs or External Costs, shall not be deemed External Costs of RPC.

5.3 The Parties agree to allocate the price of the Services between Internal Costs and External Costs in each Project Agreement and Product Schedule and in any document between the Parties or the Persons concerned which should amend said Project Agreement and Product Schedule, especially the price and/or the allocation of the price of the related Services between Internal Costs and External Costs.

5.4 Over the Initial Term, FLAMEL hereby agrees and undertakes to order and pay a minimum amount for Services each Year of the Initial Term for Internal Costs, under this Agreement ("**Minimum Yearly Volume**"), as follows and subject second paragraph of this clause 5.4:

- First Year: € 3 500 000;
- Second Year: € 3 500 000;
- Third Year: € 3 500 000;
- Fourth and fifth Year: € 4 000 000, per Year.

The Parties agree to add the twenty percent (20%) fees paid by FLAMEL each Year over the External Costs as provided in clause 5.1 hereinabove, to the amount of the Internal Costs paid the same Year for determining FLAMEL to reach the Minimum Yearly Volume of the related Year.

5.5 Over the Initial Term, RPC shall invoice FLAMEL each calendar month of a Year, one-twelfth (1/12) of the Minimum Yearly Volume of the related Year. FLAMEL shall pay the RPC's invoice upon receipt.

5.6 Within thirty (30) days from the end of any Year during the Initial Term, RPC shall provide a detailed report of the Internal Costs and of the fees over the External Costs, relating to the Services provided to FLAMEL under this Agreement and paid in accordance with related Project Agreement and Product Schedule during the elapsed Year. This clause shall survive the termination of this Agreement for any reason, including the expiration of the Initial Term for the purpose of providing the report referred to in this clause 5.5 and proceed with the payment of the balance of the Minimum Yearly Volume as provided in clauses 5.6 and 5.9 hereinafter, if any.

5.7 In the event, FLAMEL shall fail to order such volume of Services meeting the Minimum Yearly Volume as evaluated in accordance with clause 5.4 above for the related elapsed Year, FLAMEL shall have a period of twelve (12) months to make up such shortfall by purchasing additional Services; provided however, that in no event shall the total amount of any shortfall be greater than €1,000,000. ..

5.8 In the event FLAMEL purchases Services under this Agreement in excess of the Minimum Yearly Volume for the related Year, such amount, up to €1,000,000, can be used to reduce FLAMEL'S purchase commitment for the next Year.

5.9 For the avoidance of doubt, but subject to the ordering each Year of the Initial Term of the related Minimum Yearly Volume and provided the terms of clause 5.8 above, FLAMEL's total obligation to purchase services from RPC and/or RPC's Affiliates under this Agreement shall not be greater than €18 500 000 of Internal Costs increased by the 20% fees on the External Costs, over the Initial Term plus one (1) Year.

6 Effect of termination during the Initial Period

6.1 If during the Initial Period, FLAMEL becomes insolvent and/or be placed under the supervisory or management of any public receiver upon the opening of any bankruptcy or other procedure of such nature under any Applicable Laws and Regulations, the Parties hereby agree and FLAMEL hereby acknowledges, that the balance of the Minimum Yearly Volume due by FLAMEL to RPC under clause 5.4 of the Agreement until the expiration of the Initial Period, shall be repaid by acceleration ("*déchéance du terme*"). Effective as of the date of publication of the judgement opening said procedure or proceeding, FLAMEL shall be liable to repay immediately and irrevocably said balance to RPC.

6.2 Subject to six (6) month prior written notice and the payment by FLAMEL of the balance of the Minimum Yearly Volume due by FLAMEL to RPC under clause 5.4 herein from the date of termination of this Agreement by FLAMEL until the end of the Initial Period, FLAMEL shall be entitled to terminate this agreement for any reason during the Initial Period.

6.3 Notwithstanding anything to the contrary in this Agreement, the Service Agreement and/or the Supply Agreement, this Agreement cannot be terminated by any Party for any reason unless agreed in writing by the Parties, or further to a final decision of the Arbitral Court as referred to in clause 8.2 hereinafter.

7 Covenants and Representations

7.1 FLAMEL shall provide promptly upon the Effective Date to RPC any and all necessary information and documentation for permitting RPC to file to the French competent administration the demand for being granted with the status of a CIR registered Person under the Applicable Laws and Regulations in force.

7.2 FLAMEL hereby declares and warrants that it shall request from RPC to provide only such Services encompassed in the domain of RPC and/or one of its Affiliates at the day such Services is requested by FLAMEL.

7.3 RPC hereby declares and warrants that it shall make its best efforts to accept and provide any Services requested by FLAMEL which shall enter into in its own domain or the domain of any of its Affiliates.

7.4 Nothing in the Agreement or any Service Agreement, Supply Agreement, or any related Project Agreement or Product Schedule can be interpreted as RPC to guaranty to keep as employees of RPC or of any of its Affiliates, for providing any Services, any of the employees, especially the scientists, which have been transferred to RPC, further to the transaction as referred to in the APA.

7.5 When Flamel will consider the commercial manufacture of any of the drug products in the specified territories as set forth on Schedule 7.5 hereto, Flamel covenants to grant RPC with the related contract manufacturing rights, subject to RPC having made to Flamel a commercially competitive offer within thirty (30) days of Flamel's notification to RPC of its decision thereon.

When Flamel will decide to scale up to commercial scale any drug products other than those listed into Schedule 7.5 hereto, Flamel hereby undertakes to offer RPC to present in its own name and/or on behalf and/or on the name of any of its Affiliates within thirty (30) days of Flamel's notification, an offer to contract therefore before entering in any agreement with any third party.

8 Resolution of dispute

8.1 If the Parties are not able to solve a dispute related to the implementation of this Agreement, either Party may request from the other to have the CEO of FLAMEL and President of RPC to meet and discuss in order to resolve the dispute.

8.2 If said representatives of the Parties are not able to close the dispute within forty (40) days from the date when the meeting took place and otherwise agreed in writing during this meeting, the Parties shall then refer the dispute to proceedings under the ICC Mediation Rules. If the dispute has not been settled pursuant to the said Rules within sixty (60) days following the filing of a Request for Mediation or within such other period as the Parties may agree in writing, such dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules of Arbitration and under French Applicable Laws and Regulations.

9 Miscellaneous

9.1 Neither Party shall assign, transfer or sub-contract any of its rights or obligations under this Agreement without obtaining the prior written consent of the other Party; except that, RPC may assign the benefit or burden of this Agreement to any Affiliate without the need to obtain such consent.

9.2 The Parties are independent contractors and none of the provisions of this Agreement shall be deemed to constitute a partnership or joint venture between the Parties. No Party shall have any authority, nor hold itself out as having any such authority, to bind any other Party in any way.

9.3 No failure or delay by either Party in exercising any of its rights under this Agreement shall be deemed to be a waiver of that right, and no waiver by either Party of a breach of any provision of this Agreement shall be deemed to be a waiver of any subsequent breach of the same or any other provision.

9.4 All notices required under the terms of this Agreement or any Project Agreement shall be in writing and shall be validly given if sent by recorded delivery mail or courier service to the respective person as set out below or such person as may be notified by one Party to the other in writing from time to time. All notices shall be deemed to have been received six (6) days after they are sent.

For: FLAMEL FLAMEL TECHNOLOGIES SA

Address: Parc Club du Moulin à Vent
33, avenue du Docteur Georges Lévy
69200 VÉNISSIEUX, FRANCE

For the attention of: Président Directeur Général
With a copy to: Sr. Vice President, General Counsel

For: RPC RECIPHARM PESSAC

Address: rue Archimède, 33600 PESSAC, France
Facsimile : + 33 5 56 36 58 91
For the attention of: Président

With a copy to: RECIPHARM AB (publ)

Address Lagervägen 7, SE-136 50 Jordbro, Sweden
Facsimile: 0046 8 81 87 03
For the attention of: Legal

9.5 Each Party agrees to keep strictly confidential all the Information as defined into the APA and Relevant Information as defined into the Service Agreement and the Supply Agreement, including this Agreement, under the same terms and conditions as referred to in said agreements.

RECIPHAM PESSAC	**FLAMEL TECHNOLOGIES SA**
Signature	Signature
Name:	Name:
Title:	Title:
Signature	Signature
Name:	Name:
Title:	Title:

Schedule 7.5

PRODUCT	TERRITORY
LiquiTime® Ibuprofen	Europe
Guaifenesin	Europe
Medusa™ Exenatide	Worldwide

SERVICE AGREEMENT

By and between

(1) RECIPHARM PESSAC

and

(2) FLAMEL TECHNOLOGIES

SERVICE AGREEMENT

THIS SERVICE AGREEMENT (the **"Agreement"**) is effective on December 1st, 2014 (the **"Effective Date"**) and is made by between:

RECIPHARM PESSAC, a French *Société par Actions Simplifiée* under registration process and having its principal place of business at, rue Archimède, 33600 Pessac France**,** ("**SUPPLIER**").

FLAMEL TECHNOLOGIES SA, registered under the laws of France under registration number 379 001 530 and having its principal office at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX ("**CUSTOMER**").

WHEREAS:

(A) CUSTOMER is engaged in the research and development of pharmaceutical products and wishes SUPPLIER to perform the Services (as hereinafter defined); and

(B) SUPPLIER is a contract research organisation specialised in the formulation, development and manufacturing of pharmaceutical products.

(C) The Parties entered into a transaction under various agreements and in particular a Master Agreement which with the Quality Assurance Agreement shall govern the overall relations between the Parties with regard to the Services to be provided by SUPPLIER to CUSTOMER under this Agreement and the relevant Project Agreement.

NOW, THEREFORE, the Parties agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement:

"Affiliate(s)" means any corporation or other entity that controls, is controlled by, or is under common control with, a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than 50% of the voting securities or other ownership interests of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity;

'Applicable Laws' means all relevant statutes, laws, directives, regulations, ordinances guidance notes and codes that apply to the Services in the country where such Services are performed, and those specifically set out below, applicable to a Project or the Services in force from time to time during this Agreement including applicable: (i) FDA Guidance Documents on current cGMP and compliance, including the Guidelines on the Preparation of Investigational New Drug Products (Human and Animal) and the Draft Guidance for Industry: Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production; (ii) Applicable European, US and ICH cGMP and cGLP; and (iii) all other regulations specified in the relevant Project Agreement);

'Arising Intellectual Property' shall have the meaning given in clause 6.1;

'Background Intellectual Property' shall have the meaning given in clause 6.4;

'Business Day(s)' means a day other than a Saturday, Sunday or a day on which banks are not open for business in France or the Country where the Services will be performed under this Agreement and the related Project Agreement ;

'Certificate of Analysis' means SUPPLIER's standard form certificate of analysis confirming the results of tests conducted on Service Materials;

'cGMP' means the current good manufacturing practice requirements as applicable: (i) in the European Union; (ii) in the United States of America; and (iii) in accordance with ICH requirements. As in force from time to time during the term of this Agreement;

'Competent Authority/(ies)' means a national or supra-national authority responsible for the control of medicinal products;

"**Effective Date**" is defined in preamble of the Agreement;

'External Costs' means the amount paid by SUPPLIER or the SUPPLIER Affiliate for any Service specific materials, goods, supplies, and equipment of any nature for providing the Service under the related Project Agreement when SUPPLIER or the related SUPPLIER Affiliate shall have not the resources, capacity or ability to provide such part of the Service whatever this Person is deemed to be a subcontractor or not, and any tax to be invoiced to CUSTOMER under Applicable Laws and Regulations;

"Force Majeure Event' means, in relation to either Party, any circumstances beyond the reasonable control of that Party (including, without limitation, fire, floods, embargoes, shortages, epidemics, quarantines, war, acts of God, acts, omissions or delays in acting by any governmental authorities and any strike, lock-out or other form of industrial action or other form of action with respect to employment relationships);

'cGLP' means the current Good Laboratory Practice being a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived as applicable: (i) in the European Union; (ii) in the United States of America; and (iii) in accordance with ICH requirements. As in force from time to time during the term of this Agreement;

'Intellectual Property' means all intellectual property rights, including (without limitation) patents, supplementary protection certificates, petty patents, utility models, trademarks, database rights, rights in designs, copyrights (whether or not any of these are registered or capable of being registered) and including all applications and the right to apply for registered protection of the foregoing and all inventions, trade secrets, know-how, techniques and confidential information and other proprietary knowledge and information, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world, in each case for their full term and together with any renewals or extensions;

'Internal Costs' means (i) fully allocated cost of a full time equivalent ("FTE") for providing the Service under the related Project Agreement, such fully allocated costs comprises direct costs incurred directly for the provision of the Services by SUPPLIER or the SUPPLIER Affiliate under the related Project Agreement (including but not limited to labour, materials, goods and supplies) and indirect costs specifically allocable to the provision of Services by Supplier or the SUPPLIER Affiliate under the related Project Agreement (including but not limited to administrative labour costs, maintenance, insurance the part of depreciation allocated to assets used in the provision of the related Services) ; such calculation being based upon accepted contract manufacturing industry standards and generally accepted accounting principles ;

'Master Agreement' means the agreement entered into by and between the Parties on Effective Date where the Parties have agreed upon, among other things, overall conditions for providing the Services;

'Materials' means all compounds, materials and other substances supplied by CUSTOMER to SUPPLIER for use under a Project Agreement;

'Parties' means CUSTOMER and SUPPLIER;

'Party' means CUSTOMER or SUPPLIER as appropriate;

'Permitted Recipients' means those employees or contractors of the receiving Party who would reasonably require access of the Relevant Information for the proper enjoyment or performance by that Party of its rights and obligations under this Agreement or a Project Agreement;

'Project' means a specific project related to pharmaceutical development activities and the manufacturing of drug products for clinical use which CUSTOMER and SUPPLIER agree to enter into under the terms of this Agreement and the relevant Project Agreement;

'Project Agreement' means each agreement made under this Agreement in accordance with clause 2 relating to a Project in the form set out in Appendix 1 to this Agreement;

'Quality Agreement' means a quality agreement setting out the Parties responsibilities for quality assurance under Applicable Laws;

'Relevant Information' means any data or information (whether or not recorded in a document, and whether or not marked as confidential), which is disclosed by one Party to the other or is obtained by either Party from any information so disclosed or from any materials which are made available by or on behalf of one Party to the other Party or is otherwise obtained by one Party, which are not publicly known. Relevant Information shall include without limitation information relating to the business of either Party, including clinical and product development plans, strategies, patent disclosures, patent applications, structures, models, techniques, know-how, trade secrets, processes, compositions, formulations, compounds and apparatus relating to the same and proprietary information related to the current, future, and proposed products or services of the disclosing Party, including for the avoidance of doubt Service Data which shall be Relevant Information of CUSTOMER;

'Service Data' means all data and information produced as a result of the performance of the Services;

'Service Materials' means all materials produced as a result of the performance of the Services;

'Services' means the services to be performed by SUPPLIER pursuant to the relevant Project Agreement;

'SOPs' means the relevant standard operating procedures to be used by SUPPLIER during the performance of the Services that have been approved in writing by CUSTOMER; and

'Starting Fee' means any applicable starting fee paid as a deposit for initiation of a Project as stated in the Project Agreement.

1.2 Any reference in this Agreement to:

(a) "person" includes companies, firms or other organisations;

(b) an Appendix is a reference to an Appendix to this Agreement; or

(c) a clause is a reference to a clause of this Agreement.

(d) The words "in particular", "include", "included" and "including" are to be construed without limitation to the generality of the preceding words.

In this Agreement, words importing the singular shall include the plural and vice versa.

2. STRUCTURE OF THIS AGREEMENT AND PROJECT AGREEMENTS

2.1 In consideration of the mutual promises and covenants set forth in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, CUSTOMER appoints SUPPLIER on a non-exclusive basis (if not agreed otherwise in a specific Project Agreement) to provide the Services to CUSTOMER and SUPPLIER agrees to make its best commercial effort to accept and undertake such appointment on the terms and conditions set out in this Agreement.

2.2 The Parties agree to conclude a separate Project Agreement for each Project to which the general conditions of this Agreement are applicable unless otherwise specifically agreed in the relevant Project Agreement. Where Services to be performed pursuant to a Project Agreement include clinical or cGMP activities the Parties agree to negotiate in good faith and to enter into a separate Quality Agreement as soon as practicable following the Effective Date. In case of any conflict between this Agreement and the provisions of a Project Agreement and/or a Quality Agreement, the provisions of this Agreement shall prevail if the conflict is not solely of a technical/quality nature where the Quality Agreement or the Project Agreement shall prevail. In the event that a conflict could reasonably be interpreted as both legal/commercial and technical/quality in nature then this Agreement shall prevail. In case of any conflict between a Project Agreement and a Quality Agreement the provisions of the Project Agreement shall prevail if the conflict is not solely of a quality nature where the Quality Agreement shall prevail.

2.3 Each Project Agreement will include detailed information concerning a given Project, including without limitation a description of the Services to be provided, the names of certain of the individuals providing the Services (as applicable), Project milestones and completion dates, a budget, a payment schedule related to the Project, all of which will be signed by an authorised representative of each Party.

2.4 In order to comply with the terms and conditions of the Master Agreement, the Parties agree to identify for each Project and shall allocate in each Project Agreement the Internal Costs and the External Costs of SUPPLIER in the Price for the Services. The Parties shall take into consideration any amendment to this allocation for each Change Order as referred to in clause 3.2 herein.

2.5 Furthermore, CUSTOMER has no right to receive deliverables or other Services specified in Project Agreements that have not been executed by authorised representatives of both Parties. No work will be performed by SUPPLIER until both Parties have signed a Project Agreement, subject to the terms and conditions set out in this Agreement.

3. PERFORMANCE OF SERVICES

In respect of each Project:

3.1 SUPPLIER agrees to use its best commercial efforts to perform the Services applying its reasonable professional standards in its performance of the Services and using its best commercial efforts to meet the timelines in accordance with:

(a) this Agreement and the relevant Project Agreement;
(b) the Quality Agreement;
(c) any other reasonable instructions given by CUSTOMER in writing;
(d) the SOPs; and
(e) all Applicable Laws.

3.2 It is recognised that during a Project delay, changes, variations, or modifications to the Project Agreement may become advisable because of results observed, or at CUSTOMER's request (**"Amendment"**). Any Amendment proposed by either SUPPLIER or CUSTOMER shall be notified to the other Party in writing and SUPPLIER will generate and provide to CUSTOMER a change order, substantially in the form attached hereto as Appendix 2 (**"Change Order"**), with a cost and time estimate for implementing the proposed Amendment. The revised cost estimate will be based on the rates specified in the original Project Agreement. SUPPLIER shall not effect any Amendment until authorised representatives of both Parties have agreed and signed the Change Order. SUPPLIER shall not unreasonably withhold, delay or condition consent to any Change Order.

3.3 SUPPLIER shall ensure that the Services are performed by employees who possess relevant skills, experience, and qualifications.

3.4 SUPPLIER shall within reasonable time advise CUSTOMER in writing of the occurrence of any event that may materially delay or affect the performance of the Services or the progress of a Project.

4. DATA AND REPORTS

4.1 The Service Data shall be the sole property of CUSTOMER.

4.2 SUPPLIER agrees during the term of this Agreement and the relevant Project Agreement and thereafter, unless otherwise agreed in writing with CUSTOMER, to maintain the original records of the Service Data securely and in accordance with Applicable Laws.

4.3 SUPPLIER shall maintain as confidential the Service Data and all information relating thereto supplied by CUSTOMER pursuant to this Agreement. SUPPLIER shall disclose the Service Data and information relating thereto only to those of its employees who need to know such information or be in possession of the Service Data for the purpose of performing the Services in relation to the Project in question and are bound by confidentiality terms no less onerous than those imposed on SUPPLIER under this Agreement.

4.4 In a timely manner with regard to the nature of the related Services, with best SUPPLIER endeavours to do it within sixty (60) days of completion of the Services, SUPPLIER shall submit to CUSTOMER a report on the Services in a format approved by and acceptable to CUSTOMER, such approval and acceptance not to be unreasonably withheld, and in accordance with the requirements of the Project Agreement. Upon receipt of the report, CUSTOMER shall be entitled to discuss the contents thereof with SUPPLIER and to receive such further information as CUSTOMER may reasonably require.

4.5 CUSTOMER shall inform SUPPLIER of any non-conformance within thirty (30) days after receipt of the report for the applicable Services. If CUSTOMER fails to deliver such notice, CUSTOMER shall be deemed to have accepted any and all Services, unless CUSTOMER can demonstrate that such non-conformance was not identifiable between the time of delivery and acceptance within the thirty (30) days notice period. Any Services that do not adequately comply with the Project Agreement, if such failure is due to acts or omissions of SUPPLIER, shall at CUSTOMER's discretion either: (i) be repeated at SUPPLIER expense if reasonable; or (ii) the cost of the Services shall be refunded by SUPPLIER to CUSTOMER and the Minimum Yearly Volume is not increased by such refunded amount for the Year where the related Service is recorded as referred to in the Master Agreement. In such event, any disputes over conformance shall be referred to an independent laboratory to be appointed by agreement between SUPPLIER and CUSTOMER. Except in the case of fraud or manifest error on the part of such independent expert, the decision of such independent expert will be binding upon the Parties and the cost of such determination shall be paid by the Party in error. In case the Parties are not able to agree on appointment of the independent expert, the Parties agree to submit the dispute to administered expertise proceedings in accordance with the Rules for Expertise of the International Chamber of Commerce

5. MATERIALS

5.1 CUSTOMER will provide SUPPLIER with amounts of Materials necessary in the opinion of CUSTOMER for the performance of the Project in question. If applicable, CUSTOMER will furnish SUPPLIER with safety data sheets for the Materials and, where available, certificates of analysis. CUSTOMER will also provide SUPPLIER with such information concerning the Materials as CUSTOMER deems necessary to perform the Services, including, but not limited to, information concerning the stability of the Materials, their storage, transportation and applicable health, safety and environmental requirements.

5.2 Upon termination of the Services in relation to the Project in question, any remaining Materials or Service Materials will be promptly returned to CUSTOMER (reasonably incurred costs in effecting such return shall be borne by CUSTOMER), or, at CUSTOMER's written option, destroyed by SUPPLIER at CUSTOMER costs and charges, and if CUSTOMER requires the destruction of the remaining Materials or Service Materials, SUPPLIER shall provide to CUSTOMER reasonable documentary evidence of such destruction.

5.3 SUPPLIER shall use the Materials or Service Materials only for the purposes of the Project in question and in accordance with Applicable Laws.

5.4 SUPPLIER shall ensure that access to the Materials and Service Materials is restricted to its own personnel or contractors in its own laboratories. SUPPLIER shall not transfer the Materials, Service Materials or any part thereof outside such laboratories, other than to deliver to CUSTOMER, without CUSTOMER's prior written consent, which shall not unreasonably withheld, nor use the Materials other than in the due performance of the Services in relation to the Project in question.

5.5 SUPPLIER shall retain any remaining Materials or Service Materials under appropriate conditions for a period of three years after submission of the final report of the Services to CUSTOMER in accordance with clause 4.4. CUSTOMER shall reimburse SUPPLIER for its reasonably incurred cost and expense arising from such retention. The Service Materials shall be the property of CUSTOMER and SUPPLIER will contact CUSTOMER at the end of such three year period for CUSTOMER's instructions as to the Service Materials. Notwithstanding the provisions of this clause, SUPPLIER shall retain and store samples of all Service Material released by SUPPLIER's quality department under a Project Agreement for such period as required by regulatory obligations prescribed by Applicable Laws.

5.6 If at the written request of CUSTOMER any Materials or Service Materials are disposed of or delivered to CUSTOMER, by SUPPLIER in accordance with such written request in accordance with clause 5.5, SUPPLIER shall be relieved by CUSTOMER of any further responsibility for such Materials or Service Materials with respect to the activities performed in relation to such Materials or Service Materials after the said disposal or delivery, including any claims made against CUSTOMER by third parties.

5.7 All Materials shall be delivered by CUSTOMER to SUPPLIER DPP (Delivered Duty Paid) Incoterms 2010 at SUPPLIER's premises designated into the Project Agreement. CUSTOMER shall provide SUPPLIER with advance notice in writing of the anticipated date of delivery. CUSTOMER shall contract with the carrier for all Materials.

5.8 Delivery of all Service Materials by SUPPLIER to CUSTOMER or such third party as may be specified by CUSTOMER shall, at CUSTOMER's cost and expense, be delivered Ex Works SUPPLIER'S Pessac plant or SUPPLIER Affiliate plant, Incoterms 2010 unless otherwise specifically agreed in the related Project Agreement.

5.9 In respect of delivery by SUPPLIER of any Service Materials required hereunder to be produced in accordance with cGMP, SUPPLIER will supply at the time of delivery a Certificate of Analysis and any other required supporting regulatory documents relating to such Service Materials.

6. INTELLECTUAL AND PHYSICAL PROPERTY

6.1 All Intellectual Property, other than the SUPPLIER Property (as defined below), arising as a result of the Services performed by or on behalf of either of the Parties including, without limitation, the Intellectual Property in the Service Data (**"Arising Intellectual Property"**) shall be the sole and exclusive property of CUSTOMER and SUPPLIER assigns any rights it may have in Arising Intellectual Property to CUSTOMER.

6.2 CUSTOMER acknowledges that SUPPLIER possesses certain Intellectual Property relating to, laboratory analyses, analytical methods, manufacturing processes, procedures, and techniques which have been independently developed by SUPPLIER, or a third Party, without the benefit of any Materials, Service Materials, CUSTOMER's Intellectual Property, or the Arising Intellectual Property (the **"SUPPLIER Property"**). CUSTOMER agrees that any SUPPLIER Property or improvements thereto which are created, modified or developed by SUPPLIER pursuant to this Agreement and which do not exclusively relate to the Materials, Service Materials, CUSTOMER's Intellectual Property, are the sole and exclusive property of SUPPLIER. Any such improvements shall be treated as, and included within the definition of, SUPPLIER Property.

6.3 CUSTOMER hereby grants to SUPPLIER for the term of the Agreement a royalty free, non-exclusive, worldwide, limited licence to use such of CUSTOMER's Intellectual Property, as is disclosed by CUSTOMER to SUPPLIER, to the extent the same are useful or necessary for the performance of the Services. This licence terminates on the completion of the Services as provided in the related Project Agreement upon provision of the final report as referred to in clause 4.4 hereinabove. Nothing in this Agreement or any Project Agreement constitutes a grant of any right or licence under such Intellectual Property except for the foregoing.

6.4 Nothing in this Agreement shall affect SUPPLIER's or CUSTOMER's ownership of any Intellectual Property existing prior to the commencement of the Services or created outside the Services (**"Background Intellectual Property"**).

6.5 Without limiting the foregoing, CUSTOMER reserves all rights and title (including ownership) in the physical property of the Materials and Service Materials. SUPPLIER shall hold all Materials and Service Materials to CUSTOMER's order and shall not do or permit to be done anything incompatible with CUSTOMER's right and title in the Materials and Service Materials. SUPPLIER further acknowledges that CUSTOMER holds the Intellectual Property including, for the avoidance of doubt, the Background Intellectual Property and Arising Intellectual Property, in the Materials or Service Materials including without limitation an ownership interest in patents and pending patent applications that cover compositions, methods and/or uses of the Materials or Service Materials of CUSTOMER.

7. PAYMENT AND INVOICING

7.1 The Parties agree and undertake to determine the price for the Services in accordance with applicable provisions of the Master Agreement and such price for each Service shall be allocated in accordance with clause 2.4 hereinabove.

7.2 The Parties shall set forth in the related Project Agreement the payment schedule for the Services and the amount of the Starting Fee, if any. All prices are exclusive of applicable sales taxes, which shall be paid by CUSTOMER at the prevailing rate.

7.3 All invoices shall be payable in full within thirty (30) days after receipt of the invoice. CUSTOMER shall pay invoices and payments of undisputed invoice shall be made within thirty (30) days following the date of issue of the invoice. If the undisputed invoice is not paid within this timeframe, penalty interest plus recovery charges shall be charged to CUSTOMER in accordance with the Applicable Laws.

8. FACILITY VISITS

8.1 SUPPLIER shall give access to its premises to CUSTOMER and its authorised representatives or licensees for the exclusive purpose to observe the progress of the implementation of the Services in a specific Project. Such access should be requested by CUSTOMER upon reasonable prior written notice from CUSTOMER and during normal business hours and at CUSTOMER costs. CUSTOMER may visit any of the premises used by SUPPLIER for the provision of the Services in the relevant Project, talk with SUPPLIER personnel and inspect and copy all files, records, books, proofs, models and all preparatory materials which CUSTOMER may reasonably require to verify that SUPPLIER is in compliance with its obligations under this Agreement, including the relevant Project Agreement where it is possible to do so without breaching any obligation of confidentiality, Applicable Law or regulatory requirement.

8.2 All information disclosed or ascertained by CUSTOMER in connection with any audit or examination or in connection with any correspondence between SUPPLIER and any Competent Authorities that is not Relevant Information of CUSTOMER will be deemed to constitute Relevant Information of SUPPLIER, and CUSTOMER will not disclose this to any third party or use such information for any purpose other than conducting the foresaid audit or inspection under this Clause 8. SUPPLIER shall provide all such reasonable assistance and facilities in connection with the inspection as CUSTOMER may reasonably require. SUPPLIER also agrees to allow representatives of applicable Competent Authorities to enter and inspect any of its premises used by SUPPLIER for the provision of the Services.

8.3 SUPPLIER shall permit any Competent Authority to visit any of the premises used by SUPPLIER for the provision of the Services. SUPPLIER shall, as soon as reasonably possible, inform CUSTOMER of any intended inspection of SUPPLIER premises by any Competent Authority where such inspection relates to the Services or processes and procedure relating to such Services. CUSTOMER shall have the right, but not the obligation, if allowed by the Competent Authority, to be present at any such inspection or regulatory action provided such inspection or action directly relates to any Project or Services. SUPPLIER shall as soon as reasonably possible inform CUSTOMER of any adverse comments, finding or reports related to SUPPLIER or its premises relating to any Services from any such Competent Authority and to the extent that such information is capable of being disclosed by SUPPLIER without breaching any obligation of confidentiality, Applicable Law or regulatory requirement, shall provide CUSTOMER with a copy of any written report from any such Competent Authority and details of any adverse comments, findings or reports within five (5) Business Days of receipt. SUPPLIER shall as soon as reasonably possible answer on deficiencies identified during audit by CUSTOMER or any Competent Authority of such premises. SUPPLIER shall advise CUSTOMER on a regular basis as to the status of any corrective action, where it is possible to do so without breaching any obligation of confidentiality, Applicable Law or regulatory requirement, including, but not limited to, providing CUSTOMER with copies of any relevant correspondence with the respective Competent Authority. For the avoidance of doubt the Confidentiality provisions at Clause 15 of this Agreement shall apply to any audit by CUSTOMER or any Competent Authority.

8.4 The personnel of either Party visiting the premises of the other Party shall at all times conform to the regulations and restrictions in respect of access to restricted areas, conduct, safety and working conditions provided that such are drawn to the attention of the visitors.

9. REPRESENTATIVES

9.1 SUPPLIER’s project representative in relation to a Project shall be as identified in the relevant Project Agreement, where SUPPLIER wishes to change the project representative for any reason it shall inform CUSTOMER of its nominated substitute.

9.2 CUSTOMER’s representative in relation to a Project shall be as identified in the relevant Project Agreement, or such other person nominated by CUSTOMER from time to time.

10. WARRANTIES, LIABILITY AND INDEMNITY

10.1 SUPPLIER warrants and represents to CUSTOMER that:

10.1.1 it has the necessary permits, facilities, third party contractors and skilled personnel that may be reasonably anticipated to be necessary for a contract research organisation to provide the Services.

10.1.2 it will use its best commercial efforts to perform the Services as set forth in the Project Agreements, and any Quality Agreement in compliance with this Agreement and SOPs and all Applicable Laws;

10.1.3 SUPPLIER owns or has the right to use any Intellectual Property to be used for to the due provision of the Services and that it has the right and title to give CUSTOMER unrestricted use of the Service Materials and Service Data, provided by SUPPLIER to CUSTOMER pursuant to the Services; and

10.1.4 to the best of its knowledge, the Intellectual Property of SUPPLIER used in the Services does not infringe third party Intellectual Property.

10.2 CUSTOMER warrants and represents to SUPPLIER that:

10.2.1 CUSTOMER has the right to enter into this Agreement;

10.2.2 CUSTOMER has and shall at all times throughout the term of this Agreement have the right to supply the Materials to SUPPLIER and the necessary rights to licence or permit SUPPLIER to use the same for the purpose of the Services and, if applicable, CUSTOMER's testing of such Materials, shall at the time of delivery to SUPPLIER comply with cGMP;

10.2.3 CUSTOMER owns or has the unrestricted right to use any Intellectual Property to be used pursuant to this Agreement and each Project Agreement and that it has the right and title to give SUPPLIER licence to use such Intellectual Property for the provision of the Services; and

10.2.4 any of the Materials, Relevant Information and Intellectual Property to be provided or allowed access to by CUSTOMER hereunder and not owned by CUSTOMER are licensed to CUSTOMER under a licence which will permit their use by SUPPLIER to perform the related Services.

10.3 SUPPLIER hereby indemnifies and holds harmless CUSTOMER and each of its directors and officers (the **"CUSTOMER Parties"**) against any and all losses, demands, claims, liabilities, damages, costs and expenses (including but not limited to court costs and reasonable documented attorney's fees and expenses together with any applicable taxes thereon) that the CUSTOMER Parties have suffered or incurred directly in consequence of the following:

10.3.1 the infringement or breach of any third party rights including Intellectual Property by SUPPLIER, except to the extent that any infringement is caused by the acts or omissions of CUSTOMER other than in accordance with this Agreement.

10.3.2 a material inaccuracy due to the fault of SUPPLIER in a Certificate of Analysis such that the results of the analytical tests identified in the relevant Project Agreement were materially incorrect.

10.3.3 the misrepresentation, negligence or material breach of obligations under this Agreement or any Project Agreement, breach of statutory duty or intentional misconduct of SUPPLIER or any of its directors, officers, employees, or permitted sub-contractors, assignees or agents, in particular but not limited to the failure of Service Materials released by SUPPLIER to comply with Applicable Laws, and

10.3.4 any loss or damage to the Materials or Service Materials due to SUPPLIER's negligence or wilful misconduct or fire or any other natural disaster at SUPPLIER's Facility as covered under SUPPLIER's insurance.

10.4 CUSTOMER hereby indemnifies and holds harmless SUPPLIER and each of its directors and officers and testing laboratories (the **"SUPPLIER Parties"**) against any and all losses, demands, claims, liabilities, damages, costs and expenses (including but not limited to court costs and reasonable documented attorney's fees and expenses together with any applicable taxes thereon) that the SUPPLIER Parties may or have suffered or incurred in consequence of the following:

10.4.1 the infringement or breach of any third party rights including Intellectual Property by CUSTOMER, except to the extent that any infringement is caused by the acts or omissions of SUPPLIER other than in accordance with this Agreement.

10.4.2 the misrepresentation, negligence, material breach of obligations under this Agreement or any Project Agreement, breach of statutory duty or intentional misconduct of CUSTOMER or any of its directors, officers, employees, or permitted sub-contractors, assignees or agents.

10.5 The Party (the **"Indemnitee"**) that intends to claim indemnification under this clause 10 shall:

10.5.1 promptly, and in any event within fifteen (15) Business Days of it receiving notice of the claim, demand, threat or action, notify the other Party (the **"Indemnitor"**) in writing in general terms of any claim, demand, threat or action which has or has the potential to give rise to the Indemnitee seeking to rely on and claim the benefit of the indemnification together with notification of the Indemnitee's intention to rely on such indemnity, provided that, failure to give such notice shall not relieve the Indemnitor of its indemnification obligations except and only to the extent such failure actually and materially prejudices the ability of the Indemnitor to defend against such claims;

10.5.2 not prejudice any defence to any claim or attempt to settle or compromise such claim;

10.5.3 subject to its other rights and obligations and compliance with the procedures set out in this clause 10 permit the Indemnitor to have overall control of the conduct of the negotiations and the proceedings including any counterclaim subject the Indemnitor having duly appointed experienced attorneys who will professionally and thoroughly defend and prosecute any claim that gives rise to an indemnity claim;

10.5.4 cooperate as reasonably requested by the Indemnitor, at the Indemnitor's expense, in the conduct of such claim (and any counterclaim); and

10.5.5 have the right (at the Indemnitor's expense) to instruct independent counsel and participate in all proceedings and negotiations whether named or not as a party in the claim or proceedings.

10.6 The Indemnitor shall not settle or consent to an adverse judgement in any such claim, demand, action or other proceeding that adversely affects the rights or interests of any Indemnitee or imposes additional obligations (financial or otherwise) on such Indemnitee, without the prior express written consent of such Indemnitee (such consent to be at the Indemnitee's sole discretion).

10.7 The Parties shall promptly and in good faith discuss ways, whether by modifications to the Services, licensing or otherwise, to settle or overcome a claim under the indemnities. In the event that formal legal proceedings are commenced the Parties shall use their best endeavours to conduct such discussions expeditiously.

10.8 Without prejudice to this clause 10 neither Party shall be liable to the other Party for any loss or damage howsoever caused (even if foreseeable or in the contemplation of SUPPLIER or CUSTOMER) in respect of:

10.8.1 loss of profits, business, business opportunities or revenue; or

10.8.2 special, indirect or consequential loss.

10.9 Any and all liability of SUPPLIER to CUSTOMER howsoever arising in respect of this Agreement or any Project Agreement and its performance shall for each Project be limited to an amount equal to one hundred (100) % of the amount to be reasonably received by SUPPLIER from CUSTOMER under the relevant Project Agreement.

10.10 Nothing in this Agreement or any Project Agreement shall purport or attempt or serve to exclude or restrict any liability for: (i) death or personal injury resulting directly from either Party's negligence in its performance of the Services; or (ii) liability for any fraud or fraudulent misrepresentation.

11. DURATION OF AGREEMENT AND PROJECT AGREEMENTS

11.1 This Agreement shall come into force on the Effective Date and shall continue in force until expiry of all the rights and obligations hereunder unless terminated earlier in accordance with its terms and subject to the respective rights and obligations of the Parties under the Master Agreement.

11.2 The duration of each Project shall be set out in the relevant Project Agreement.

12. TERMINATION

12.1 The termination of this Agreement is subject to the provisions of the Master Agreement, especially with regard to the Initial Term as referred to in said Master Agreement and such clause related to the Minimum Yearly Volume.

12.2 Without prejudice of the provisions of the Master Agreement related to the Minimum Yearly Volume and without prejudice to any other rights or remedy it may have, either Party may terminate any Project Agreement, as follows:

12.2.1 if the other Party is in material breach of the Agreement or relevant Project Agreement and, in the case of a breach capable of a remedy, the breach is not remedied within twenty (20) Business Days of the other Party receiving notice specifying the breach and requiring its remedy. Save that termination of the Agreement pursuant to this Clause 12.2.1 where a Party is only in material breach of a Project Agreement shall only be permitted where such material breach has a detrimental effect on such Party’s abilities to meet its obligations under other Project Agreements; or

12.2.2 immediately if the other Party becomes insolvent or if an order is made or a resolution is passed for the winding up of the other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction) or if an administrator, administrative receiver or receiver is appointed in respect of the whole or any part of the other Party’s assets or business or if the other Party makes any composition with its creditors or takes or suffers any similar or analogous action in any jurisdiction to occur.

13. EFFECTS OF TERMINATION

13.1 Upon termination of this Agreement, SUPPLIER shall immediately provide to CUSTOMER the Relevant Information disclosed by SUPPLIER to CUSTOMER and the Service Data and any copies thereof, and the Materials and the Service Materials.

13.2 The provisions of clauses 1 (Definitions) 4 (Data and Reports) 5 (Materials) 6 (Intellectual and Physical Property) 8.2 (Information relating to dealings with Competent Authorities) 10 (Warranties, Liability and Indemnity) 11 (Confidentiality) 13 (Effects of Termination) 16.10 (Governing Law) shall survive termination of this Agreement and any Project Agreement.

13.3 At the request of CUSTOMER and provided that the termination is not due to CUSTOMER breaching this Agreement, SUPPLIER shall, if reasonably possible, complete any outstanding Project subject to the terms of this Agreement (mutatis mutandis) and the relevant Project Agreement notwithstanding the termination of this Agreement.

14. NATURE OF AGREEMENT

14.1 Neither Parties shall assign, transfer or sub-contract any of its rights or obligations under this Agreement or any Project Agreement without obtaining the prior written consent of the other Party; except that, either Party may assign the benefit or burden of this Agreement to any Affiliate without the need to obtain such consent.

14.2 The Parties are independent contractors and none of the provisions of this Agreement shall be deemed to constitute a partnership or joint venture between the Parties. No Party shall have any authority, nor hold itself out as having any such authority, to bind any other Party in any way.

14.3 Save where specifically stated to the contrary in this Agreement or in any Project Agreement, each Party shall bear its own costs in entering into and performing its obligations under the Agreement and any Project Agreement.

14.4 Each Party warrants to the other that it has the authority to enter into this Agreement and any Project Agreement and perform its obligations thereunder.

14.5 This Agreement and each Project Agreement are govern by the Master Agreement for the duration of said Master Agreement and subject to the provisions of the Master Agreement contain the entire agreement between the Parties with respect to its subject matter, supersedes all previous agreements or understandings with respect thereto, and may not be modified except by an instrument in writing signed by the duly authorised representatives of the Parties.

14.6 No failure or delay by either Party in exercising any of its rights under this Agreement or a Project Agreement shall be deemed to be a waiver of that right, and no waiver by either Party of a breach of any provision of this Agreement or the relevant Project Agreement shall be deemed to be a waiver of any subsequent breach of the same or any other provision.

14.7 If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by Applicable Laws and if the rights or obligations of any Party will not be materially and adversely affected: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement; (b) all other provisions of this Agreement shall remain in full force and effect; and (c) the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Laws and achieves, as nearly as possible, the original intention of the Parties. To the fullest extent permitted by Applicable Laws, the Parties waive any provision of Applicable Laws that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

14.8 All notices required under the terms of this Agreement or any Project Agreement shall be in writing and shall be validly given if sent by recorded delivery mail or courier service to the respective person as set out below, or such person as may be notified by one Party to the other in writing from time to time. All notices shall be deemed to have been received three (3) Business Days after they are sent.

For: CUSTOMER FLAMEL TECHNOLOGIES

Address: Parc Club du Moulin à Vent
33, avenue du Docteur Georges Lévy
69200 VÉNISSIEUX, FRANCE

For the attention of: Président Directeur Général
With a copy to: Sr. Vice President, General Counsel

For: SUPPLIER RECIPHARM PESSAC

Address: rue Archimède, 33600 PESSAC, France
Facsimile: + 33 5 56 36 58 91
For the attention of: Président

With a copy to: RECIPHARM AB (publ)

Address Lagervägen 7, SE-136 50 Jordbro, Sweden
Facsimile: 0046 8 81 87 03
For the attention of: Legal

15. INSURANCE

15.1 During the duration of this Agreement, and for three (3) years thereafter, each Party represents and warrants to the other Party that it has insurance coverage with a reputable insurance company of a type and amount typical in the pharmaceutical business and industry sufficient to secure the performance of its obligations hereunder.

15.2 Each Party shall provide evidence of such insurance whenever reasonably requested by the other Party. The Parties covenants and agrees not to do or to omit any matter or thing which may prejudice or render voidable such insurance.

15.3 Any Materials supplied by CUSTOMER shall be and at all times remain at the risk of CUSTOMER, and CUSTOMER shall insure such Materials to their full replacement value while on SUPPLIER's premises unless and until they are incorporated into Service Material or destroyed as a result of the Services.

16. CONFIDENTIALITY

16.1 In consideration of one Party (the **"Disclosing Party"**) making available its Relevant Information to the other (the **"Recipient Party"**), the Recipient Party hereby undertakes that it shall, and shall procure that each of its Permitted Recipients shall:

16.1.1 treat and safeguard as private and confidential all the Relevant Information of the Disclosing Party;

16.1.2 use the Relevant Information of the Disclosing Party only during the duration of this Agreement and the relevant Project Agreement for those purposes reasonably necessary for or anticipated under this Agreement and without prejudice to the generality of the foregoing, not use any Relevant Information of the Disclosing Party to obtain any commercial advantage over the Disclosing Party;

16.1.3 ensure the proper and secure storage of all Relevant Information of the Disclosing Party applying standards of care reasonably expected and no less stringent than standards applied to protection of the Recipient Party's own confidential information;

16.1.4 not at any time without the Disclosing Party’s prior written consent disclose or reveal, whether directly or indirectly any of the Relevant Information of the Disclosing Party to any person whatsoever save its Permitted Recipients, and then only on a limited need to know basis, who shall be informed by it of the confidential nature of the Relevant Information and of the confidentiality terms of this Agreement and for whom it hereby accepts full responsibility in the event that any such person shall breach the duty of confidence imposed upon them; and

16.1.5 not at any time have any discussion, correspondence or contact with any third party concerning the Relevant Information of the Disclosing without the prior written consent of the Disclosing Party.

16.2 The obligations in this Agreement regarding Relevant Information do not apply to information:

16.2.1 which, at the time of its disclosure by the Disclosing Party, was wholly available to the public and could be obtained without reference to the Relevant Information by any person with no more than reasonable diligence;

16.2.2 which becomes generally available to the public after such disclosure otherwise than by reason of a breach of any of the undertakings in this Agreement or any breaches of confidence by the Recipient Party or its Permitted Recipients;

16.2.3 which is, at the time of such disclosure and as evidenced by the Recipient Party's written records, lawfully already within its possession; or

16.2.4 to the extent that the Recipient Party or any of its Permitted Recipients is compelled to disclose the Relevant Information by law or by any stock exchange or other Competent Authority having jurisdiction over it or them (but, for the avoidance of doubt, only to that extent).

16.3 Other than the limited and restricted rights of use set out in this clause 11 nothing in this Agreement or any Project Agreement intends to or has the effect of granting any right, title, licence or interest in or to the Recipient Party or Permitted Recipients in respect of the Disclosing Party's Relevant Information.

16.4 If the Recipient Party or any of its Permitted Recipients becomes compelled to disclose any Relevant Information of confidentiality or a breach or threatened breach or becomes apparent or becomes aware of any misuse of the Relevant Information, the Recipient Party shall inform the Disclosing Party in writing of such obligation or fact as soon as possible after it is informed, or becomes aware, of it and if possible, before any Relevant Information is disclosed, so that (if the Disclosing Party in its absolute discretion shall see fit) a protective order or other appropriate remedy may be sought. The Recipient Party agrees to assist and co operate (and shall procure that each of its Permitted Recipients shall, as appropriate, assist and co-operate) in any action which the Disclosing Party may decide to take. The Recipient Party shall notify the Disclosing Party prior to each disclosure of Relevant Information if it is under any obligation which would or might compel it to disclose any Relevant Information and subsequent to such disclosure it shall not voluntarily assume any such obligation.

16.5 Except as otherwise provided for in this Agreement or the relevant Project Agreement or otherwise required by law or administrative authorities, neither CUSTOMER nor SUPPLIER shall disclose any terms or conditions of this Agreement or any Project Agreement to any third party without the prior written consent of the other Party.

16.6 Upon termination or expiry of this Agreement or the relevant Project Agreement or at the request of the Disclosing Party, the Recipient Party shall promptly return to the Disclosing Party any and all Relevant Information (including copies of documents, computer records and records on all other media) then in its possession or under its control except where such Relevant Information is covered under surviving licence rights between the Parties, or, at the Disclosing Parties option and request, destroy any and all Relevant Information, and if the Disclosing Party requires the destruction of the remaining Relevant Information, the Recipient Party shall provide to the Disclosing Party written confirmation of such destruction.

16.7 The provisions of this clause shall survive termination of this Agreement for a period of seven (7) years.

16.8 The Parties agree not to advertise, disclose or publish in any way the existence of this Agreement or any Project Agreement without the other Party's prior written consent such consent not to be unreasonably withheld. Save that CUSTOMER may make such a disclosure in respect of any negotiations or due diligence exercises with a view to entering into a contractual relationship, in such circumstances SUPPLIER's consent shall not be required.

16.9 The name of a Party or the names of any of its staff shall not be used for any advertising, promotional, or other public purposes by the other Party without the prior written consent of the first Party.

16.10 The Recipient Party acknowledges that disclosure or distribution of the Relevant Information or any part of it or use of the Relevant Information or any part of it contrary to the terms of this Agreement may cause irreparable harm for which damages at law may not be an adequate remedy, and agrees that the provisions of this Agreement prohibiting disclosure or distribution of the Information or use contrary to the provisions hereof may be specifically enforced by a court of competent jurisdiction in addition to any and all other remedies available at law or in equity.

16.11 For the avoidance of doubt SUPPLIER shall treat the Service Data as Relevant Information of CUSTOMER.

16.12 If the Disclosing Party is a listed company, the Relevant Information may contain unpublished information that could affect the market value of the share of the Disclosing Party. Therefore, the Recipient Party shall inform each individual who will have access to the Relevant Information that he or she may be subject to applicable rules relating to insider trading.

17. FORCE MAJEURE

17.1 In the event any Party is delayed or hindered in or prevented from the performance of any act required hereunder by reason of a Force Majeure Event, then performance of such act will be excused for the period of such delay, provided however, that such Party shall exert its reasonable efforts to overcome such Force Majeure Event and to resume performance of its obligations in a timely manner.

17.2 Notice of the commencement and ending of such Force Majeure Event will be provided by such Party to the other Party within ten (10) Business Days. Any timeline or milestone obligations of such Party affected by the Force Majeure Event will be extended for a period of time equal to the number of days of the delay, provided however that, but subject to subject to the provisions of the Master Agreement, especially with regard to the Initial Term as referred to in said Master Agreement and such clauses related to the Minimum Yearly Volume, in the event that a Party is unable to overcome any Force Majeure Event within: (i) sixty (60) Business Days, the other Party may terminate Project Agreements under which the affected Services are being provided or, beyond the Initial Term, terminate this Agreement if all Project Agreements have been terminated. In case the Project Agreement is then terminated by CUSTOMER because SUPPLIER is unable to overcome the related Force Majeure Event, the Minimum Yearly Volume for the Year where the related Project Agreement is recorded as referred to in the Master Agreement shall be reduced by the price for the related Project Agreement.

18. GOVERNING LAW AND DISPUTES

18.1 The interpretation and construction of this Agreement and each Project Agreement shall be governed by the substantive laws of France.

18.2 In the event that agreement on a matter cannot be reached within thirty (30) days (or sooner, if required), the Parties shall first try to settle their differences amicably between themselves. Any Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice, appropriate representatives of the Parties shall meet for attempted resolution by such bona fide negotiations.

18.3 Except as set forth in clause 4.5 herein above, if the representatives of the Parties empowered to settle a dispute are not able to close the dispute within forty (40) days from the date of the written notice, the Parties shall then refer the dispute to proceedings under the ICC Mediation Rules. If the dispute has not been settled pursuant to the said Rules within sixty (60) days following the filing of a Request for Mediation or within such other period as the Parties may agree in writing, such dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules of Arbitration.

19. COUNTERPARTS

19.1 This Agreement is executed in two (2) counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the Effective Date.

SIGNED for and on behalf of SUPPLIER	SIGNED for and on behalf of CUSTOMER
Signature	Signature
Name:	Name:
Title:	Title:
Signature	Signature
Name:	Name:
Title:	Title:

APPENDIX 1

PROJECT AGREEMENT

THIS PROJECT AGREEMENT (the **"Project Agreement"**) is effective on [**201YMMDD**] (the **"Effective Date"**) and is made by between:

(1) **Recipharm X** [INSERT APPLICABLE COMPANY], registered under the laws of [INSERT COUNTRY] under registration number [INSERT NUMBER] and having an office at [INSERT ADRESS], ("SUPPLIER").

(2) **FLAMEL TECHNOLOGIES SA,** a French *Société Anonyme* with the registered number 379 001 530 and having its principal office at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX ("CUSTOMER").

WHEREAS:

(A) The Parties entered into a Service Agreement on [INSERT DATE] (the **"Service Agreement"**).

(B) Clause 2.2 of the Service Agreement provides that Project Agreements specifying the details of Services may be entered into pursuant to the Service Agreement.

(C) The Parties wish to enter into this Project Agreement subject to the Service Agreement.

NOW THEREFORE, the Parties agree as follows:

I. This Project Agreement shall be incorporated by reference and made a part of the Service Agreement with effect from the Project Effective Date.

II. The Parties agree to follow all other terms and conditions of the Service Agreement which shall be unchanged and shall continue in full force and effect.

III. Capitalised terms utilised herein and not otherwise defined shall have their respective meanings set forth in the Service Agreement.

IV. The scope of Services is hereinafter set forth:

i) **Scope of Work**

There will be no Appendix A; each service provided in the proposed Appendix A as provided by Seller shall have to be inserted in an appropriate and separate Project Schedule as scope of the Work.

ii) Designated Personnel

Title	**Title of work to be entered**	
SUPPLIER	**Name**	**Phone** **(Fax)** **Email**
Project Representative	Insert project contact names	Insert project contact fax/phone/email
Add others as required	Insert project contact names	Insert project contact fax/phone/email
CUSTOMER	**Name**	**Phone** **(Fax)** **Email**
Project Representative	Project personnel will be entered	Contact fax/phone/email will be entered.
Add others as required	Insert project contact names	Insert project contact fax/phone/email
Invoice forwarded to:	Insert project contact name	Insert address

iii) Timeline/Project Milestones/Deliverables

Key timings, deliverables and milestones are the following

See comment in Scope of Works

iv) Allocation of Responsibilities/Necessary Approvals

Same comments that for scope of Works

v) Budget/Payment Terms

Same comments that for scope of Works
This section will determine any associated costs, payment (against milestones), payments based on agreed outputs. This will reflect the proposals made and agreed per the quotation in response to ***CUSTOMER****'s Invitation to tender. It will also cover any specific agreed purchases including materials and equipment if applicable.*

vi) Project Related Documents

Same comments that for scope of Works. This will detail the appropriate documentation to be provided by the Parties pursuant to the Project Agreement.

Document	**Comment**
Description	Any additional comments/requirements

vii) Special Terms & Conditions

To cover any special terms not addressed in the above sections.

For the avoidance of doubt, all terms of the Service Agreement remain in force without modification, in particular those relating to Intellectual Property rights, Confidentiality and Non Infringement of third party rights.

IN WITNESS WHEREOF, the following have caused this Project Agreement to be executed by their respective duly authorised representatives effective as of the day and year stated above.

SIGNED for and on behalf of SUPPLIER [...]	SIGNED for and on behalf of CUSTOMER […]
Signature	Signature
Name:	Name:
Title:	Title:
Signature	Signature
Name:	Name:
Title:	Title:

APPENDIX 2

CHANGE ORDER

CHANGE ORDER FORM

PROJECT AGREEMENT NUMBER:

PROJECT NAME/DESCRIPTION:

RECIPHARM CONTACT PERSON:

DATE OF REQUEST: **PREPARED BY:**

BRIEFLY DESCRIBE ORIGINAL ASSUMPTION AND NEW REQUEST BELOW:

IMPACT (estimated effort and/or timeline):

ESTIMATED COST:

Payment Terms:

Amendment:

This Change Order constitutes an Amendment to the Service Agreement effective on [YYYYMMDD] ("Service Agreement") and the Project Agreement as stated above between [CUSTOMER] and Recipharm X and shall apply only to the scope of Services listed herein or attached hereto. In all other respects the terms and conditions of the Service Agreement and the relevant Project Agreement shall remain in full force and effect and shall be applied to this Amendment.

SUPPLIER	**FLAMEL TECHNOLOGIES**
(Signature)	(Signature)
(Date)	(Date)

SUPPLY AGREEMENT

By and between

(1) RECIPHARM PESSAC

and

(2) FLAMEL TECHNOLOGIES

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "Agreement") is effective on December 1st, 2014 and is made by and between:

RECIPHARM PESSAC, a French *Société par Actions Simplifiée* under registration process and having its principal place of business at, rue Archimède, 33600 Pessac France**,** ("**SUPPLIER**").

FLAMEL TECHNOLOGIES SA, registered under the laws of France under registration number 379 001 530 and having its principal office at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX ("**CUSTOMER**").

WHEREAS:

(A) SUPPLIER is a contract manufacturing company, with the ability and capacity to Process any pharmaceutical products, directly in its own premises or in the premises of one of its Affiliates.

(B) CUSTOMER is the owner of the rights pertaining to the manufacture and /or the marketing of various pharmaceutical products and is willing to have SUPPLIER as manufacturer of certain of its products.

(C) The Parties entered into a transaction under various agreements and in particular a Master Agreement and a Quality Assurance Agreement, which shall govern the overall relations between the Parties with regard to the manufacture by SUPPLIER and supply to CUSTOMER of Products.

NOW, THEREFORE, the Parties agree as follows:

1. DEFINITIONS

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

1.1 "Affiliates" means any corporation or other entity that controls, is controlled by, or is under common control with, a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than 50% of the voting securities or other ownership interests of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity.

1.2 "Applicable Laws and Regulations" with respect to each Product, has the meaning defined in the Quality Assurance Agreement and the applicable Product Requirements.

1.3 'Business Day(s)' means a day other than a Saturday, Sunday or a day on which banks are not open for business in France or the Country where the Services will be performed under this Agreement and the related Product Schedule;

1.4 “Confidential Information” means any business, marketing, financial technical, scientific information, know-how, trade secrets or other information, in any form or medium disclosed by any Party pursuant to or in the course of this Agreement or any Product Schedule and whether disclosed orally or in writing which, at the time of disclosure, is either designated as confidential or proprietary (or like designation), is disclosed in circumstances of confidence, or would be understood by the Parties, exercising reasonable business judgment, to be confidential. Confidential Information includes, without limitation, all Intellectual Property Rights, Know-How or other information and products arising from or disclosed for implementing a Product Schedule or in the course of this Agreement, the terms and conditions of this Agreement and the fact of collaboration between the Parties.

1.5 “Disclosing Party” means the Party disclosing Confidential Information.

1.6 “Effective Date” means the date indicated above

1.7 “External Costs” means the amount paid by SUPPLIER or the SUPPLIER Affiliate for any Product specific materials, goods, supplies, and equipment of any nature for Supplying under the related Product Schedule when SUPPLIER or the related SUPPLIER Affiliate shall have not the resources, capacity or ability to provide such part of the Supply whatever this Person is deemed to be a subcontractor or not, and any tax to be invoiced to CUSTOMER under Applicable Law and Regulations.

1.8 “Force Majeure” has the meaning defined in the Force Majeure Section.

1.9 “Forecast” has the meaning set forth in Section 7.1.

1.10 “Intellectual Property Rights” means Confidential Information, Know-How, trade secrets, patent rights, trademarks, service marks, trade names, design rights, copyright (including rights in computer software) and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights, and all rights or forms of protection having equivalent or similar effect, in any part of the world.

1.11 “Know-How” means: (i) all technical information or data relating to the Products, whether protected by Intellectual Property Rights or not, including but not limited to technology, processes, specifications, formulas, procedures, techniques, practices and instructions of, and scientific, analytical and technical data and studies for, the synthesis, manufacturing, pharmaceutical processing, formulation, packaging, labelling storage and transportation of the Products; and (ii) non-clinical and clinical data and studies relating to the Products

1.12 “Internal Costs” means (i) fully allocated cost of Supplying the Products under the related Product Schedule, such fully allocated costs comprises direct costs incurred directly for the Supply of the related Products by SUPPLIER (including but not limited to labour, materials, goods and supplies) and indirect costs specifically allocable to Supplying the related Products by SUPPLIER (including but not limited to administrative labour costs, maintenance, insurance the part of depreciation allocated to assets used in the Supply of the related Product) ; such calculation being based upon accepted contract manufacturing industry standards and generally accepted accounting principles.

1.13 “Master Agreement” means the agreement entered into by and between the Parties on Effective Date where the Parties have agreed upon, among other things, overall conditions for supplying the Products.

1.14 “Parties” means CUSTOMER and SUPPLIER and “Party” means either CUSTOMER or SUPPLIER.

1.15 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.16 “Price” with respect to each Product, means the amount payable for such the Supply of the Product, as determined in accordance with the prevailing provisions of the Master Agreement, the terms of Article 10 herein and the relevant Product Schedule.

1.17 “Product Requirements”, with respect to each Product, means the requirements for such Product, as specified in the relevant Product Schedule as the same may be updated from time to time in accordance with the Quality Assurance Agreement and the regulatory approved artwork.

1.18 “Product Schedule Effective Date” means, with respect to each Product Schedule, the date on which such Product Schedule becomes effective, as set forth in such Product Schedule.

1.19 “Product Schedule” means a schedule, in the form set forth in Exhibit 1, agreed, and signed by the Parties in accordance with Section 6.1.

1.20 “Product(s)” means the clinical product, intermediate product and/or finished product to be supplied pursuant to, and as detailed in, each Product Schedule and, in addition, the various forms and further developments which the same pharmaceutical Product may take.

1.21 “Quality Assurance Agreement” or “QAA” means the quality assurance agreement entered into by the Parties, a copy of which is attached hereto as Exhibit 2 as the same may be amended from time to time.

1.22 “Supply” means the manufacturing, packaging, testing, release, and delivery with respect of the Product to the extent, and as detailed in each Product Schedule.

1.23 “Receiving Party” means the Party to whom Confidential Information is disclosed.

1.24 “Term” means the period beginning on the Effective Date and continuing as set out in Article 18.

2. CONSTRUCTION

2.1 Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word “or” has the inclusive meaning represented by the phrase “and/or”. The headings of this Agreement are for convenience of reference only. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

2.2 If there is any inconsistency between a Product Schedule or an Exhibit and this Agreement, the terms of this Agreement shall govern. If there is any inconsistency between this Agreement and the terms of the Master Agreement, the terms of the Master Agreement shall govern.

2.3 The Exhibits and the Product Schedules (as amended from time to time by agreement of the Parties in writing) form part of this Agreement and have the same force and effect as if expressly set out in the body of the Agreement. Any reference to the Agreement includes the Exhibits and the Product Schedules. Any breach of the Exhibits or Product Schedules shall be deemed as a breach of this Agreement.

3. AMENDMENT

3.1 Any amendment or modification of this Agreement must be in writing and signed by authorised representatives of both Parties.

4. SUPPLY OF PRODUCTS

4.1 SUPPLIER agrees to Supply, and CUSTOMER agrees to purchase, the Products agreed in the Product Schedules under this Agreement.

5. TECH TRANSFER

5.1 To the extent required, CUSTOMER shall disclose such part of its Intellectual Property Rights to SUPPLIER as is necessary and useful in the Supply of the Product to CUSTOMER. The Parties shall, if SUPPLIER deems it necessary, establish a joint project team, which shall manage the disclosure of Customer's Intellectual Property Rights in accordance with the technology transfer plan including the hand-over, setting out the activities of the technology transfer process, in order to secure the establishment of the Supply and quality control of the Products at SUPPLIER’s facilities, as specified in the applicable Service Schedule, and agree on any changes to the Product Requirements prior to commencement of the Supply of the Product. After the completion of the technology transfer and the above activities, the joint project team will be dissolved. The Parties shall allocate sufficient resources to perform the above activities. CUSTOMER shall remunerate SUPPLIER for its reasonable activities and any start-up costs as agreed by the Parties.

5.2 CUSTOMER disclosing its Intellectual Property Rights is responsible for such rights not infringing on any third party Intellectual Property Rights; SUPPLIER shall be held indemnified and compensated for any such additional costs arising from any infringement claim from said third party.

6. PRODUCT SCHEDULES

6.1 The Parties agree to conclude a separate Product Schedule for each Product which shall be governed by the general conditions of this Agreement unless otherwise agreed specifically in the relevant Product Schedule. This Agreement sets forth the terms and conditions under which SUPPLIER shall Supply, and under which CUSTOMER shall purchase Products pursuant to the applicable Product Schedules. SUPPLIER’s engagement for Supply shall be on an exclusive basis, unless otherwise agreed in the Product Schedule

6.2 In order to comply with the terms and conditions of the Master Agreement, the Parties agree to identify for each Product and shall allocate in each Product Schedule the Internal Costs and the External Costs of SUPPLIER in the price for the Supply of the Product. The Parties shall identify and amend the allocation of the price when a change is implemented in the Supply of the Product as referred to in clauses 15 and 16 herein.

6.3 Any number of Product Schedules may be executed pursuant to this Agreement during the Term.

6.4 Each Product Schedule will operate for the term specified in the Product Schedule, unless earlier terminated in accordance with Article 18.

7. FORECASTING FOR COMMERCIAL PRODUCT

7.1 Unless otherwise agreed by the Parties in writing in the applicable Product Schedule, and when the Parties shall agree to have SUPPLIER delivering Products on a commercial basis, CUSTOMER shall, each month, provide SUPPLIER with a non-binding work plan related to each Product Schedule for the following twelve (12) month period ("**Forecast**"). The Forecast submitted in September each year shall however cover fifteen (15) months, if the term of the Service Schedule continues for the following year, and shall comply with such specific terms and conditions the Parties may agree in the related Product Schedule.

7.2 CUSTOMER shall be entitled to modify the quantities set forth in the Forecast until an applicable purchase order is approved by SUPPLIER. Following SUPPLIER's approval of such purchase order and, subject to the minimum volume of Products the Parties may agree in the Product Schedule, the Forecast quantities may be varied by CUSTOMER by not more than fifteen percent (15%) from the amount set forth in each approved purchase order.

7.3 SUPPLIER shall without delay notify CUSTOMER if SUPPLIER does not have the capacity to deliver Products in accordance with the Forecast.

7.4 SUPPLIER shall base the planning and purchasing of raw materials/packaging components upon Forecasts provided by CUSTOMER. Even though the Forecast is non-binding, SUPPLIER may use the Forecast to plan and buy raw materials. Specific raw materials bought in accordance with a Forecast, which SUPPLIER is not able to use within the Term or beyond the termination of the related Product Schedule may be sold at its purchase price to CUSTOMER or scrapped at reasonable costs, at CUSTOMER's written request and at CUSTOMER's costs. These raw materials will be kept at SUPPLIER's warehouse, unless otherwise agreed between the Parties and in accordance with the Applicable Laws and Regulations.

8. PURCHASE ORDERS

8.1 When the Parties shall agree to have SUPPLIER delivering Products on a commercial basis, SUPPLIER shall have the responsibility to deliver Products according to CUSTOMER written purchase orders when confirmed by SUPPLIER as described hereunder.

8.2 CUSTOMER shall send written purchase orders for each Product to SUPPLIER. Such purchase orders shall be sent no less than four (4) months before the expected delivery date, unless otherwise agreed in the related Product Schedule. SUPPLIER shall confirm the receipt of the purchase order as well as confirm a delivery date within twenty (20) calendar days after receipt. SUPPLIER shall always be allowed the minimum lead-time specified in the relevant Product Schedule.

8.3 Any deviation from the confirmed delivery date is to be communicated to CUSTOMER as soon as possible in order to enable CUSTOMER to take necessary action to minimize any negative effects in the market.

8.4 CUSTOMER shall inform SUPPLIER of any major changes in the market or other information, which may have impact on Forecast or/and purchase orders.

9. DELIVERY AND TITLE

9.1 SUPPLIER shall Supply each Product ordered by CUSTOMER Ex Works SUPPLIER'S Pessac plant Incoterms 2010 unless otherwise specifically agreed in the related Product Schedule and in accordance with the terms set out in the confirmed order.

9.2 Title to the Products shall pass to CUSTOMER upon delivery and payment. Risk of the Product shall pass to CUSTOMER upon delivery.

10. PRICE

10.1 The Parties agree and undertake to determine the Price for the Supply of the Products in accordance with applicable provisions of the Master Agreement and such price of the Supply for each Product shall be allocated in accordance with clause 6.2 hereinabove

10.2 The Price is exclusive of value added tax, which, if payable, shall be borne and paid by CUSTOMER against the provision by SUPPLIER of an appropriate invoice.

10.3 The Prices will be revised annually in good faith, not later than 30 September, and any change shall become effective as from 1 January the following year, in accordance with the public index as published by the French Ministry of Labour named "*Indices de salaires mensuels de base de l'ensemble des salaries de l'industrie pharmaceutique (base 100 en décembre 2008)*" (Price indexes for monthly salaries of the personnel in the pharmaceutical industry (base 100 in December 2008)). Month of reference for this index for this Agreement is September 2013= 111,6. http://www.leem.org/article/les-indices-des-salaires-de-lindustrie-pharmaceutique , subject to the price increase being limited to a maximum of 3%.

10.4 . Notwithstanding Section 10.3, if changes in manufacturing and production costs and material prices as defined in the Price Review Parameters in the Product Schedule materially increase or decrease the cost required to perform the Supply Services, SUPPLIER shall provide CUSTOMER with a quotation, showing the equitable adjustments that should be made to the Price to reflect the increase, and, if the Parties agree on terms, the Product Schedule and the Price shall be amended accordingly.

11. PAYMENT AND INVOICING

11.1 SUPPLIER shall issue an invoice at delivery of Products to CUSTOMER for the applicable Price for the Products delivered to CUSTOMER. The invoice shall contain a reference identifying the CUSTOMER purchase order as well as the relevant CUSTOMER Product article number.

11.2 All invoices shall be payable in full within thirty (30) days following the date of issue of the invoice. If the undisputed invoice is not paid within this timeframe, penalty interest plus recovery charges shall be charged to CUSTOMER in accordance with the Applicable Laws and Regulations.

12. SHORTFALLS, DAMAGES & DEFECTS

The terms and conditions of this Article 12 shall apply only when the Parties shall agree to have SUPPLIER delivering Products on a commercial basis.

12.1 If any shipment of Product delivered by SUPPLIER contains any damage, shortage or defect of the Product due to SUPPLIER's breach of this Agreement, CUSTOMER shall notify SUPPLIER a) within twenty (20) days of receipt of such shipment if such damage, shortage or defect can be ascertained by the exercise of reasonable diligence upon examination by CUSTOMER on receipt of such shipment, or b) within ten (10) days after discovery of the same if such damage, shortage or defect cannot be ascertained by the exercise of reasonable diligence upon examination by CUSTOMER on receipt of such shipment (including non conformities relating to stability).

12.2 If there is any defect in or damage to any Product delivered by SUPPLIER due to acts or omissions of SUPPLIER ("**Non-Conforming Product**"), SUPPLIER shall at CUSTOMER'S option without any undue delay either;

12.2.1 replace the Non-Conforming Product with conforming Product, at SUPPLIER's expense; or

12.2.2 refund to CUSTOMER the cost paid to SUPPLIER by CUSTOMER for such Non-Conforming Product, or, if the invoice has not been paid, cancel the invoice and the Minimum Yearly Volume is not increased by such refunded amount or amount of such cancelled invoice for the Year where the related Non-Conforming Product is to be recorded as referred to in the Master Agreement.

12.3 If a dispute arises between the Parties as to any claimed damage or defect in the Product or shortage of Products delivered, which cannot be resolved by the Parties within thirty (30) days of a claim being notified by CUSTOMER to SUPPLIER, either Party may require that the matter in dispute be referred to an independent expert (such as an independent testing laboratory) selected by agreement of the Parties. Such referral will be solely for the purpose of establishing whether or not there is any shortage, damage or defect (as the case may be) in the relevant Product delivered by SUPPLIER to CUSTOMER. Except in the case of fraud or manifest error on the part of such independent expert, the decision of such independent expert will be binding upon the Parties. If the independent expert decides there was no shortage, damage, or defect in the Product in question, the costs of the independent expert will be borne by CUSTOMER. In all other circumstances, the costs of the independent expert will be borne by SUPPLIER. In case the Parties are not able to agree on appointment of the independent expert, the Parties agree to submit the dispute to administered expertise proceedings in accordance with the Rules for Expertise of the International Chamber of Commerce.

12.4 SUPPLIER shall indemnify CUSTOMER for damages in relation to or arising solely out of any breach of this Agreement by SUPPLIER.

12.5 Any and all liability of SUPPLIER to CUSTOMER howsoever arising in respect of this Agreement and its performance under a Product Schedule shall be limited to an amount equal to one hundred (100) per cent of the amount to be reasonably received by SUPPLIER from CUSTOMER under the related Product Schedule for the calendar year when the matter giving rise to such loss or damage has occurred.

12.6 Save as set out in this Agreement SUPPLIER makes no warranty of whatsoever nature in respect of the Supply of the Product and all conditions, warranties stipulations or other statements as to the Products or defects therein, including (but without limiting the foregoing) the efficacy toxicity or safety of the Product, or its satisfactory quality performance or fitness for purpose, whether express or implied, by statute common law or otherwise howsoever, are hereby excluded to the fullest extent permissible by Applicable Laws and Regulations.

12.7 CUSTOMER shall indemnify SUPPLIER for damages in relation to or arising out of any breach of this Agreement by CUSTOMER or any product liability claim on SUPPLIER which is not a result of SUPPLIER's breach of this Agreement.

12.8 The Party claiming an indemnification for damages hereunder must promptly notify the other of any claim, not accept any compromise or settlement of such claim or take any material steps in relation to such claim without the prior consent of the other party and shall co-operate fully with the other party in the handling of any such claim.

12.9 Neither Party shall in no circumstances be liable to the other Party nor any third party for any consequential or indirect loss or damage or loss of profit of whatsoever nature including (but not limited to) damage to goodwill, loss of market share, existing or prospective nor the cost of any delay of any regulatory programme.

13. QUALITY

13.1 In Supplying Product to CUSTOMER, SUPPLIER shall comply with all of the provisions and requirements of the Product Schedule, Quality Assurance Agreement and the Applicable Laws and Regulations.

13.2 SUPPLIER and CUSTOMER agree to cooperate in attempting to resolve all product quality complaints as set out in the Quality Assurance Agreement.

14. PRODUCT RECALL

14.1 CUSTOMER shall have sole discretion over whether and under what circumstances to require the recall of batches of Product. In the event that a recall of a batch from sale is necessary as a result of the fault or negligence of SUPPLIER, SUPPLIER shall be responsible for all direct costs relating thereto. CUSTOMER shall bear the costs of SUPPLIER for any recall in any other circumstances.

15. PRINTED PACKAGING AND ARTWORK

15.1 SUPPLIER shall, at CUSTOMER's cost, be responsible for the handling of artwork on the printed packaging, if agreed with CUSTOMER.

15.2 Subject to the provision of clause 6.2 on allocation of price, SUPPLIER shall, at CUSTOMERS' cost, be responsible for printing plates used for printed packaging materials, if agreed with CUSTOMER.

15.3 CUSTOMER is responsible to make sure that said artworks are not infringing any third party intellectual property rights in the relevant countries of Supply and commercialisation and are in accordance with the Applicable Laws to the commercialisation of the Products in the relevant countries/territories.

16. REMUNERATION AND RESPONSIBILITIES FOR CHANGES OF PRODUCT

16.1 Subject to the provision of clause 6.2 on allocation of price, costs for any change of the Product shall be included in the Price, except in the following cases where remuneration for such costs shall be additional reimbursed by CUSTOMER to SUPPLIER:

16.1.1 when the changes are initiated by CUSTOMER, then SUPPLIER shall be remunerated by CUSTOMER for its costs for necessary services and materials needed to perform such change (including remuneration for waste or scrapped);

16.1.2 when external circumstances, due to reasons out of SUPPLIER's control, e.g. governmental authorities', EU or similar organisations, whether regional or global directives or regulations, or other third parties decisions, or changes, are issued which require changes of the Product; the Parties will meet to discuss and resolve the external issue and negotiate the changes to be made prior to implementation; and if changes, of said circumstances, are decided to be made by CUSTOMER then CUSTOMER shall remunerate SUPPLIER for its costs; and

16.1.3 when the changes in sub-sections 16.1.1 and 16.1.2 result in changes in production costs, the Parties shall agree on any Price adjustment prior to implementation of such changes.

16.2 If CUSTOMER or any third party or regulatory authority initiates a change the Parties shall in good faith plan for the change in order to minimize the cost of waste.

17. ADDITIONAL REPRESENTATIONS AND WARRANTIES

17.1 SUPPLIER represents and warrants to CUSTOMER that;

17.1.1 SUPPLIER will inform CUSTOMER promptly in writing of any event, which in the reasonable judgment of SUPPLIER may adversely affect (i) SUPPLIER's ability to Supply the Products or (ii) the suitability of the Products for CUSTOMER's use.

17.2 CUSTOMER represents and warrants that;

17.2.1 it has and will maintain throughout the term of this Agreement appropriate regulatory approvals for the Product and it has notified SUPPLIER of any special requirements in respect of record-keeping that may be necessary to comply with CUSTOMER's adverse event, Product defect or recall procedure and that it shall notify SUPPLIER of any hazards to the health or safety of any personnel of SUPPLIER or the possibility of cross contamination of any other products being manufactured or stored by SUPPLIER and CUSTOMER shall keep SUPPLIER so advised throughout the continuance of this Agreement, whether such hazards or possibilities are inherent in the Product or otherwise.

18. TERM AND TERMINATION

18.1 The termination of this Agreement is subject to the provisions of the Master Agreement, especially with regard to the Initial Term as referred to in said Master Agreement and such clause related to the Minimum Yearly Volume.

18.2 Without prejudice to the provisions of the Master Agreement related to the Minimum Yearly Volume, any Product Schedule individually, may be terminated immediately by either Party upon notice to the other Party as follows:

18.2.1 in the event of a material breach of this Agreement by the other Party, where such breach is capable of cure and measures to initiate the cure has not begun within thirty (30) days after notice of such breach;

18.2.2 in the event of a material breach of this Agreement by the other Party where such breach is not capable of cure; and

18.2.3 if the other Party shall file in any court or agency, pursuant to any statute or regulation of any country, a petition in bankruptcy or insolvency or for reorganization or for an the appointment of a receiver or trustee of such other Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

18.3 Without prejudice to any other rights or remedies which either Party may have, upon the termination of this Agreement, or a Product Schedule howsoever the same occurs, each Party shall;

18.3.1 immediately pay to the other Party all undisputed sums which at the date of termination are due and payable to the other Party under this Agreement or the relevant Product Schedule;

18.3.2 immediately cease all use of any property of the other Party, including any Intellectual Property Rights of the other Party under this Agreement or the relevant Product Schedule; and

18.3.3 the Parties shall fulfil the obligations provided in clause 7.4; and

18.3.4 within twenty eight (28) days of such termination, return to the other Party any property of the other Party in its possession, custody or control, including all Confidential Information of that Party and copies of it under this Agreement or the relevant Product Schedule; provided, however, that a Party may retain one (1) copy of the other Party's Confidential Information in order to ensure compliance with its obligations set forth in this Agreement.

18.4 Articles 1, 2, 14, 19, 21 and 23 and this Section 18.4 will survive expiration or termination of this Agreement, and howsoever the same occurs.

19. NATURE OF AGREEMENT

19.1 Neither Parties shall assign, transfer or sub-contract any of its rights or obligations under this Agreement or any Product Schedule without obtaining the prior written consent of the other Party; except that, either Party may assign the benefit or burden of this Agreement to any Affiliate, with sufficient capacity and economic strength for such an obligation, without the need to obtain such consent.

19.2 The Parties are independent contractors and none of the provisions of this Agreement shall be deemed to constitute a partnership or joint venture between the Parties. No Party shall have any authority, nor hold itself out as having any such authority, to bind any other Party in any way.

19.3 Save where specifically stated to the contrary in this Agreement or in any Product Schedule, each Party shall bear its own costs in entering into and performing its obligations under the Agreement and any Product Schedule.

19.4 Each Party warrants to the other that it has the authority to enter into this Agreement and any Product Schedule and perform its obligations under this Agreement and any Product Schedule.

19.5 This Agreement and each Product Schedule are governed by the Master Agreement for the duration of said Master Agreement and subject to the provisions of the Master Agreement contain the entire agreement between the Parties with respect to its subject matter, supersedes all previous agreements or understandings with respect thereto and may not be modified except by an instrument in writing signed by the duly authorized representatives of the Parties.

19.6 No failure or delay by either Party in exercising any of its rights under this Agreement or a Product Schedule shall be deemed to be a waiver of that right, and no waiver by either Party of a breach of any provision of this Agreement or the relevant Product Schedule shall be deemed to be a waiver of any subsequent breach of the same or any other provision.

19.7 If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law and if the rights or obligations of any Party will not be materially and adversely affected: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement; (b) all other provisions of this Agreement shall remain in full force and effect; and (c) the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the Parties. To the fullest extent permitted by applicable law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

19.8 All notices required under the terms of this Agreement or any Product Schedule shall be in writing and shall be validly given if sent by recorded delivery mail or courier service to the respective person as set out below, or such person as may be notified by one Party to the other in writing from time to time. All notices shall be deemed to have been received three (3) Business Days after they are sent.

For: CUSTOMER :	FLAMEL TECHNOLOGIES
Address:	Parc Club du Moulin à Vent 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX, FRANCE
For the attention of:	Président Directeur Général
With a copy to:	Sr. Vice President, General Counsel
For: SUPPLIER:	RECIPHARM PESSAC
Address:	rue Archimède, 33600 PESSAC, France
Facsimile:	+ 33 5 56 36 58 91
For the attention of:	Président
With a copy to:	RECIPHARM AB (publ)
Address	Lagervägen 7, SE-136 50 Jordbro, Sweden
Facsimile:	0046 8 81 87 03
For the attention of:	Legal

20. INSURANCE

20.1 During the duration of this Agreement, and for three (3) years thereafter, each Party represents and warrants to the other Party that it has insurance coverage with a reputable insurance company of a type and amount typical in the pharmaceutical business and industry sufficient to secure the performance of its obligations hereunder.

20.2 Each Party shall provide evidence of such insurance whenever reasonably requested by the other Party. The Parties covenants and agrees not to do or to omit any matter or thing which may prejudice or render voidable such insurance.

20.3 Any raw materials supplied by CUSTOMER shall be and at all times remain at the risk of CUSTOMER, and CUSTOMER shall insure such raw materials to their full replacement value while on SUPPLIER's premises unless and until they are incorporated into Products. Notwithstanding the foregoing, SUPPLIER shall be responsible for any loss or damage to CUSTOMER's raw materials to the extent such loss or damage was due to the negligence of wilful misconduct of SUPPLIER or fire or any other natural disaster at SUPPLIER's Facility as covered under SUPPLIER's insurance .

21. CONFIDENTIALITY

21.1 Except as otherwise provided in this Agreement, any Confidential Information, which is disclosed by or on behalf of a Disclosing Party to the Receiving Party will remain the property of the Disclosing Party.

21.2 The Receiving Party undertakes:

21.2.1 to use the Confidential Information solely and exclusively for the purposes of this Agreement (or such other purpose as is agreed in writing between the Parties at the time of disclosure), and not to use the Confidential Information for any other purpose whatsoever, including the development, manufacture, marketing, sale or licensing of any process or product or any other commercial purpose anywhere in the world, unless the Parties enter into an agreement specifying otherwise; and

21.2.2 to maintain the confidentiality of the Confidential Information and not to disclose it directly or indirectly to any other company, organisation, individual or third Person, except as permitted by Section 21.3.

21.3 Notwithstanding Section 21.2, the Receiving Party may disclose Confidential Information to any of its Affiliates, and its and its Affiliate's directors, employees and professional advisers who need to know the Confidential Information in order to fulfil the purpose of this Agreement, provided that the Receiving Party procures that prior to such disclosure, each such Person to whom Confidential Information is to be disclosed is made aware of the obligations contained in this Agreement, and adheres to these terms as if it were a party to this Agreement.

21.4 The provisions of Section 21.2 will not apply to any Confidential Information which the Receiving Party can demonstrate, to the reasonable satisfaction of the Disclosing Party;

21.4.1 was already in the possession of the Receiving Party or any of its Affiliates and at the Receiving Party's or any of its Affiliates' free use and disposal or in the public domain (through in each case no fault of the Receiving Party or any of its Affiliates or no breach of this Agreement by the Receiving Party) prior to its disclosure by the Disclosing Party under this Agreement; or

21.4.2 is purchased or otherwise legally acquired by the Receiving Party or any of its Affiliates at any time from a third Person having and the right to disclose it; or

21.4.3 comes into the public domain, otherwise than through the fault of the Receiving Party or any of its Affiliates; or

21.4.4 is independently generated by the Receiving Party or any of its Affiliates without any recourse or reference to the Confidential Information.

21.5 The obligations of each Party in this Section will survive for a period of ten (10) years after the date of expiration or termination of this Agreement.

22. FORCE MAJEURE

22.1 In the event any Party is delayed or hindered in or prevented from the performance of any act required hereunder by reason of a Force Majeure Event, then performance of such act will be excused for the period of such delay, provided however, that such Party shall exert its reasonable efforts to overcome such Force Majeure Event and to resume performance of its obligations in a timely manner.

22.2 Notice of the commencement and ending of such Force Majeure Event will be provided by such Party to the other Party within ten (10) Business Days. Any timeline or milestone obligations of such Party affected by the Force Majeure Event will be extended for a period of time equal to the number of days of the delay, provided however that, but subject to the provisions of the Master Agreement, especially with regard to the Initial Term as referred to in said Master Agreement and such clauses related to the Minimum Yearly Volume, in the event that a Party is unable to overcome any Force Majeure Event within: (i) sixty (60) Business Days, the other Party may terminate Product Schedules under which the affected Supply are being provided or, (ii) beyond the Initial Term, terminate this Agreement if all Product Schedules have been terminated. In case the Product Schedule is then terminated by CUSTOMER because SUPPLIER is unable to overcome the related Force Majeure Event, the Minimum Yearly Volume for the Year where the related Product Schedule is recorded as referred to in the Master Agreement shall be reduced by the price for the related Product Schedule.

23. GOVERNING LAW AND DISPUTES

23.1 The interpretation and construction of this Agreement shall be governed by the substantive laws of France.

23.2 In the event that agreement on a matter cannot be reached within thirty (30) days (or sooner, if required), the Parties shall first try to settle their differences amicably between themselves. Any Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice, appropriate representatives of the Parties shall meet for attempted resolution by such bona fide negotiations.

23.3 Except as set forth in Section 12.3, if the representatives of the Parties empowered to settle a dispute are not able to close the dispute within forty (40) days from the date of the written notice, the Parties shall then refer the dispute to proceedings under the ICC Mediation Rules. If the dispute has not been settled pursuant to the said Rules within sixty (60) days following the filing of a Request for Mediation or within such other period as the Parties may agree in writing, such dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules of Arbitration. The language used in the arbitration proceedings shall be English.

24. COUNTERPARTS

24.1 This Agreement is executed in two (2) counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the Effective Date.

SIGNED for and on behalf of SIGNED for and on behalf of

SIGNED for and on behalf of Recipharm Pessac	SIGNED for and on behalf of Flamel Technologies
Signature	Signature
Name:	Name:
Title:	Title:

Exhibit 1 Form Product Schedule

Product Schedule No [X]

for Supply of [PRODUCT]

TO THE SUPPLY AGREEMENT DATED [YYYYMMDD] ("Agreement"), entered into between:

(1) **Recipharm X** [INSERT APPLICABLE COMPANY], registered under the laws of [INSERT COUNTRY] under registration number [INSERT NUMBER] and having an office at [INSERT ADRESS], ("SUPPLIER").

(2) **FLAMEL TECHNOLOGIES SA,** a French *Société Anonyme* with the registered number 379 001 530 and having its principal office at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy 69200 VÉNISSIEUX ("CUSTOMER").

This Product Schedule is made effective as of [...] (the "Product Schedule Effective Date") and shall continue in effect for a Term of sixty (60) months with prolongation as set out in Article 18 of the Agreement. This Product Schedule is entered pursuant to, and is subject to all of the terms and conditions contained in the Agreement. Together, this Product Schedule and the Agreement form a binding agreement between the Parties in relation to the details set out in this Product Schedule.

This Product Schedule consists of the following parts

Part A Product and Product Requirements

Part B Pricing and Payment

PART A: PRODUCT AND PRODUCT REQUIREMENTS

1. Product

   [...]

2. Product Requirements

[refer to relevant PR in the QAA]

3. Minimum lead time.

   The minimum lead time for delivery of Product shall be at least four (4) months.

4. Applicable Law and Regulation, GMP, for the Product shall be [COUNTRY]

PART B: PRICING AND PAYMENT

1. Price

2. Invoice address;

_____

_____

_____

_____

_____

3. Price Review Parameters

The price review shall take into consideration volumes forecasted, verified changed costs for raw material and other material, labour costs and other manufacturing costs. The purpose of the price revision is to change the Price according to the change in SUPPLIER’s manufacturing costs.

4. Compensation in case of CUSTOMER termination according to Article 18.3

The compensation payable under Section 18.3 will be;

(a) the Price for any stock of the Product not yet released and delivered to CUSTOMER; and

(b) the volumes of Product in progress;

(c) SUPPLIER’s direct costs for raw materials and other materials in SUPPLIER’s stock at the date of such termination and purchased for the use in the Supply of theProduct. The compensation under this sub-paragraph (b) is given provided that;

(i) the volumes of raw materials and other materials are within CUSTOMER's latest forecast;

(ii) the raw materials and other materials cannot reasonably be used for other purposes by SUPPLIER; and

(iii) CUSTOMER is entitled to collect such raw materials and other materials for its own use or sale, without additional charge.

This Product Schedule is executed by the authorized representatives of the Parties as of the date first written above.

IN WITNESS WHEREOF, the Parties have executed this Product Schedule on the Product Schedule Effective Date.

SIGNED for and on behalf of	SIGNED for and on behalf of
Recipharm [...]	[...]
Signature	Signature
Name: [NAME]	Name: [NAME]
Title: General Manager	Title: [TITLE]

Exhibit 4.15

CONFIDENTIAL TREATMENT REQUESTED

THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS ("[***]") HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

Execution Version

MEMBERSHIP INTEREST PURCHASE AGREEMENT

by and among

ÉCLAT HOLDINGS, LLC,
a Delaware limited liability company;

ÉCLAT PHARMACEUTICALS, LLC,
a Delaware limited liability company;

FLAMEL TECHNOLOGIES SA, a société anonyme organized under the laws of the Republic of France and

FLAMEL US HOLDINGS, INC.,
a Delaware corporation;

Dated as of March 13, 2012

[Confidential Treatment Requested]

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Exhibits

MEMBERSHIP INTEREST PURCHASE AGREEMENT

THIS MEMBERSHIP INTEREST PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of March 13, 2012, by and among **ÉCLAT HOLDINGS, LLC**, a Delaware limited liability company (the "***Seller***"), **ÉCLAT PHARMACEUTICALS, LLC**, a Delaware limited liability company (the "***Company***"), **FLAMEL US HOLDINGS, INC**., a Delaware corporation (the "***Buyer***") and **FLAMEL TECHNOLOGIES SA**, a société anonyme organized under the laws of the Republic of France ("***Flamel***"). Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

RECITALS

The Seller desires to sell, and the Buyer desires to purchase, all of the issued and outstanding membership interests of the Company, consisting of 10,000 Units (the "***Units***"), for the consideration and on the terms set forth herein.

AGREEMENT

The Parties to this Agreement, intending to be legally bound, agree as follows:

1. DESCRIPTION OF TRANSACTION

1.1 Purchase and Sale.

On the terms and subject to the conditions of this Agreement, effective at the Effective Time, Seller shall sell and deliver to the Buyer, and the Buyer shall purchase and accept from Seller, all of the Units, free and clear of all Encumbrances, in exchange for the consideration set forth herein.

1.2 Consideration.

In consideration of the sale of the Units, the Buyer shall pay and/or issue, as applicable, to the Seller the Note and the Warrant Consideration at Closing and shall pay the Deferred Consideration in accordance with Section 1.7.

(a) The "*Note*" shall be a secured promissory note issued by the Buyer in favor of the Seller at Closing pursuant to the Note Agreement attached hereto as **Exhibit B** (the "***Loan Agreement***") with a principal amount equal to $12,000,000.

(b) The "*Warrant Consideration*" shall consist of issuance of the Warrant Agreements (the "*Warrant Agreement*") attached hereto as **Exhibit C** by Flamel which Flamel shall contribute to the Buyer and the Buyer shall immediately transfer to the Seller at Closing. As promptly as practicable after Closing, but not later than September 30, 2012, Flamel shall convene a meeting of the holders of its Ordinary Shares in accordance with French law and Flamel's organizational documents for the purpose of voting on the approvals set forth in the definition of "Shareholder Approval Date" in the Warrant Agreement. Flamel and its Board of Directors shall recommend that holders of its Ordinary Shares approve the items set forth in the definition of "Shareholder Approval Date" in the Warrant Agreement at any meeting held with respect to such approval. For the avoidance of doubt, nothing in this Section **1.2(b)** shall be construed to modify the definition of "Shareholder Approval Date" under the Warrant Agreement.

1.3 Closing Balance Sheet and Adjusted Working Capital Statement.

(a) **Schedule 1.3(a)** sets forth an agreed estimate of the Adjusted Working Capital, which amount shall be equal to at least $2,000,000 (the "***Estimated Adjusted Working Capital***").

(b) Within 60 days after the Closing, the Buyer will prepare and deliver to Seller (i) a consolidated balance sheet (the "*Closing Balance Sheet*") of the Company as of the Effective Time, prepared in accordance with GAAP, applied consistently in the same manner as the Financial Statements (including the methodologies for calculating reserves) and (ii) a statement setting forth in reasonable detail the actual Adjusted Working Capital as of the Effective Time based on the Closing Balance Sheet (the "***Adjusted Working Capital Statement***").

(c) The Seller shall have the right to review the work papers of the Buyer used in preparing the Closing Balance Sheet, and shall have reasonable access to the books and records of the Company for purposes of verifying the accuracy and fairness of the presentation of the Closing Balance Sheet and the Adjusted Working Capital Statement; provided, that such access shall be in a manner that does not interfere with the normal business operations of the Buyer.

(d) If the Seller does not accept the Closing Balance Sheet or the Adjusted Working Capital Statement, the Seller shall give written notice to the Buyer within 30 days after delivery thereof that sets forth in reasonable detail the basis and the purported amount for each objection (the "***Working Capital Objection Notice***"). If the Seller does not provide such Working Capital Objection Notice within such 30-day period, the Seller shall be deemed to have accepted the Closing Balance Sheet and the Adjusted Working Capital Statement.

(e) The Buyer and the Seller shall use reasonable commercial efforts in good faith to resolve any objections raised in the Working Capital Objection Notice for 30 days. If the Buyer and the Seller are unable to resolve any disagreement within 30 days after delivery of the Working Capital Objection Notice, the parties will engage Grant Thornton (the "***Reviewing Accountant***") to resolve the issues in dispute. The Reviewing Accountant will apply accounting principles, in accordance with the provisions of this Agreement, to the issues at hand and will not have the power to alter, modify, amend, add to or subtract from any term or provision of this Agreement, and the Reviewing Accountant's engagement will be limited in scope to the disputed issues and amounts identified in the Working Capital Objection Notice. The parties will instruct the Reviewing Accountant to elect the position of either the Buyer or the Seller as a resolution for each item of disagreement, not to impose an alternative resolution with respect to any item of disagreement, to make its determination based solely on presentations and supporting material provided by the Parties and not pursuant to any independent review and to render its decision within 30 days of the engagement. The fees, costs and expenses of the Reviewing Accountant will be paid by the Seller and by the Buyer in the same proportion that the aggregate amount of the disputed items submitted to the Reviewing Accountant that are unsuccessfully disputed by such party, as finally determined by the Reviewing Accountant, bears to the amount of such disputed items so submitted. The determination of the Reviewing Accountant will be final and binding on the Parties.

1.4 Post-Closing Payments.

Within five Business Days after the Closing Balance Sheet is deemed final pursuant to Section 1.3, (i) if the actual Adjusted Working Capital exceeds $2,000,000, then Buyer shall pay to Seller the amount of such excess in cash, and (ii) if the actual Adjusted Working Capital is less than $2,000,000, then the Seller shall pay the Buyer the amount of such deficiency in cash.

1.5 Indebtedness.

Immediately prior to the Closing, the current lenders of the Company Indebtedness shall contribute all rights, title and interest constituting or related to the Company Indebtedness to the Seller as capital contributions, and the Seller shall further contribute all such rights title and interest to the Company, with the effect that at Closing there shall be no Company Indebtedness, all documents related to the Company Indebtedness are terminated and all liens thereunder are released (the "*Company Indebtedness Termination*").

1.6 Closing; Effective Time; Closing Deliveries.

(a) Closing; Effective Time. The consummation of the transactions contemplated by this Agreement (the "***Closing***") shall take place remotely by the electronic or other exchange of documents and signature pages, on the date hereof, such date referred to herein as the "***Closing Date***". The Closing will be effective as of 12:01 a.m. on the Closing Date (the "***Effective Time***"), and all actions scheduled in this Agreement to take place at the Closing shall be deemed to occur simultaneously at such time.

(b) Closing Documents Delivered to the Sellers. At or prior to the Closing, the Seller shall have received:

(i) The Loan Agreement and the Note executed and delivered by the Buyer;

(ii) The Warrant Agreement executed and issued by Flamel evidencing the Warrant Consideration;

(iii) The Registration Rights Agreement, attached hereto as **Exhibit D**, executed and delivered Flamel;

(iv) The Security Agreement (the "***Security Agreement***"), attached hereto as **Exhibit E**, executed and delivered by the Company;

(v) The Guaranty attached hereto as **Exhibit F**, executed and delivered by Flamel (the ***"Flamel Guaranty"***); and

(vi) The Guaranty attached hereto as **Exhibit G**, executed and delivered by the Company (the ***"Company Guaranty"***).

(c) Closing Documents Delivered to the Buyer. At or prior to the Closing, the Buyer shall have received:

(i) Resignation letters, in form and substance reasonably acceptable to Buyer, of each of the managers and certain officers specified by the Buyer of the Company Parties, effective as of the Effective Time;

(ii) A certificate executed by the Secretary of the Seller certifying that (A) attached thereto is a true and complete copy of the Seller's certificate of formation and all amendments thereto and then in effect, certified by the Secretary of State of the State of Delaware; (B) attached thereto is a certificate of good standing of the Seller from the Secretary of State of the State of Delaware, dated not more than five days before the Closing Date; (C) attached thereto is a true and complete copy of the Seller's limited liability company agreement and all amendments thereto and then in effect; (D) attached thereto is a true and complete copy of the resolutions adopted by the members and managers of the Seller authorizing the execution, delivery and performance of the Agreement and transactions contemplated hereby; and (E) as to the incumbency and signatures of each individual who will execute documents at the Closing on behalf of the Seller;

(iii) A certificate executed by the Secretary of the Company certifying that (A) attached thereto is a true and complete copy of the Company's certificate of formation and all amendments thereto and then in effect, certified by the Secretary of State of the State of Delaware; (B) attached thereto are certificates of good standing of the Company from its jurisdiction of organization and in each jurisdiction in which it is licensed or qualified to conduct business; dated not more than five days before the Closing Date; (C) attached thereto is a true and complete copy of the Company's limited liability company agreement and all amendments thereto and then in effect; (D) attached thereto is a true and complete copy of the resolutions adopted by the members and managers of the Company authorizing the execution, delivery and performance of the Agreement and transactions contemplated hereby, and (E) as to the incumbency and signatures of each individual who will execute documents at the Closing on behalf of the Company;

(iv) Documentation from the Company evidencing the Company Indebtedness Termination which provides that (A) after giving effect to the contributions set forth in **Section 1.5**, (1) all agreements related to the Company Indebtedness are terminated, (2) all obligations related to the Company Indebtedness are deemed paid in full, and (3) all liens related to the Company Indebtedness are released and (B) the Seller and the Company authorize the Buyer to file any UCC termination statements deemed appropriate by the Buyer to effect the Company Indebtedness Termination; and

(v) Documentation from FSC Laboratories acknowledging receipt and payment in full of all amounts due by the Company under the FSC Agreement.

1.7 Deferred Consideration.

(a) Deferred Payments. The Buyer shall pay (or cause to be paid) to the Seller (or its successors and assigns) quarterly deferred payments (each, a "***Launch Products Deferred Payment***") equal to 20.0% of Launch Products Gross Profit for such quarter (collectively, the "***Launch Products Deferred Consideration***"). The Buyer shall pay (or cause to be paid) to the Seller (or its successors and assigns) quarterly deferred payments (each, a "***Hycet Deferred Payment***") equal to 100.0% of Hycet Gross Profit for such quarter (collectively, the "***Hycet Deferred Consideration***"), up to a maximum of $1,000,000.

(b) Payment of the Deferred Payments. The Launch Products Deferred Payments described in **Section 1.7(a)** shall accrue daily and shall be paid quarterly in arrears for each quarter from and after the Closing. The Hycet Deferred Payments described in **Section 1.7(a)** shall accrue daily and shall be paid quarterly in arrears for each quarter from and after the Closing until $1,000,000 in the aggregate of Hycet Deferred Payments have been paid to the Seller. No later than two Business Days following the date Flamel files its Earnings Report (if a public filing) or has prepared its Earnings Report (if not a public filing) for each calendar quarter (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 Buyer shall pay to the Seller the Launch Products Deferred Payment and Hycet Deferred Payment, as applicable, for such quarter. On the same day it makes a Launch Products Deferred Payment or Hycet Deferred Payment pursuant to this **Section 1.7(b)**, the Buyer shall deliver or cause to be delivered to the Seller a written statement showing all Net Sales of Product and Net Sales of Launch Products, as applicable, during such quarter and the Buyer's computation of such Launch Products Gross Profit and Hycet Gross Profit, as applicable, and the corresponding Launch Products Deferred Payment and Hycet Deferred Payment, as applicable (each a "***Deferred Payment Calculation***"). All Launch Products Deferred Payments and Hycet Deferred Payments shall be made by wire transfer of immediately available funds to the account(s) designated in writing by the Seller no later than five Business Days prior to the date such Launch Products Deferred Payment and Hycet Deferred Payment shall be due.

(c) Delinquent Deferred Payments. Any Launch Products Deferred Payment or Hycet Deferred 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 written notice (the "***Audit Notice***"), the Seller shall have the right to audit the books and records of the Buyer and the Company Parties for the purpose of determining the correctness of their computation and payment of any Launch Products Deferred Payment and/or Hycet Deferred Payment for up to three years prior to the date of the Audit Notice and for the purposes of determining compliance with the other covenants set forth in this **Section 1.7**. Such audit may not be conducted more than once in any calendar year and shall be conducted during normal business hours at the Seller's cost, provided, that any accounting firm or other Representative involved enters into a reasonable confidentiality agreement with the Company (to be approved by the Company in its sole reasonable discretion) prior to commencing any such audit. The Buyer shall provide the Seller and its advisors with reasonable access to all pertinent books and records of the Company related to the Product or the Launch Products and shall reasonably cooperate with the Seller's and its advisors' efforts to conduct such audits. The Seller may object to any Deferred Payment Calculation by delivering a written notice of objection (a "***Deferred Payment Calculation Objection Notice***"), which shall specify the items in the applicable Deferred Payment Calculation disputed by Seller and shall describe in reasonable detail the basis for such objection, as well as the amount in dispute. If Seller delivers a Deferred Payment Calculation Objection Notice, Buyer and Seller shall negotiate in good faith for up to ten Business Days to resolve the disputed items and agree upon the resulting amount of the Launch Products Deferred Payment and/or Hycet Deferred Payment that is the subject of the Deferred Payment Calculation Objection Notice. If Buyer and Seller are unable to reach agreement within ten Business Days after the Deferred Payment Calculation Objection Notice has been delivered, all unresolved disputed items shall be promptly referred to the Reviewing Accountant. The Reviewing Accountant shall be directed to render a written report on the unresolved disputed items with respect to the applicable Deferred Payment Calculation as promptly as practicable, but in no event greater than 30 days after such submission to the Reviewing Accountant, and to resolve only those unresolved disputed items set forth in the Deferred Payment Calculation Objection Notice. If unresolved disputed items are submitted to the Reviewing Accountant, Buyer and Seller shall each furnish to the Reviewing Accountant such work papers, schedules and other documents and information relating to the unresolved disputed items as the Reviewing Accountant may reasonably request. The Reviewing Accountant shall resolve the disputed items based solely on the applicable definitions and other terms in this Agreement and the presentations by Buyer and Seller, and not by independent review. The Reviewing Accountant will not have the power to alter, modify, amend, add to or subtract from any term or provision of this Agreement. The resolution of the dispute and the calculation of the Launch Products Deferred Payment and/or Hycet Deferred Payment that is the subject of the Deferred Payment Calculation Objection Notice by the Reviewing Accountant shall be final and binding on the parties hereto. If there has been an underpayment of the aggregate Launch Products Deferred Payment and/or Hycet Deferred Payment due for the period being audited of more than five percent (5%) of the amount due for the period, the Buyer shall reimburse the Seller for the reasonable out-of pocket costs (including Reviewing Accountants' fees) incurred by the Seller pursuant to this **Section 1.7(d)**.

(e) Assignment or Sublicense by the Buyer. The Buyer shall continue to be obligated to pay the Launch Products Deferred Payments and Hycet Deferred Payments on all sales by all direct or indirect licensees and assignees of any rights to sell, market or otherwise distribute the Product and/or the Launch Products, and the provisions of this **Section 1.7** shall apply to all such sales as if made directly by the Buyer.

(f) Covenants of the Buyer.

(i) Regulatory Approvals. The Company shall use all commercially reasonable efforts to obtain approval of each NDA necessary to sell each Launch Product in the United States of America. Without limiting the foregoing, the Company shall (A) initiate development and manufacturing of all Launch Products through a third-party (if this has not already occurred as of Closing) and (B) pursue a pre-IND/pre-NDA meeting with the FDA for each of the Launch Products (if this has not already occurred as of Closing). The Company shall also use commercially reasonable efforts to (x) cause registration batches of each Launch Product to be manufactured and (y) cause stability testing to be completed for each Launch Product, in each case unless the FDA states in the pre-IND/pre-NDA meeting applicable to such Launch Product that such Launch Product would not be approved without clinical trials or other unexpected conditions to approval that would make continued efforts to obtain the NDA necessary for commercialization of the Launch Product not commercially viable.

(ii) Marketing of Launch Products. Upon approval to market any Launch Product, the Company shall take all commercially reasonable and appropriate actions to manufacture or have manufactured, package, label, distribute, offer for sale and sell such Launch Product. The Company shall take all commercially reasonable and appropriate actions to manufacture or have manufactured, package, label, distribute, offer for sale and sell Product for so long as it has an obligation to pay any Hycet Deferred Payment.

(iii) Credit Facility Restrictions. The Buyer and Flamel each represents and warrants that there are no restrictions or limitations on Buyer's ability to make the payments that are or may be required to be paid to the Seller under this Agreement (directly or pursuant to the Flamel Guaranty or the Company Guaranty, as applicable) in any Contract of Flamel, the Buyer or the Buyer's Subsidiaries (including in any loan agreement, note debenture or other document evidencing any indebtedness of Flamel, the Buyer and its Subsidiaries). Flamel shall not enter into, or amend, any Contract of it or its Subsidiaries after the Closing the effect of which is to place any restrictions or limitations on Flamel's or the Company Parties' ability to make the payments that are or may be required to be paid to the Seller under this Agreement (directly or pursuant to the Flamel Guaranty or the Company Guaranty, as applicable); provided, however, that the foregoing restriction shall not apply to (i) up to €15,000,000 of indebtedness of Flamel or its Subsidiaries owed to the French government (or one of its instrumentalities or agencies) or (ii) indebtedness incurred by Flamel or its Subsidiaries the proceeds of which are used to make any payments due under the Warrant Agreement.

(iv) No Transfer Without Consent. The Company 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 Buyer and the Company) all of the Buyer's and the Company's obligations under this Agreement; provided, however, 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 Product and/or Launch Products solely on behalf of, or for the benefit of, the Company or (ii) the direct or indirect license of Product Intellectual Property or Product Regulatory Rights for any reason other than to make, have made, use, promote, import, offer to sell or sell Product and/or Launch Products.

(g) Acceleration. Notwithstanding anything to the contrary contained in this **Section 1.7** (including, without limitation, the quarterly structuring of deferred payments set forth above), upon and at any time after the occurrence of any Acceleration Trigger Event, (x) an amount equal to the Accelerated Earn-Out Value (together with any applicable interest accrued thereon) 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 Buyer, and (y) the Seller may exercise any and all other rights and remedies available to it under this Agreement and applicable law. At least once per year, the Buyer will update in good faith its sales projections for the Product and the Launch Products.

(h) No Security**.** The parties hereto understand and agree that (i) the contingent rights to receive any Launch Products Deferred Payment and Hycet Deferred Payment shall not be represented by any form of certificate or other instrument and do not constitute an equity or ownership interest in Buyer or the Company, (ii) Seller shall not have any rights as a securityholder of Buyer or the Company as a result of Seller's contingent right to receive any Launch Products Deferred Payment and Hycet Deferred Payment hereunder, and (iii) no interest is payable with respect to any Launch Products Deferred Payment and Hycet Deferred Payment except as provided in **Section 1.7(c)**.

(i) Security Interest. The Parties hereby acknowledge the grant of a security interest by Eclat Pharmaceuticals, LLC in the collateral set forth in the Security Agreement to secure the payment of the Launch Products Deferred Payments and Hycet Deferred Payments.

1.8 Warrant Valuation.

The Buyer and the Seller agree that the value of the Warrant Consideration is set forth in Schedule 1.8.

1.9 FSC Agreement.

Immediately prior to the Effective Time, the Company shall pay all amounts due to FSC under the FSC Agreement, and the cash used to make such payment shall for purposes of clarification not be included in Adjusted Working Capital.

2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Each Company Party represents and warrants to the Buyer as set forth below, except as set forth in the written disclosure schedule delivered or made available by the Company Parties to the Buyer (the "***Disclosure Schedule***"). The Disclosure Schedule shall be arranged in sections and subsections corresponding to the numbered and lettered sections and subsections contained in this Agreement. The Disclosure Schedule may include items that are not material in order to avoid any misunderstanding, and any such inclusion, or any references to dollar amounts, shall not be deemed to be an acknowledgment or representation that such items are material, to establish any standard of materiality or to define further the meaning of such terms for purposes of this Agreement. Any information or matter disclosed on a Schedule shall be deemed to be disclosed on such Schedule and each other Schedule to the extent it is reasonably apparent on the face of the disclosure that such disclosure is applicable to such other Schedule.

2.1 Organization; Good Standing.

Each Company Party is duly organized, validly existing and in good standing under the laws of the state of its formation. Each Company Party has the requisite power and authority to own, lease or use its properties and assets and to conduct its business as presently conducted. Schedule 2.1 sets forth each jurisdiction in which any Company Party is licensed or qualified to do business, and each Company Party is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the assets or properties owned or leased by it or the operation of its business as currently conducted makes such licensing or qualification necessary. Schedule 2.1 lists all of the officers and directors of each Company Party.

2.2 Consents and Approvals; No Violation.

Except as disclosed in Schedule 2.2, neither the execution and delivery of this Agreement by the Seller nor the performance of its obligations hereunder nor the consummation by the Seller of the transactions contemplated hereby will: (i) conflict with or result in a breach, violation, or default of or under the certificate of formation or other governing or organizational document of any Company Party, (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 Seller or any Company Party is a party or by which Seller or any Company Party is bound or to which any of their respective properties and assets are subject (including any Contract) or any Governmental Authorization affecting the properties, assets or business of the Company Parties, (iii) result in the creation of any Encumbrance (other than Permitted Encumbrances) on the assets or Equity Interests of any Company Party, or (iv) conflict with or result in a violation or breach of any provision of any Legal Requirement applicable to the Seller or the Company Parties.

2.3 Capital Stock; Subsidiaries.

(a) The issued and outstanding membership interests of the Company consist of 10,000 Units. The Units transferred to the Buyer pursuant to this Agreement represent 100% of the issued and outstanding Equity Interests of the Company. The Seller is the sole record and beneficial owner and holder, free and clear of all Encumbrances, of all of the Units, and upon consummation of the transactions contemplated by this Agreement, Buyer shall own all the Units, free and clear of all Encumbrances except those created by Buyer. All of the Units were issued in compliance with all applicable Legal Requirements. None of the Units were issued in violation of any agreement, arrangement or commitment to which Seller or any Company Party is a party or is subject to or in violation of any preemptive or similar rights of any Person. There are no outstanding warrants, options, agreements, convertible or exchangeable securities or other agreements, arrangements or commitments of any character pursuant to which the Company is or may become obligated to issue, sell, purchase, return or redeem any Units, membership interests or any other securities or interests, and there are no Equity Interests of the Company reserved for issuance for any purpose. The Company does not have any Contract to acquire any capital stock of or other Equity Interest in any Person.

(b) The only Subsidiary of the Company is Talec Pharma, LLC. The Company is the sole record and beneficial owner and holder, free and clear of all Encumbrances, of all of the Equity Interests of Talec Pharma, LLC. All of the Equity Interests of Talec Pharma, LLC were issued in compliance with all applicable Legal Requirements. There are no outstanding warrants, options, agreements, convertible or exchangeable securities or other agreements, arrangements or commitments of any character pursuant to which any Subsidiary is or may become obligated to issue, sell, purchase, return or redeem any Equity Interests, membership interests or any other securities or interests, and there are no Equity Interests of any Subsidiary reserved for issuance for any purpose. No Subsidiary has any Contract to acquire any capital stock of or other Equity Interest in any Person.

2.4 Financial Statements. Schedule 2.4

Contains the consolidated, unaudited balance sheet of the Company Parties as of December 31, 2011 (the "*Balance Sheet*", and such date the "*Balance Sheet Date*") and a consolidated, unaudited statement of income for the Company Parties for the year then ended (collectively, the "*Financial Statements*"). The Financial Statements (i) fairly present in all material respects the results of operations and financial position of the Company Parties for the periods and as of the dates referred to in the Financial Statements and (ii) have been prepared in a manner consistent with the books and records of the Company Parties and in accordance with GAAP throughout the periods covered thereby, subject to the absence of notes.

2.5 Absence of Changes.

Since the Balance Sheet Date, except as set forth on Schedule 2.5:

(a) no Company Party has declared, accrued, set aside or paid any dividend or made any other distribution in respect of any of its Equity Interests, and has not repurchased, redeemed or otherwise reacquired any of its Equity Interests.

(b) there has been no amendment to the certificate of formation or other governing or organizational document of any Company Party, and no Company Party has adopted, effected or been a party to any merger, recapitalization or reclassification of its Equity Interests;

(c) no Company Party has 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;

(d) no Company Party has formed any Subsidiary, made any capital investment in or acquired any equity interest in any other Entity;

(e) the Company Parties have not made any capital expenditures which exceed $75,000 in the aggregate;

(f) no Company Party has (i) entered into or permitted any of the assets owned or used by it to become bound by any Contract that contemplates or involves (A) the payment or delivery of cash or other consideration in an amount or having a value in excess of $75,000 in the aggregate, or (B) the lease, purchase or sale of any product, or performance of services by or to a Company Party having a value in excess of $75,000 in the aggregate, or (ii) waived any right or remedy under any Contract other than in the Ordinary Course of Business, or amended or prematurely terminated any Contract other than in the Ordinary Course of Business;

(g) no Company Party has (i) acquired, leased or licensed any right or other property or asset from any other Person, (ii) sold, transferred, assigned or otherwise disposed of, or leased or licensed, any right, or other property or asset to any other Person, or (iii) waived or relinquished any right, except, in each case, in the Ordinary Course of Business;

(h) no material damage, destruction or loss (whether or not covered by insurance) has occurred to any asset of any Company Party;

(i) no Company Party has made any pledge of any of its assets or otherwise permitted any of its assets to become subject to any material Encumbrance other than Permitted Encumbrances, except for pledges of immaterial assets made in the Ordinary Course of Business;

(j) no Company Party has (i) lent money to any Person, (ii) incurred, assumed or guaranteed any indebtedness for borrowed money or (iii) issued or sold any debt securities or options, warrants, calls or similar rights to acquire any debt securities of any Company Party;

(k) no Company Party has changed any of its personnel policies or other business policies, or any of its methods of accounting or accounting practices in any material respect;

(l) no Company Party has (i) granted any bonuses, whether monetary or otherwise, or increase in any wages, salary, severance, pension or other compensation or benefits in respect of its employees, officers, directors, independent contractors or consultants, (ii) changed the terms of employment for any employee or any termination of any employees for which the aggregate costs and expenses exceed $10,000, or (iii) taken any action to accelerate the vesting or payment of any compensation or benefit for any employee, officer, director, independent contractor or consultant;

(m) no Company Party has made any loan to (or forgiveness of any loan to) other than ordinary course expense advancements, or entered into any other transaction with, any of its stockholders, directors, officers and employees;

(n) no Company Party has entered into a new line of business or abandoned or discontinued any existing line of business;

(o) no Company Party has (i) made any material Tax election, or adopted or changed any material accounting method in respect of Taxes, (ii) entered into any closing agreement, settled or compromised any claim or assessment in respect of Taxes other than with respect to a claim or assessment which existed on the date hereof and in an amount not greater than the liability or reserve that has been recorded with respect thereto in the Balance Sheet, or (iii) consented to any extension or waiver of any limitation period with respect to any claim or assessment for Taxes;

(p) no Company Party has threatened, commenced or settled any Legal Proceeding; and

(q) no Company Party has agreed to take, or committed to take, any of the actions referred to in clauses "(a)" through "(p)" above.

2.6 Tax Matters.

Except as set forth on Schedule 2.6, (a) the Company Parties have prepared and timely filed (taking into account any extension of time within which to file) all Tax Returns required to be filed by any of them prior to the Closing Date and all such filed Tax Returns are complete and accurate in all material respects, (b) the Company Parties have paid all material Taxes that are required to be paid by any of them prior to the Closing Date (whether or not shown on any Tax Return), (c) no claim has ever been made by a Tax Authority in a jurisdiction where the Company Parties do not file Tax Returns claiming that any Company Party is or may be subject to taxation in that jurisdiction, (d) the Company Parties have withheld and paid all material Taxes required to be withheld and paid in connection with amounts paid or owing to any employee or member, (e) there are no Liens for Taxes (other than Taxes not yet due and payable) upon any assets of any Company Party, (f) no deficiencies have been asserted in writing or assessed by any taxing authority against any Company Party, (g) the Company Parties have not received written notice of any pending or threatened audits, examinations, investigations or other proceedings in respect of any Taxes or Tax Returns of the Company Parties and there are no currently effective waivers (or requests for waivers) of the time to assess any Taxes of the Company Parties, (h) no Company Party has participated in any "reportable transaction" within the meaning of Treasury Regulation Section 1.6011-4(b)(2), (i) the Company is classified as a corporation for U.S. federal income tax purposes, (j) no Company Party is a party to any Tax allocation or sharing agreement or has been a member of an affiliated group filing a consolidated Tax Return or has any liability for the Taxes of any other person under Treasury Reg. Section 1.1502-6 (or any similar provision) as a transferee or successor, by contract, or otherwise, (k) no Company Party will be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of (i) a change in method of accounting as described in IRC Section 481, (ii) a "closing agreement" as described in IRC Section 7121 or (iii) an installment sale or open sale transaction occurring before the Closing Date, (l) no Company Party is a party to any agreement, contract, arrangement or plan that has resulted or could result, separately or in the aggregate, in the payment of any "excess parachute payment" within the meaning of IRC Section 280G and (m) the Company Parties have made available to Buyer true, correct and complete copies of all Tax Returns filed and Tax examination reports and Tax deficiencies received by the Company Parties.

2.7 Claims.

There are no claims or Legal Proceedings that are currently pending against any Company Party, or to the Company's Knowledge that are (a) threatened against any Company Party or (b) that challenge, or reasonably could be expected to prevent or delay the transactions contemplated by this Agreement.

2.8 Compliance with Laws.

(a) Each Company Party has complied and is now in compliance with all Legal Requirements applicable to it or its business, properties or assets. No Company Party has 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 such Company Party to undertake or pay for any response action required by any Legal Requirement.

(b) All Governmental Authorizations required for each Company Party to conduct its business as currently conducted have been obtained by it and are valid and in full force and effect. No Company Party holds any open Investigational New Drug ***("IND")*** application or New Drug Application ***("NDA")***. All fees and charges with respect to such Governmental Authorizations due and payable as of the date hereof have been paid in full, except for those fees and charges the failure of which to pay in full would not, individually or in the aggregate, have an adverse effect on the material operations of the business, or any fees payable to FDA. No event has occurred that, with or without notice or lapse of time or both, would reasonably be expected to result in the revocation, suspension, lapse or limitation of any Governmental Authorizations of the Company Parties.

2.9 Employee and Labor Matters; Benefit Plans.

(a) The Company has delivered to the Buyer a complete and accurate list of the name, job title, current annual compensation, accrued vacation and severance pay of each officer, director and employee of the Company Parties. There is no Contract (i) for the employment of any individual or (ii) relating to the payment of any severance or termination payment, bonus or employee benefit to any employee or former employee.

(b) The Company is not a party to any collective bargaining agreement or other labor Contract. There is no pending or, to the Company's Knowledge, threatened (i) strike, slowdown or work stoppage, or (ii) application for certification of a collective bargaining agent for any of the Company's employees. There is no lockout of any employees of the Company, and no such action is contemplated by the Company.

(c) **Schedule 2.9(c)** lists any independent contractors who currently provide services to any Company Party.

(d) No Company Party has maintained, established, sponsored, participated in, or contributed to any: (i) employee benefit pension plan (as defined in Section 3(2) of ERISA) ("***Pension Plan***") subject to Title IV of ERISA; (ii) multiple employer plan subject to Section 413 of the Code; (iii) multiemployer plan within the meaning of Section (3)(37) of ERISA; (iv) multiple employer welfare arrangement subject to Section 3(40) of ERISA, or (v) a program or arrangement subject to Section 419, 419A or 501(c)(9) of the Code. No Company Party has maintained a Pension Plan or multiemployer plan, or the equivalent thereof, in a foreign jurisdiction (a "***Foreign Plan***").

(e) No Company Party (i) has been required to be treated as a single employer with any other Person under Section 4001(b)(1) of ERISA or Section 414(b), (c), (m) or (o) of the Code, (ii) has been a member of an "affiliated service group" within the meaning of Section 414(m) of the Code, or (iii) has made a complete or partial withdrawal from a multiemployer plan, as such term is defined in Section 3(37) of ERISA, resulting in "withdrawal liability," as such term is defined in Section 4201 of ERISA (without regard to subsequent reduction or waiver of such liability under either Section 4207 or 4208 of ERISA).

2.10 Insurance.

The Company Parties maintain the insurance coverage set forth on Schedule 2.10. No Company Party has received any written notice or other communication regarding any actual or possible (a) cancellation or invalidation of any insurance policy, (b) refusal of any coverage or rejection of any claim under any insurance policy, or (c) material adjustment in the amount of the premiums payable with respect to any insurance policy.

2.11 Real Property. Schedule 2.11

identifies all real property leased by any Company Party and the lease agreement related thereto, copies of which have been made available to the Buyer (the "*Leased Real Property*"). No Company Party owns any real property.

2.12 Bank Accounts. Schedule 2.12

lists each bank account maintained by the Company Parties at any bank or other financial institution, including the name of the bank or financial institution, the account number and the names of all individuals authorized to draw on or make withdrawals from such accounts.

2.13 Regulatory Compliance.

(a) No Company Party has received any notices or correspondence from the FDA or any Governmental Body exercising comparable authority requiring the recall, termination or suspension of sale of the Product or otherwise alleging that any Company Party is not in compliance in all material respects with all applicable Legal Requirements.

(b) Neither the Company nor any of its officers and employees, nor, to the Company's Knowledge, any of its agents and contractors is the subject of any pending or threatened investigation by 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. Neither the Company nor any of its officers and employees, nor, to the Company's Knowledge, any of its agents and contractors has (A) made any untrue statement of material fact or fraudulent statement to FDA, DEA, or any other Governmental Body; (B) failed to disclose a material fact required to be disclosed to 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 FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy.

(c) Neither the Company, nor its officers or employees have been debarred or have 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. § 1320a7, disqualification as a clinical investigator under 21 C.F.R. § 312.70 or any similar Legal Requirements, and neither the Company nor any of its officers or employees, has engaged in any conduct that would reasonably be expected to result in debarment, exclusion, or disqualification from U.S. federal health care programs.

(d) Neither the Company nor any of its officers has received any written notice or communication from the FDA, DEA, or other Governmental Body requiring termination or suspension of sale of the Product or alleging noncompliance with any applicable FDA Law, DEA Law, or other applicable Legal Requirements with regard to the Product or any Launch Product. Neither the Company nor any of its officers has been or is subject to any enforcement proceedings by the FDA, DEA, or other Governmental Body and, to the Company's Knowledge, no such proceedings have been threatened.

2.14 Accounts Receivable.

All accounts receivable of the Company Parties represent valid, undisputed and bona fide claims of the Company not subject to claims of set-off or other defenses or counterclaims other than normal cash discounts accrued in the Ordinary Course of Business.

2.15 Proprietary Rights.

(a) **Schedule 2.15(a)** lists each registered Proprietary Right that the Company Parties use in their business. The Company Parties own or have the right to use all of the Proprietary Rights that the Company Parties use in their business. Except as disclosed in **Schedule 2.15(a)**, the Company Parties have no obligation to pay any royalty to any Person relating to any Proprietary Right used by the Company.

(b) To the Company's Knowledge, (i) no Company Party is infringing upon any Proprietary Right of any other Person and (ii) no Person is infringing upon any Proprietary Right of any Company Party. No claims are pending against any Company Party by any Person: (A) that such Person has any right, title or interest in or to any of the Company Parties' Proprietary Rights; (B) that such Person has the right to use any of the Company Parties' Proprietary Rights; or (C) to the effect that any action by any Company Party infringes any Proprietary Right of such Person.

2.16 Supply Arrangement. Schedule 2.17

sets forth a list of all supply agreements for goods or services related to the Product and Launch Products ("*Product Suppliers*"). No Company Party has received any written notice that any of its Product Suppliers has ceased, or intends to cease, to supply goods or services or to otherwise terminate or materially reduce its relationship with such Company Party.

2.17 Contracts.

(a) **Schedule 2.17(a)** sets forth a complete and accurate list of each Contract of any Company Party that falls into one or more of the following categories:

(i) is a Contract that is or relates to the performance of services or delivery of goods or materials of an amount or value in excess of $50,000 per year and is not cancelable without penalty on 120 days' notice or less;

(ii) is a Contract that is or relates to the grant or receipt by a Company Party of any license or royalty fees or other similar payment obligations to or from any Person in excess of $50,000 per year;

(iii) is a Contract that is a lease agreement with respect to real property;

(iv) is a Contract of any Company Party with any other Company Party, the Seller or any affiliate of the Seller;

(v) is a Contract with investment bankers, financial advisors, attorneys, accountants or other advisors retained by any Company Party involving payments by any Company Party of more than $50,000 on an annual basis;

(vi) is a Contract that provides for the indemnification by any Company Party of any person except for any such Contract that was entered into in the Ordinary Course of Business;

(vii) is a Contract pursuant to which any indebtedness of the Company Parties is outstanding or may be incurred and all guarantees of or by the Company Parties of any indebtedness of any other person (excluding trade payables in the Ordinary Course of Business);

(viii) is a partnership, joint venture agreement or other similar agreement involving co-investment with a third party to which any Company Party is a party;

(ix) is a Contract with a Governmental Body which imposes any material obligation or restriction on any Company Party; or

(x) is a Contract that contains non-competition, exclusivity, or other covenants limiting or restricting the ability of a Company Party to engage directly or indirectly in any business.

The contracts or instruments required to be set forth in **Schedule 2.17(a)** are referred to herein as the "***Material Contracts***."

(b) The Company has heretofore delivered to the Buyer true and complete copies of all the Material Contracts.

(c) Each of the Material Contracts is in full force and effect, constitutes a valid and binding obligation of a Company Party and, to the Company's Knowledge, the other parties thereto, is legally enforceable against such Company Party and, to the Company's Knowledge, the other parties thereto, in accordance with its terms, except as enforcement may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer or other laws relating to or limiting creditor's rights generally or by general principles of equity.

(d) No Company Party is in breach or default in any material respect under any Material Contract and, to the Company's Knowledge, no other party to any of the Material Contracts is in breach or default in any material respect thereunder.

2.18 Title to Assets.

The Company has good and valid title to, or a valid leasehold interest in, all real property and personal property and other assets reflected in the Financial Statements or acquired after the Balance Sheet Date, other than properties and assets sold or otherwise disposed of in the Ordinary Course of Business since the Balance Sheet Date.

2.19 Necessary Assets.

The Leased Real Property, the Proprietary Rights, the tangible personal property owned by the Company Parties and all other assets owned, licensed or leased by the Company Parties constitute all of the assets that are necessary to permit the Buyer to operate the Company Parties' business immediately after the Closing Date in substantially the same manner as it is operated immediately prior to the Closing Date.

2.20 No State Antitakeover Statute.

There is no state business combination, control share or other antitakeover statute or similar statute or regulation that is or becomes operative with respect to this Agreement or any of the transactions contemplated by this Agreement. If any such state business combination, control share or other antitakeover statute or similar statute or regulation is or becomes operative with respect to this Agreement or any of the transactions contemplated by this Agreement, the Company has taken all actions necessary to ensure that this Agreement and any of the transactions contemplated by this Agreement may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise to minimize the effect of such statute or regulation.

2.21 Brokers.

No broker, finder or other Person is or will be entitled to any brokerage fees, commissions or finder's fees from the Seller or any Company Party or by reason of any action taken by the Seller or any Company Party.

2.22 Transaction Payments.

There are no payments payable by the Company to any director, officer, employee or former director, officer or employee of the Company arising at or prior to the Closing from or as a result of the consummation of the transactions contemplated by this Agreement, including any payments for stock appreciation or similar rights, any severance or bonus plan payment, any payment of deferred compensation, any transaction bonus or change in control payment, or any similar payment ("*Company Transaction Payments*"). As of the Closing, there are no outstanding or unsatisfied Company Transaction Payments.

2.23 No Other Representations or Warranties.

EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 2 AND SECTION 3, NEITHER THE SELLER NOR THE COMPANY MAKES, AND NO PARTY SHALL BE ENTITLED TO RELY UPON, ANY REPRESENTATION OR WARRANTY AS TO ANY FACT OR MATTER ABOUT THE COMPANY PARTIES OR THE SELLER.

3. REPRESENTATIONS AND WARRANTIES OF THE SELLER

The Seller represents and warrants to the Buyer as follows.

3.1 Organization; Good Standing.

The Seller is duly organized, validly existing and in good standing under the laws of the state of its formation.

3.2 Authority; Enforceability.

The Seller has the absolute and unrestricted right, authority, power and capacity to (i) execute and deliver each certificate, document and agreement to be executed by the Seller in connection herewith (collectively, the "*Seller Documents*") and (ii) perform its obligations thereunder. The execution and delivery of the Seller Documents and the consummation of the transactions contemplated thereby have been duly and validly authorized by the Seller. Each Seller Document has been duly and validly executed and delivered by the Seller and constitutes the legal, valid and binding obligation of the Seller, enforceable against it in accordance with its terms except (x) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and other similar Legal Requirements of general application affecting enforcement of creditors' rights generally and (y) the availability of the remedy of specific performance or injunctive or other forms of equitable relief may be subject to equitable defenses and would be subject to the discretion of the court before which any such proceeding may be brought.

3.3 Consents and Approvals; No Violation.

Neither the execution and delivery of the Seller Documents by the Seller nor the performance of its obligations thereunder nor the consummation by the Seller of the transactions contemplated thereby will: (i) conflict with or result in a breach, violation, or default of or under, (ii) give any third party the right to modify, terminate or accelerate any liability or obligations of, (iii) result in the creation of any Encumbrance (other than Permitted Encumbrances) on the Units, or (iv) require any Consent by or declaration or notice to any third party or Governmental Body pursuant to (A) the certificate of formation or other governing documents of the Seller or (B) any Legal Requirement.

3.4 No Other Representations or Warranties.

EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 3 AND SECTION 2, NEITHER THE SELLER NOR THE COMPANY MAKES, AND NO PARTY SHALL BE ENTITLED TO RELY UPON, ANY REPRESENTATION OR WARRANTY AS TO ANY FACT OR MATTER ABOUT THE COMPANY PARTIES OR THE SELLERS.

4. REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer represents and warrants to the Seller as follows.

4.1 Organization; Good Standing.

The Buyer is duly organized, validly existing and in good standing under the laws of Delaware. The Buyer has the requisite power and authority to own, lease or use its properties and assets and to conduct its business as presently conducted.

4.2 Authority; Enforceability.

The Buyer has the absolute and unrestricted right, authority, power and capacity to (i) execute and deliver each certificate, document and agreement to be executed by the Buyer in connection herewith (collectively, the "*Buyer Documents*") and (ii) perform its obligations thereunder. The execution and delivery of the Buyer Documents and the consummation of the transactions contemplated thereby have been duly and validly authorized by the Buyer. Each Buyer Document has been duly and validly executed and delivered by the Buyer and constitutes the legal, valid and binding obligation of the Buyer, enforceable against it in accordance with its terms except (x) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and other similar Legal Requirements of general application affecting enforcement of creditors' rights generally and (y) the availability of the remedy of specific performance or injunctive or other forms of equitable relief may be subject to equitable defenses and would be subject to the discretion of the court before which any such proceeding may be brought.

4.3 Consents and Approvals; No Violation.

Neither the execution and delivery of the Buyer Documents by the Buyer nor the performance of its obligations thereunder nor the consummation by the Buyer of the transactions contemplated thereby will: (i) conflict with or result in a breach, violation, or default of or under, (ii) give any third party the right to modify, terminate or accelerate any liability or obligations of, (iii) result in the creation of any Encumbrance (other than Permitted Encumbrances) on the assets of the Buyer under or pursuant to, or (iv) require any Consent by or declaration or notice to any third party or Governmental Body pursuant to (A) the governing documents of the Buyer, (B) any Buyer Contracts, or (C) any Legal Requirement.

4.4 No Restrictions.

There are no restrictions on, or conditions to, the Buyer's ability to make all of the payments contemplated in this Agreement in any Contract of the Buyer (including any loan agreement, note, indenture or similar financing document).

4.5 No Other Representations or Warranties.

EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 4, THE BUYER DOES NOT MAKE, AND NO PARTY SHALL BE ENTITLED TO RELY UPON, ANY REPRESENTATION OR WARRANTY AS TO ANY FACT OR MATTER ABOUT THE BUYER.

5. ADDITIONAL AGREEMENTS OF THE PARTIES

5.1 Indemnification of Officers and Directors.

(a) The Company shall purchase, at its sole cost and expense, and pay all premiums under, a six-year tail insurance policy, with an effective date as of the Closing Date, which maintains in effect for six years from the Closing Date the current directors' and officers' liability insurance policies maintained by the Company Parties on terms and conditions that are not materially less favorable than those of such policy in effect as of the date hereof.

(b) Subject to the Buyer's rights to indemnification as provided in **Section 6.2**, from and after the Closing Date for a period of six years, the Company shall fulfill and honor in all respects the obligations of the Company pursuant to any required indemnification provisions of the Company under its certificate of formation and Operating Agreement as are in effect on the date of this Agreement; provided that such indemnification shall be subject to any limitation imposed from time to time under any Legal Requirements, including the DGCL.

5.2 Disclosure.

Without limiting any Party's obligations under existing confidentiality agreements, each Party shall not, and shall not permit any of its Subsidiaries or any Representative of such Party to, issue any press release or make any disclosure regarding the transactions contemplated hereunder unless: (a) the other Parties shall have approved such press release or disclosure in writing; or (b) such Party shall have determined in good faith, upon the advice of outside legal counsel, that such disclosure is required by applicable Legal Requirements or stock exchange rule or regulation and, to the extent practicable, before such press release or disclosure is issued or made, such Party advises the other Parties of, and consults with the other Parties regarding, the text of such press release or disclosure. Notwithstanding the foregoing, nothing in this **Section 5.2** shall prevent a Party from making disclosures: (a) to Persons employed or engaged by such Party in evaluating, approving, structuring or administering this Agreement, so long as such Persons are notified of, and agree to maintain, the confidential nature of such information; (b) to such Party's legal counsel or accountants, partners or investors (including outside auditors and legal counsel of such Party's accountants, partners or investors) or to such Party's employees, officers, directors or affiliates, so long as such Persons are notified of, and agree to maintain, the confidential nature of such information; (c) to any investor or potential investor of such Party, in connection with investment decisions with respect to such Party or otherwise in connection with customary reports to such investors or potential investors regarding such Party's portfolio and performance, so long as such Persons are notified of, and agree to maintain, the confidential nature of such information; or (d) to any assignee or potential assignee that has agreed to comply with the covenant contained in this **Section 5.2** (and any such assignee or potential assignee may disclose such information to Persons employed or engaged by it as described in clauses (a) - (c) above).

5.3 Maintenance of Books and Records.

Each of the Buyer, Seller and the Company Parties shall preserve all pre-Closing Date records possessed by or under the control of such party relating to the Company Parties in accordance with the Company's existing document retention policies and procedures. During the five year period following the Closing Date, upon any reasonable request from the Buyer or the Seller or any of their respective Representatives, the party holding such records shall provide to the requesting party or its Representatives reasonable access to such records during normal business hours at the cost of the requesting party or its Representatives. Records may be sought under this **Section 5.3** for any reasonable purpose, including to the extent reasonably required in connection with the audit, accounting, Tax, litigation, federal securities disclosure or other similar proper business purpose of the party seeking such records. Neither Buyer nor Seller shall be obligated to provide the other party with access to any books and records pursuant to this **Section 5.3** where such access would violate any Legal Requirement.

5.4 Taxes.

(a) The Company shall (and the Buyer shall cause the Company to), at the Company's expense, engage and direct the Company's existing accounting firm, Swink, Fiehler & Co., P.C., to prepare any and all Tax Returns for all Tax periods that end on or before the Closing Date; provided, that such Tax Returns shall be prepared in a manner consistent with past practices for Tax Returns (unless otherwise required by applicable Legal Requirements) from periods prior to the Closing. At least 20 days prior to the due date for filing any such Tax Return, the Company shall deliver, or caused to be delivered, to the Seller such Tax Return for its review and approval. Unless the Seller gives written notice to the Company at least 5 days prior to the due date for filing any such Tax Return specifying in reasonable detail all disputed items and the basis therefor, the Seller shall be deemed to have accepted and agreed to such Tax Return. The Seller shall pay to the applicable Tax authority any Taxes due on such Tax Returns to the extent not taken into account in determining the Adjusted Working Capital.

(b) If the Seller timely notifies the Company of its objection to any Tax Return prepared hereunder, the Buyer, the Company and the Seller shall, within the next 5 days (the "***Tax Resolution Period***"), attempt to resolve their differences and any resolution by them as to any disputed amounts shall be final, binding and conclusive. If at the conclusion of the Tax Resolution Period amounts remain in dispute, then all amounts remaining in dispute shall then be submitted, as soon as practicable, to the Reviewing Accountant. The parties agree to execute a reasonable engagement letter if requested by the Reviewing Accountant. The Reviewing Accountant shall act as an arbitrator to determine only those issues still in dispute.

The Reviewing Accountant's determination shall be made within 30 days after their selection, shall be set forth in a written statement delivered to the Buyer, the Company and the Sellers and shall be final, binding and conclusive. If a draft Tax Return is subject to an ongoing dispute under this **Section 5.4(b)** at the time that it is required to be filed, then such Tax Return shall be filed as initially prepared by the filing party, with an amended Tax Return reflecting the resolution by the Reviewing Accountant to be filed following the Reviewing Accountant's resolution of the dispute. All fees and expenses of the Reviewing Accountant in connection with any dispute submitted to the Reviewing Accountant shall be allocated between the Buyer and the Seller in the same proportion that such party's aggregate dollar amount of unsuccessfully disputed items submitted to the Reviewing Accountant bears to the total dollar amount of disputed items so submitted.

(c) After the Closing, upon reasonable written notice, the Buyer (or the Company Parties) and the Seller shall furnish or cause to be furnished to each other, as promptly as practicable, such information and assistance (to the extent within the control of such party) relating to the Company Parties (including access to books, records and personnel) as is reasonably requested for the filing of all Tax Returns (including any extensions thereof), the making of any election related to Taxes, the preparation for any audit, and the prosecution or defense of any action related to any Tax Return. The Buyer and the Company Parties agree to retain all books and records with respect to Tax matters and pertinent to the Company Parties relating to any taxable period beginning before the Closing Date until the expiration of the statute of limitations.

(d) Neither the Buyer nor any Company Party may amend a Tax Return of any of the Company Parties with respect to a taxable period beginning before the Closing Date, or file or amend any tax election with respect to any of the Company Parties with respect to a taxable period beginning before the Closing Date, in each case, without the prior written consent of the Seller (which consent may not be unreasonably withheld or delayed).

(e) Except as otherwise provided in this **Section 5.4**, to the extent any determination of the Taxes of any of the Company Parties, whether as a result of an audit, a claim for refund, the filing of an amended Tax Return, or otherwise, results in any refund or credit of Taxes paid by the Company Parties for any period prior to the Closing Date, the Buyer shall cause the applicable Company Parties to promptly pay any such refund or credit, and any interest received thereon, to the Seller upon receipt or realization thereof; provided, that, no such refund shall be payable with respect to the carryback of net operating losses, credits or other tax attributes generated in Tax periods or any portion thereof beginning after the Closing Date, or with respect to any amounts taken into account in determining the Adjusted Working Capital.

(f) The Buyer shall file a consolidated (or combined, as applicable) federal and state tax return that includes the Company Parties for the Buyer's taxable year ending after the Closing Date.

5.5 Eclat Name.

Seller acknowledges and agrees that as of the Effective Time, the"Éclat" name and any associated trademarks, service marks, trade names, brand names, logos, trade dress and other proprietary indicia of goods and services, whether registered or unregistered, shall be part of the Intellectual Property transferred to Buyer. Seller further acknowledges and agrees, effective as of the Effective Time, to change the name of the Seller to delete any reference to the name "Éclat" and to take such actions and make such filings with the Secretary of State of the State of Delaware to effect such name change, and to transfer to the Buyer or abandon (as directed by the Buyer) any domain name that includes or is confusingly similar to any name, logo, or domain name that was included in the Company Intellectual Property or Licensed Intellectual Property. After the Closing Date, Seller further acknowledges and agrees not to use the name "Éclat", "Hycet", or any confusingly similar name or mark as or in a company or subsidiary name or in connection with any of Seller's or its affiliates' future products or services, and further agrees to register or use any name, logo, or domain name that includes or is confusingly similar to any name, logo, or domain name that was included in the Company Intellectual Property or Licensed Intellectual Property.

5.6 **Further Assurances**. Following the Closing, 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 carry out the provisions hereof and give effect to the transactions contemplated by

6. INDEMNIFICATION

6.1 Survival.

Subject to the limitations and other provisions of this Agreement, the representations and warranties contained herein shall survive the Closing and shall remain in full force and effect until the date that is three (3) years from the Closing Date; provided, that the Fundamental Representations and the representations and warranties in **Article 4** shall survive indefinitely and the representations and warranties in **Section 2.6** (Tax Matters), **Section 2.8** (Compliance With Laws), **Section 2.9** (Employee and Labor Matters; Benefit Plans), **Section 2.13** (Regulatory Compliance) and **Section 2.15** (Proprietary Rights) shall survive for the full period of all applicable statutes of limitations (giving effect to any waiver, mitigation or extension thereof) plus 60 days. All covenants and agreements of the parties contained herein shall survive the Closing indefinitely or for the period explicitly specified therein.

Notwithstanding the foregoing, any claims asserted in good faith with reasonable specificity (to the extent known at such time) and in writing by notice from the non-breaching party to the breaching party prior to the expiration date of the applicable survival period shall not thereafter be barred by the expiration of the relevant representation or warranty, and such claims shall survive until finally resolved.

6.2 Seller Indemnification.

Subject to the limitations set forth in this **Section 6**, the Buyer shall be entitled to be indemnified and held harmless solely out of a right of set-off against amounts due under the Note, any Launch Products Deferred Payment or any Hycet Deferred Payment, as applicable in accordance with **Section 6.6**, for any and all losses, damages, liabilities, deficiencies, judgments, interest, penalties, fines and costs or expenses of whatever kind, including reasonable attorneys' fees, resulting from:

(a) any inaccuracy in or breach of any representation or warranty contained in **Section 2** or **Section 3** of this Agreement; and

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Seller pursuant to this Agreement.

6.3 Buyer Indemnification.

The Buyer shall indemnify and hold harmless the Seller for, and shall pay to the Seller, any and all losses, damages, liabilities, deficiencies, judgments, interest, penalties, fines and costs or expenses of whatever kind, including reasonable attorneys' fees, resulting from:

(a) any inaccuracy in or breach of any representation or warranty contained in **Section 4** of this Agreement; and

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Buyer pursuant to this Agreement.

6.4 Limitations.

Notwithstanding anything set forth in this Agreement to the contrary:

(a) The Seller shall not have any liability under this Agreement other than a right of the Buyer to set-off against amounts due under the Note in accordance with **Section 6.6** and shall not have any liability in the aggregate at any time in excess of an amount equal to the amounts due under the Note; provided, however, that the foregoing limitation shall not apply to recovery under **Section 6.2(a)** for any inaccuracy in or breach of any Fundamental Representations or the representations and warranties in **Section 2.8** (Compliance With Laws), for which the Buyer shall also be entitled to set-off against the Launch Products Deferred Payments and the Hycet Deferred Payments in accordance with **Section 6.6**.

(b) The Buyer shall not be entitled to recovery under **Section 6.2(a)** unless the amount of damages resulting from an individual breach of the representations and warranties (or series of related breaches) exceeds $5,000.

(c) Except for breaches of any Fundamental Representations, the Buyer shall not be entitled to recovery under **Section 6.2(a)** unless and until the aggregate amount of the damages due to the Buyer exceeds $90,000, in which event the Buyer shall be entitled to recovery for the full amount of damages from the first dollar.

(d) For purposes of this **Section 6**, any inaccuracy in or breach of any representation or warranty shall be determined without regard to any materiality or other similar qualification contained in or otherwise applicable to such representation or warranty.

(e) The Buyer shall not be entitled to recovery for any damages to the extent such damages are reserved for as a liability or contra-asset in the Closing Balance Sheet as finally determined in accordance with this Agreement and are taken into account in the determination of the Adjusted Working Capital.

(f) All damages recoverable by the Buyer as a right of the Buyer to set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with Section 6.6 shall be net of any proceeds the Buyer actually recovers under any available insurance less any related costs and expenses, including the aggregate cost of pursuing any related insurance claims and any related increases in insurance premiums. Following the Closing, the Buyer and the Company Parties shall use commercially reasonable efforts to claim and recover in full any damages or losses under any insurance policies maintained by or for the benefit of the Buyer or the Company Parties or otherwise covering the business of the Company Parties if and to the extent they are seeking indemnification for such damages or losses hereunder.

(g) Notwithstanding any other provision in this Agreement to the contrary, the Buyer shall not be entitled to a right of set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with **Section 6.6** for any for damage to reputation, lost business opportunities, lost profits, mental or emotional distress, incidental, special, consequential, exemplary, punitive, or indirect damages, interference with business operations or diminution in value.

(h) All amounts recovered by the Buyer as a right of set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with **Section 6.6** shall be treated by the Parties as an adjustment to the consideration for the Units.

6.5 Procedure for Indemnification – Third-Party Claims.

(a) If the Buyer shall claim a right of set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with **Section 6.6** hereunder arising from any claim or demand of a third party, the Buyer shall notify the Seller in writing of the basis for such claim or demand and such notice shall set forth the nature of the claim or demand in reasonable detail.

(b) If any Legal Proceeding is brought by a third party against the Buyer and the Buyer gives notice to the Seller pursuant to **Section 6.5(a)**, the Seller shall be entitled to participate in such Legal Proceeding and, to the extent that it wishes, to assume the defense of such Legal Proceeding if (i) the Seller provides written notice to the Buyer that the Seller intends to undertake such defense and (ii) the Seller conducts the defense of the third-party claim diligently. The Buyer shall, in its sole discretion, have the right to employ separate counsel (who may be selected by the Buyer in its sole discretion) in any such action and to participate in the defense thereof, and the fees and expenses of such counsel shall be paid by the Buyer. The Buyer shall cooperate in all reasonable respects with the Seller and its counsel in the defense or compromise of such claim or demand. If the Seller assumes the defense of a Legal Proceeding, no compromise or settlement of such claims may be effected by the Seller without the Buyer's consent unless (A) there is no finding or admission of any violation of law or any violation of the rights of any Person and no material adverse effect on the Buyer with respect to any other claims that may be made against it or (B) the sole relief provided is monetary damages that are paid in full as a right of set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with **Section 6.6**.

(c) If (i) notice is given to the Seller of the commencement of any third-party Legal Proceeding and the Seller does not, within thirty days after the Buyer's notice is given, give notice to the Buyer of its election to assume the defense of such Legal Proceeding or (ii) any of the conditions set forth in clauses (i) - (ii) of **Section 6.5(b)** above become unsatisfied, the Buyer shall (upon notice to the Seller) have the right to undertake the defense, compromise or settlement of such claim; provided that no compromise or settlement of such claim may be affected by the Buyer without the Seller's consent, which shall not be unreasonably withheld or delayed, if (A) the Buyer will receive as a right of set-off against amounts due under the Note and/or the Launch Products Deferred Payments, as applicable, in accordance with **Section 6.6** any amounts to be paid to compromise or settle the claim, (B) there is a finding or admission of any violation by the Seller of any Legal Requirement or the rights of any Person, or (C) the compromise or settlement would have a material adverse effect on the Seller with respect to any other claims that may be made against it.

6.6 Right of Set-Off.

The Buyer shall be entitled to set off and reduce the amounts due under the Note by any amount it is entitled to recover under **Section 6.2** (subject to the limitations set forth in this **Section 6**), but only if such amount (i) has been mutually agreed in writing by the Seller and the Buyer to be indemnifiable under **Section 6.2** or (ii) has been determined by a final, nonappealable judgment of a court of competent jurisdiction to be indemnifiable under **Section 6.2**. The Buyer shall be entitled to set off and reduce the amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments by any amount it is entitled to recover under **Section 6.2(a)** for any inaccuracy in or breach of any Fundamental Representations or the representations and warranties in **Section 2.8** (Compliance With Laws), subject to the limitations set forth in this **Section 6**, but only if such amount (i) has been mutually agreed in writing by the Seller and the Buyer to be indemnifiable under **Section 6.2** or (ii) has been determined by a final, nonappealable judgment of a court of competent jurisdiction to be indemnifiable under **Section 6.2**.

6.7 Exclusive Remedy.

Except for claims of fraud, criminal activity or willful misconduct, the right of the Buyer to set-off against amounts due under the Note, the Launch Products Deferred Payments and/or the Hycet Deferred Payments, as applicable, in accordance with **Section 6.6** for damages under **Section 6.2** shall constitute the Buyer's sole and exclusive remedy with respect to any and all claims arising under or relating to this Agreement whether for breach of contract, in tort or otherwise (including for breach of any representation, warranty, covenant or agreement), any agreement or document executed and delivered pursuant to this Agreement and the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, the Parties shall have no right of rescission following the Closing with respect to the transactions contemplated by this Agreement.

7. MISCELLANEOUS PROVISIONS

7.1 Amendment.

This Agreement may not be amended except by an instrument in writing signed on behalf of each of Party.

7.2 Waiver.

(a) 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.

(b) 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.

7.3 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.

7.4 Applicable Law; Jurisdiction.

THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF DELAWARE, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS. FLAMEL HEREBY IRREVOCABLY WAIVES ITS RIGHTS UNDER ARTICLE 14 AND ARTICLE 15 OF THE FRENCH CIVIL CODE. EACH OF THE PARTIES TO THIS AGREEMENT (A) CONSENTS TO SUBMIT ITSELF TO THE PERSONAL JURISDICTION OF THE COURT OF CHANCERY OF THE STATE OF DELAWARE 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 COURT, 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 IN **SECTION 7.6**. NOTHING IN THIS **SECTION 7.4**, HOWEVER, SHALL AFFECT THE RIGHT OF ANY PARTY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW.

7.5 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 Seller may assign its rights to payments under **Section 1.7** of this Agreement to any other Person without the prior written consent of the Buyer or any other Party. 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.

7.6 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 the address or facsimile telephone number set forth beneath the name of such Party below (or to such other address or facsimile telephone number as such Party shall have specified in a written notice given to the other Parties):

if to the Seller:

780 Third Avenue
37th Floor
New York, NY 10017
Fax: (212) 573-8111
Attention: James E. Flynn
David J. Clark

with a copy to (which shall not constitute notice):

Robinson, Bradshaw & Hinson, P.A.
101 North Tryon Street, Suite 1900
Charlotte, NC 28246
Fax: (704) 339-3428
Attention: Mark O. Henry

if to Flamel, the Buyer or the Company:

Flamel Technologies S.A.
Parc Club du Moulin a Vent
33, avenue du Docteur Georges Levy
69693 Venissieux Cedex France
Attention:

with a copy to (which shall not constitute notice):

Hogan Lovells US LLP
200 International Drive
Baltimore, MD 21202
Facsimile: (410) 659-2701
Attention: Asher M. Rubin

William I. Intner

and

Hogan Lovells US LLP
555 Thirteenth St. NW
Washington, DC 20004
Facsimile: (202) 637-5910
Attention: G. Allen Hicks

7.7 Severability.

Any term or 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 terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination shall have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

7.8 Other Remedies; Specific Performance.

Except as otherwise provided herein, 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 of the provisions of this Agreement were not performed in accordance with their 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 terms and provisions hereof, this being in addition to any other remedy to which they are entitled at law or in equity.

7.9 Noncompete.

Effective as of the Effective Time, the Seller hereby releases Michael S. Anderson from all obligations under the Confidentiality, Non-Solicitation and Non-Competition Agreement between the Seller and Michael S. Anderson, and acknowledges and agrees such agreement shall be terminated and of no further force and effect.

7.10 Judgment Currency.

(a) 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") 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 Delaware 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 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 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.

(c) Any amount due from Buyer under this **Section 7.10** 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.

7.11 Construction.

(a) 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.

(b) 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.

(c) 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."

(d) 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.

(e) 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.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

ÉCLAT HOLDINGS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: President & CEO

ÉCLAT PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: President & CEO

FLAMEL TECHNOLOGIES S.A.

By: /s/ Stephen H. Willard
Name: Stephen H. Willard
Title: Chief Executive Officer

FLAMEL US HOLDINGS, INC.

By: /s/ Stephen H. Willard
Name: Stephen H. Willard
Title: President

EXHIBIT A

CAPITALIZED TERMS

For purposes of the Agreement (including this **Exhibit A**):

"***Accelerated Earn-Out Value***" shall mean as of any date of determination, the amount of future Launch Products Deferred Payments and Hycet Deferred Payments that would be paid to Seller using the Buyer's good faith projections of future sales of the Product and the Launch Products at the time of the applicable 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) Flamel or the Company 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 the Bankruptcy Code or under any other 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 corporate action to authorize or approve any of the foregoing; or

(b) Any involuntary petition or case shall be filed or commenced against Flamel or the Company 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 the Bankruptcy Code or 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.

"***Adjusted Working Capital***" shall mean an amount equal to the net book value, determined without duplication in accordance with GAAP as consistently applied in the same manner as the Financial Statements, of the Company on a consolidated basis of (i) the cash (if any), inventory, accounts receivable, prepaid assets and other current assets, minus (ii) the accounts payable, accrued current operating liabilities (including, for purposes of clarification, any necessary accrual for Taxes in accordance with GAAP) and the Return, Rebate and Chargeback Accrual (excluding, for purposes of clarification, the Company Indebtedness, which is being satisfied pursuant to **Section 1.5**.)

"***ANDA***" means Abbreviated New Drug Application numbered 040482, approved September 25, 2003.

"***Bankruptcy Code***" means 11 U.S.C. §§ 101 et seq., as amended from time to time, and any successor statute, and all regulations from time to time promulgated thereunder.

"***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.

"***Code***" shall mean the Internal Revenue Code of 1986, as amended.

"***Company Indebtedness***" means all obligations for borrowed money owed by the Company Parties immediately prior to the Effective Time and any liens on the assets of the Company Parties securing such obligations.

"***Company Party***" means each of the Company and all of its Subsidiaries and "***Company Parties***" means the Company and all of its Subsidiaries collectively.

"***Consent***" shall mean any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

"***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%.

"***DGCL***" shall mean the General Corporation Law of the State of Delaware.

"***Direct Costs***" means the direct costs of acquiring the Product or the Launch Products, as applicable, at the actual contracted cost from a third-party manufacturer plus the cost of freight to the Company's distribution center from the third-party manufacturer. In the event that one or more of the Product, or the Launch Products, as applicable, is manufactured directly by the Buyer, the parties shall negotiate in good faith to revise the definition of "Direct Costs" to specify the costs to be included, which shall not include any sales or marketing expenses or any general overhead allocations.

"***D&O Indemnified Parties***" means each Person who was at any time prior the Effective Time a director or officer of any Company Party.

"***Earnings Report***" means, (i) during any period when Buyer is obligated to file reports under the provisions of the Securities Exchange Act of 1934, the Form 6-K filed by Buyer containing its financial information for such quarter and (ii) during any period when Buyer is not obligated to file reports under the provisions of the Securities Exchange Act of 1934, the internal financial statements prepared by Buyer.

"***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.

"***Equity Interests***" means, with respect to any Person, the capital stock, limited liability company interests, membership interests, partnership interests or other equity interests of such Person.

"***ERISA***" shall mean the Employee Retirement Income Security Act of 1974, as amended.

"***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

"***FSC Agreement***" means that certain License and Assignment Agreement dated as of June 23, 2011 by and between Eclat Pharmaceuticals, LLC and FSC Laboratories, Inc., as amended on the date hereof.

"***Fundamental Representations***" means those representations and warranties set forth in **Sections 2.1** (Organization; Good Standing), **2.2** (Consents and Approvals; No Violation), **2.3** (Capital Stock; Subsidiaries), **2.18** (Brokers), **3.2** (Authority; Enforceability) and **3.3** (Consents and Approvals; No Violation).

"***GAAP***" means generally accepted accounting principles as recognized by the American Institute of Certified Public Accountants.

"***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 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).

"***Hycet Gross Profit***" means Net Sales of the Product minus Direct Costs of the Product.

"***IRS***" shall mean the United States Internal Revenue Service.

"***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.

"***Knowledge***" means, with respect to an individual, that such individual is actually aware of the relevant fact. "Knowledge of the Company" means the actual knowledge of Michael S. Anderson, Chris Keith, Laurie Fendler or Scott Macke.

"***Launch Products***" shall mean Neostigmine Methylsulfate Injection, Phenylephrine HCl Injection, **[***]**.

"***Launch Products Gross Profit***" means Net Sales of the Launch Products minus Direct Costs of the Launch Products.

"***Legal Proceeding***" shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Body or any arbitrator or arbitration panel, whether at law or in equity.

"***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 Authority 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.

[***] Confidential treatment requested for deleted portion.

"***Net Sales***" shall mean, without duplication, the gross amount invoiced by or on behalf of the Buyer, the Company Parties or any of their Affiliates or any direct or indirect assignee or licensee of the Buyer or the Company Parties or any of their Affiliates for Product, or the Launch Products, as applicable, 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.

"***Ordinary Course of Business***" shall mean, in the case of each of the Company and its Subsidiaries, such actions taken in the ordinary course of its normal operations and consistent with its past practices.

"***Ordinary Shares***" means the Ordinary Shares with a nominal value 0.122 Euros per share of Flamel.

"***Party***" or "***Parties***" shall mean the Buyer and the Seller.

"***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 which the applicable Company Party is not in default in any material respect, and which are not, individually or in the aggregate, material to the business of the Company; (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 Company; (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 Company.

"***Person***" shall mean any individual, Entity or Governmental Body.

"***Product***" means the drug product sold under the ANDA containing hydrocodone bitartrate 7.5 mg and acetaminophen 325 mg (per 15 ml) in liquid form for oral administration.

"***Product Intellectual Property***" shall mean all Proprietary Rights held or licensed by the Company Parties that is, or may hereafter be, necessary to develop, make, have made, promote, market or sell the Product and the Launch 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 Product and each Launch Product in the United States of America.

"***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.

"***Return, Rebate and Chargeback Accrual***" shall mean the estimated liabilities of the Company Parties as of the Closing Date for returns, rebates, chargebacks and other similar liabilities.

An Entity shall be deemed to be a "***Subsidiary***" 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.

"***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.

"***Tax Return***" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information, and any amendment or supplement to any of the foregoing, filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Legal Requirement relating to any Tax.

"***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.

ADDITIONAL DEFINITIONS

Each of the following definitions is set forth in the section of the Agreement indicated below:

Definition	Section
Adjusted Working Capital Statement	1.3(b)
Agreement	Preamble
Audit Notice	1.7(d)
Balance Sheet	2.4
Balance Sheet Date	2.4
Buyer	Preamble
Buyer Documents	4.2
Closing	1.6(a)
Closing Balance Sheet	1.3(b)
Closing Date	1.6(a)
Company	Recitals
Company Transaction Payments	2.22
Disclosure Schedule	2
Deferred Payment Calculation	1.7(b)
Deferred Payment Calculation Objection Notice	1.7(d)
Effective Time	1.6(a)
Estimated Adjusted Working Capital	1.3(a)
Financial Statements	2.4
Flamel	Preamble
Foreign Plan	2.9(d)
Hycet Product Deferred Consideration	1.7(a)
Hycet Product Deferred Payment	1.7(a)
Launch Products Deferred Consideration	1.7(a)
Launch Products Deferred Payment	1.7(a)
Leased Real Property	2.11
Loan Agreement	1.2(a)
Material Contract	2.17(a)
Note	1.2(a)
Pension Plan	2.9(d)
Product Suppliers	2.16
Reviewing Accountant	1.3(e)
Seller Preamble Seller Documents	3.2
Units Recitals Warrant Agreement	1.2(b)
Warrant Consideration	1.2(b)
Working Capital Objection Notice	1.3(d)

DISCLOSURE SCHEDULES TO THE

MEMBERSHIP INTEREST PURCHASE AGREEMENT

by and among

ÉCLAT HOLDINGS, LLC,

a Delaware limited liability company;

ÉCLAT PHARMACEUTICALS, LLC,

a Delaware limited liability company;

FLAMEL TECHNOLOGIES, SA,

a société anonyme organized under the laws of the Republic of France; and

FLAMEL US HOLDINGS, INC.,

a Delaware corporation. Dated as of March 13, 2012

Capitalized terms used in these Disclosure Schedules that are not otherwise defined herein shall have the respective meanings ascribed to them in the Membership Interest Purchase Agreement referred to above.

[Confidential Treatment Requested]

Schedule 1.3(a)

Estimated Adjusted Working Capital

Cash	$	1,629,502
Inventory	$	35,551
Accounts Receivable	$	262,524
Prepaid Assets	$	433,466
Other Current Assets	$	14,713
Total	**$**	**2,375,756**
Accounts Payable	$	235,617
Accrued Operating Liabilities	$	98,968
Return Rebate and Chargeback	$	40,000
Total	**$**	**374,585**
Adjusted Working Capital	**$**	**2,001,171**

[Confidential Treatment Requested]

Schedule 1.8

Warrant Consideration

2.2mm struck at $7.44
1.1mm struck at $11.00

Aggregate Black Scholes Valuation is $3,884,210.

Schedule 2.1

Jurisdiction/Directors/Officers

Éclat Pharmaceuticals, LLC and Talec Pharma, LLC are registered to do business in Missouri, Montana, North Dakota, and Maine as foreign limited liability companies.

Éclat Pharmaceuticals, LLC Manager and Officers

Manager:
Éclat Holdings, LLC

Officers:

- Mike Anderson (President & CEO)
- Chris Keith (Vice President)
- Alex Karnal (Secretary)

Talec Pharma, LLC Manager and Officers

Manager:
Éclat Pharmaceuticals, LLC

Officers:

- Mike Anderson (President & CEO)
- Chris Keith (Vice President)
- Alex Karnal (Secretary)

Schedule 2.2

Consents and Approvals

The following agreements require consent upon the consummation of the transactions contemplated by the Agreement:

License and Assignment Agreement, dated as of June 23, 2011 between Éclat Pharmaceuticals, LLC and FSC Laboratories, Inc.

Wholesale Purchase Agreement, dated as of June 20, 2011, between Cardinal Health and Éclat Pharmaceuticals, LLC

Developing Suppliers Program Distribution Services Agreement, effective July 15, 2011, between Cardinal Health and Éclat Pharmaceuticals, LLC.

[Confidential Treatment Requested]

Schedule 2.4 Financial Statements See attached.

Consolidated
December 31, 2011 and 2010

Income Statement		**2011**		**2010**
Net revenue	$	608,777	$	
Cost of goods		303,697		—
Gross profit		305,080		
General and administration	$	1,751,135	$	141,033
Selling and marketing		622,006		29,038
Research and development		1,486,756		75,000
Total expense		3,859,898		245,071
Net loss	$	(3,554,818)	$	(245,071)

Balance Sheet		**2011**		**2010**
Cash	$	4,104,329	$	1,712,309
Accounts receivable		184,114		—
Inventory		52,285		-
Prepaid		341,342		24,693
Other current assets		3,367		-
Property		59,862		52,268
Intangibles		3,621,429		-
Deposits		5,426		12,926
		8,372,154		1,802,196
Total assets				
Accounts payable		204,472		18,415
Accrued liabilities		111,017		27,722
Other short-term		750,000		-
liabilities Long-term debt		6,000,000		-
Other long-term liabilities		2,106,554		1,130
		9,172,043		47,267
Total liabilities				
Capital accounts		3,000,000		2,000,000
Retained deficit		(245,071)		—
Net loss		(3,554,818)		(245,071)
Total capital		(799,889)		1,754,929
Total liabilities and capital	$	8,372,154	$	1,802,196

Schedule 2.5

Absence of Changes

Éclat Pharmaceuticals, LLC amended and restated its Limited Liability Company agreement, effective March 13, 2012.

Schedule 2.6(a)

Tax Matters

None

[Confidential Treatment Requested]

Schedule 2.9(c)

Independent Contractors

Michael J. Murray, M.D., Ph.D., via a Consulting Agreement, between Michael J. Murray, M.D., Ph.D. and Éclat Pharmaceuticals, LLC, dated April 8, 2011.

Diana Rogers, via a Consulting Agreement, between Diana Rogers and Éclat Pharmaceuticals, LLC, dated May 1, 2011.

[Confidential Treatment Requested]

Schedule 2.10

Insurance

Property/Automobile/Inland Marine

- Carrier- Acuity
- Effective Date- 12/10/2011
- Coverage Amount- $120,000

Employment Practices Liability

- Carrier- XL Insurance
- Effective Date- 12/10/2011
- Coverage Amount- $1,000,000

Workers Compensation

- Carrier- Travelers
- Effective Date- 12/10/2011
- Coverage Amount- $1,000,000

General Liability, including Products/Completed Operations

- Carrier- Evanston Insurance
- Effective Date- 6/16/2011
- Coverage Amount- $5,000,000

Schedule 2.11

Leased Real Property

Lease, with a commencement date of November 1, 2010, between Spirit Center Three, LLC and Éclat Pharmaceuticals, LLC for the lease of the building known as 699 Trade Center Boulevard, Chesterfield, Missouri, 63005.

[Confidential Treatment Requested]

Schedule 2.12

Bank Accounts

Accounts with Commerce Bank, N.A.:

1) Éclat Pharmaceuticals, LLC Commercial Checking- acct. #0316917845

2) Business Money Market Account- acct. #0316917860

3) Talec Pharma, LLC Commercial Checking- acct. #0316918068.

Michael Anderson and Laurie Fendler are authorized signatories for each of the bank accounts reference above.

[Confidential Treatment Requested]

Schedule 2.15(a)

Proprietary Rights

Domain Names:

www.eclatpharmaceutical.com Expiration Date: 1/18/2013

www.TALECPHARMA.COM Expiration Date: 5/2/2012

www.TALECPHARMACEUT ICAL.COM Expiration Date: 5/2/2012

www.TALECPHARMACEUTICALS.COM Expiration Date: 5/2/2012

www.ECLATPHARMA.COM Expiration Date: 12/2/2013

www.ECLATPHARMACEUT ICALS.COM Expiration Date:12/2/2013

www.Hycet.com Expiration Date: 12/19/2015

Trademark:

HYCET®, U.S. Registration Number 3,012,656[1]

[1] Pursuant to the License and Assignment Agreement, dated as of June 23, 2011 between Éclat Pharmaceuticals, LLC and FSC Laboratories, Inc., Éclat Pharmaceuticals is required to pay a fee for the use of this trademark.

Schedule 2.17(a)

Material Contracts

(i)

- Manufacturing and Supply Agreement between Éclat Pharmaceuticals, LLC and Mikart, LLC, dated June 27, 2011.
- Product Promotion Agreement, dated June 23, 2011, between FSC Pediatrics, Inc. and Éclat Pharmaceuticals, LLC
- Prosar Agreement, dated May 23, 2011, between Product Safety Resources, Inc. and Éclat Pharmaceuticals, LLC.
- Consultancy and Services Agreement, dated June 24, 2011 between Beckloff Associates, Inc. and Éclat Pharmaceuticals, LLC.
- Information Services Agreement, between IMS Health Incorporated and Éclat Pharmaceuticals, LLC, dated February 1, 2011.
- Phenylephrine HCL Injection Process Development Pricing Proposal, dated as of June 3, 2011, between Patheon UK Limited and Éclat Pharmaceuticals, LLC, as supplemented by change of scope documentation.
- **[***]** Pricing Proposal, dated November 26, 2011, between Pantheon UK Limited and Éclat Pharmaceuticals, LLC, as supplemented by change of scope documentation.
- Neostigmine Methlysulfate Injection Formulation Development Pricing Proposal, between Pantheon UK Limited and Éclat Pharmaceuticals, LLC, dated as of February 21, 2011.
- Generic Wholesale Service Agreement, dated August 1, 2011 between Cardinal Health and Talec Pharma, LLC.
- Developing Suppliers Program Distribution Services Agreement, effective July15, 2011, between Cardinal Health and Éclat Pharmaceuticals, LLC.
- Service Agreement, dated April 20, 2011, between Talec Pharmaceuticals, LLC and DDN/OBERGFEL, LLC, as amended.
- Service Agreement, dated February 14, 2011, between Éclat Pharmaceuticals, LLC and DDN/OBERGFEL, LLC, as amended.
- Data Services Agreement, dated as of June 6, 2011, between Éclat Pharmaceuticals and H.D. Smith Wholesale Drug Co.
- Distribution Services Agreement, dated as of June 14, 2011, between Amerisource Bergen Drug Corporation, Éclat Pharmaceuticals and Bellco Drug Corp.
- Letter Agreement, between Éclat Pharmaceutical Company and The Weinberg Group, dated October 20, 2010.
- Letter Agreement between Éclat Pharmaceutical Company, LLC and The Weinberg Group, dated September 3, 2010.
- Letter Agreement between Éclat Pharmaceuticals and The Weinberg Group, dated May 18, 2011.

[***] Confidential treatment requested for deleted portion.

- Agreement on Audit Execution, between Éclat Pharmaceuticals and Boehringer Ingelheim Pharma GmbH & Co. KG, dated September 30, 2011.
- Consulting Agreement, dated February 7, 2011 between Éclat Pharmaceuticals and Compliance Insight, Inc.
- Wholesale Purchase Agreement, dated as of June 20, 2011, between CardinalHealth and Éclat Pharmaceuticals, LLC.
- Sample Fulfillment Agreement, dated as November 30, 2011, between Éclat Pharmaceuticals, LLC and Foundation Care, LLC.

(ii)

- License and Assignment Agreement, dated as of June 23, 2011, between Éclat Pharmaceuticals, LLC and FSC Laboratories, Inc.
- Manufacturing and Supply Agreement between Éclat Pharmaceuticals, LLC and Mikart, LLC, dated June 27, 2011.
- Standard License Agreement, effective as of January 1, 2011, between First Databank, Inc. and Éclat Pharmaceuticals, LLC

(iii)

- Lease, with a commencement date of November 1, 2010, between Spirit CenterThree, LLC and Éclat Pharmaceuticals, LLC for the lease of the building known as 699 Trade Center Boulevard, Chesterfield, Missouri, 63005.

(iv)

- Limited Liability Company Agreement of Éclat Pharmaceuticals, LLC, effective October 18, 2010, between Éclat Holdings, LLC and Éclat Pharmaceuticals, LLC.
- Limited Liability Company Agreement of Talec Pharma, LLC, effective as of April 5, 2011, between Éclat Pharmaceuticals, LLC and Talec Pharma, LLC.

(v) None.

(vi) None.

(vii)

- Irrevocable Standby Letter of Credit for Maryland Board of Pharmacy, issued 6/27/2011 by Commerce Bank, N.A. on behalf of Éclat Pharmaceuticals, LLC.
- Note Purchase Agreement among Éclat Pharmaceuticals, LLC and the investors named therein, dated as November 1, 2010, along with the promissory notes evidencing the indebtedness thereunder.

(viii) None.

(ix)

- Pharmaceutical Pricing Agreement, dated October 28, 2011, between the Secretary of Health and Human Services and Talec Pharma, LLC.
- Pharmaceutical Pricing Agreement, dated October 28, 2011, between the Secretary of Health and Human Services and Éclat Pharmaceuticals, LLC.

(x)

- Distribution Services Agreement, dated as of June 14, 2011, between AmerisourceBergenDrug Corporation, Éclat Pharmaceuticals and Bellco Drug Corp.
- Manufacturing and Supply Agreement between Éclat Pharmaceuticals, LLC and Mikart, LLC, dated June 27, 2011.
- Consultancy and Services Agreement, dated June 24, 2011 between Beckloff Associates, Inc. and Éclat Pharmaceuticals, LLC
- Phenylephrine HCL Injection Process Development Pricing Proposal, dated as of June 3, 2011, between Patheon UK Limited and Éclat Pharmaceuticals, LLC, as supplemented by change of scope documentation.
- **[***]** Pricing Proposal, dated November 26, 2011, between Pantheon UKLimited and Éclat Pharmaceuticals, LLC, as supplemented by change of scope documentation.
- Neostigmine Methlysulfate Injection Formulation Development Pricing Proposal, between Pantheon UK Limited and Éclat Pharmaceuticals, LLC, dated as of February 21, 2011.
- Core Distribution Agreement, between McKesson Corporation and Éclat Pharmaceuticals, LLC, dated June 1, 2011, as amended.
- Generic Wholesale Service Agreement, dated August 1, 2011 between Cardinal Health and Talec Pharma, LLC.
- Supplier Agreement (Multisource and Onestop Generic Program), dated as August 1, 2011, between McKesson Corporation and Talec Pharmaceuticals, LLC.
- Pharmaceutical Pricing Agreement, dated October 28, 2011, between the Secretary of Health and Human Services and Talec Pharma, LLC.
- Pharmaceutical Pricing Agreement, dated October 28, 2011, between the Secretary of Health and Human Services and Éclat Pharmaceuticals, LLC.

[***] Confidential treatment requested for deleted portion.

Exhibit 8.1

Operating Subsidiaries of Flamel Technologies S.A.

Flamel US Holdings, Inc.

Éclat Pharmaceuticals, LLC

Talec, LLC

Flamel Irish Holdings Limited

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, 2015

/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, 2015

/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, 2014, 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.

Date: April 30, 2015

/s/ Michael S. Anderson

Michael S. Anderson
Chief Executive Officer

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, 2014, 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.

Date: April 30, 2015

/s/ Siân Crouzet

Siân Crouzet
Principal Financial Officer

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, 2015

PricewaterhouseCoopers Audit

Represented by
/s/ Nicolas Brunetaud
Nicolas Brunetaud (signed)