UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10–K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

Commission file number: 000-28508

FLAMEL TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

Republic of France	**43-1050617**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
Parc Club du Moulin à Vent **33, avenue du Docteur Georges Levy** **Vénissieux France**	**69200**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +33 472 78 34 34

Securities registered pursuant to Section 12(b) of the Act:

American Depositary Shares* Ordinary Shares**	**NASDAQ Global Market**
Title of each class	**Name of exchange on which registered**

* American Depositary Shares evidenced by American Depository Receipts. Each American Depositary Share represents one (1) Ordinary Share.
** Nominal value 0.122 Euros per share. Not for trading, but only in connection with the listing of American Depositary Shares.

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 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 has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer x Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☐

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

Aggregate market value of the voting stock held by non-affiliates of the registrant:

$845,720,744	June 30, 2015
Value	Date of Valuation

The calculation of the aggregate market value of voting stock excludes 587,450 ordinary shares of the registrant that are understood to be held by employees, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

Number of the registrant's American Depositary Shares, 0.122 Euro per share par value, outstanding as of March 7, 2016 was 40,234,506.

The following documents are incorporated by reference in the Parts of this Form 10-K indicated below:

Documents Incorporated by Reference	**Parts of Form 10-K into which Incorporated**
None	N/A

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Cautionary Disclosure Regarding Forward-Looking Statements

This annual report on Form 10-K 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" in this Part I, Item 1A, 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.
- Our newly acquired pediatric products could fail to generate enough physician interest to make them successful products.
- if third party payors choose not to reimburse our pediatric products, or to reimburse them with a greater burden on the patient, our business could suffer, irrespective of a physician's preference for using our product.. Since some of our pediatric competitors enjoy OTC status, this could cause our revenues to suffer.
- We could fail to successfully or efficiently integrate the FSC business into our existing business.
- Our acquisition of FSC, and its larger employee base, could increase our exposure to additional regulatory risks associated with the promotion of our products.
- 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 ceased to qualify as a foreign private issuer, which will 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 on Form 10-K including those set forth above and in "Risk Factors" section of this annual report on Form 10-K, describe factors, among others, that could contribute to or cause such differences.

PART I

Item 1. Business

General Overview

Flamel Technologies S.A. ("Flamel," the "Company," "we" or "us") is a specialty pharmaceutical company utilizing core competencies in drug delivery and formulation development to create safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. The Company has a balanced business model consisting of:

(i) an Unapproved Marketed Drugs ("UMDs") business with two approved products in the USA, Bloxiverz® (neostigmine methylsulfate injection) and Vazculep® (phenylephrine hydrochloride injection) that are currently marketed, and a third product currently being reviewed by the FDA, all obtained through the acquisition of Éclat Pharmaceuticals, LLC's (or "Éclat") portfolio on March 13, 2012,
(ii) a branded pediatric business, acquired through the acquisition of FSC Laboratories and FSC Pediatrics ("FSC") on February 8, 2016; and
(iii) a branded business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms.

The branded products that are based on Flamel's proprietary drug delivery platforms target high-value solid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits. Flamel is headquartered in Lyon, France and has operations in St. Louis, Missouri and Charlotte, NC, USA, and Dublin, Ireland.

Corporate Information

The Company was incorporated as a s*ociété 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 and is the acquiring entity of FSC Holdings, LLC ("FSC Holdings"). Éclat Pharmaceuticals, LLC, a Delaware limited liability company ("Éclat), is a wholly owned subsidiary of Flamel US Holdings, Inc. Talec Pharma, LLC, a Delaware limited liability company ("Talec"), is a wholly owned subsidiary of Éclat. FSC Therapeutics, LLC, a Delaware limited liability company ("FSC Therapeutics") is a wholly owned subsidiary of FSC Holdings, LLC and owns the intangible property acquired in the acquisition of FSC Holdings on February 8, 2016. FSC Laboratories, Inc. is a Delaware corporation and a wholly owned subsidiary of FSC Holdings. FSC Pediatrics, Inc. is a Delaware corporation and is a wholly owned subsidiary of FSC Laboratories. Flamel Irish Holdings, Ltd is a corporation organized under the laws of Ireland. Its wholly owned subsidiary, Flamel Ireland, Ltd., a corporation organized under the laws of Ireland, is where all intangible property was relocated on December 16, 2014. A complete list of the Company's subsidiaries can be found in Exhibit 21.1 to this annual report on form 10-K.

Our Business Model

Since the acquisitions of Éclat and FSC, 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., (ii) commercialize branded products and devices in the pediatric therapeutic area (Karbinal™ER ,Aciphex® Sprinkle™, Cefaclor and Flexichamber® (for more details, see "– Lead Products" in this Part I, Item 1), and (iii) blend novel, high-value internally developed products with our drug delivery and capabilities (for more details, see "– Other Products Under Development" in this Part I, Item 1 of this Annual Report on Form 10-K).

Flamel's business model allows us to select, develop, and then license or acquire niche branded products mainly in the U.S. for FDA approval and commercialization. By adopting this strategy, the Company makes itself less dependent on the often changing strategies of partners in the future. Nevertheless, Flamel still explores 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 "– Flamel's Drug Delivery Platforms Overview" in this Part I, Item 1 for details) or its proprietary products (as the case may be; see "– Other Products Under Development" in this Part I, Item 1 of this Annual Report on Form 10-K 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 "– Patent Restoration and Exclusivity" in this Part I, Item 1 of this Annual Report on Form 10-K), and FSC, which has focused on the commercialization of pediatric products and devices, add to our Company's 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 license and market products in both the U.S. and EU.

We anticipate this commercialization capability will allow us to retain a greater portion of the economic benefits associated with sales not only of our proprietary products, but additional Unapproved Marketed Drug products as well (see "– Other Products Under Development – Additional Products using the Unapproved Marketed Drug (or UMD) Strategy") in this Part I, Item 1 of this Annual Report on Form 10-K). In addition, we intend to pursue FDA approval of new products developed using our drug delivery platforms (see "– Other Products Under Development – Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2018" in this Part I, Item 1 of this Annual Report on Form 10-K).

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. 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. These products will be marketed either by the Company and/or by partners via licensing/distribution agreements (see "– Other Products Under Development – Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2018") in this Part I, Item 1 of this Annual Report on Form 10-K).

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

- Maximizing the commercial potential of our Unapproved Marketed Drug and pediatric 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;
- Developing and validating additional drug delivery platforms 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 2015 and 2016

On March 27, 2015, we announced positive results of first-in-man ("FIM") clinical trial with LiquiTime guaifenesin. Three different twice-daily formulations of LiquiTime guaifenesin were evaluated against immediate release guaifenesin tablets dosed every four hours in a four-way crossover pharmacokinetic study with 16 healthy volunteers (see "- Proprietary Pipeline Products in this Part I, Item 1 of this Annual Report on Form 10-K).

On April 7, 2015, we announced the departure of Mr. Steve Lisi, Senior Vice President of Business and Corporate Development at Flamel. Simultaneously, Flamel also reaffirmed its product revenue guidance for 2015 of $170 to $185 million for combined sales of Bloxiverz® and Vazculep®.

On June 26, 2015, we announced the appointment of Ms. Sandra Hatten as Senior Vice President of Quality and Regulatory Affairs and Mr. Gregory Davis as Vice President of Business and Corporate Development.

On June 29, 2015, we announced positive results from two pilot pharmacokinetic (PK) studies in healthy volunteers of FT227, an abuse-deterrent, extended-release, oral hydromorphone product using its proprietary Trigger Lock drug delivery platform. The PK studies were intended to provide sufficient data for the Company to select a preferred prototype formulation to move forward into pivotal studies (see "- Proprietary Pipeline Products" in this Part I, Item 1 of this Annual Report on Form 10-K).

On September 9, 2015, we announced that we had received a Prescription Drug User Fee Act (PDUFA) date of April 30, 2016 from the U.S. Food and Drug Administration (FDA) for our third Unapproved Marketed Drug product (see "- Additional Unapproved Marketed Drug Products in this Part I, Item 1 of this Annual Report on Form 10-K).

On October 5, 2015, we announced that our Irish subsidiary, Flamel Ireland Limited, had licensed exclusive U.S. rights to the LiquiTime drug delivery platform to Perrigo Company plc's Irish subsidiary, Elan Pharma International Limited, for the U.S. Over-the-Counter (OTC) drug market. Ibuprofen and guaifenesin were included along with five potential new products (for more details see "– Products In Development With Partners" in this Part I, Item 1 of this Annual Report on Form 10-K).

On November 23, 2015, we announced the appointment of Mr. Michael Kanan as Senior Vice President and Chief Financial Officer.

On December 22, 2015, we announced positive interim results from a Phase 1a clinical trial in healthy volunteers of a once weekly subcutaneous injection formulation of exenatide using our Medusa technology (FT228). The study achieved all safety and PK assessment objectives throughout ascending single dose administrations of FT228. The safety profile of FT228 was favorable in healthy volunteers up to a dose of 140 mcg, with an extremely low incidence of the gastrointestinal side effects commonly related to twice daily subcutaneous administration of exenatide (nausea, vomiting, abdominal discomfort, loss of appetite), in addition to a low incidence of mild injection site reactions. We plan to initiate a Phase 1b study of FT228 in Type 2 Diabetes Mellitus patients in the first quarter of 2016. One dose per week of FT228 will be administered over a one month period in order to assess safety in patients, the steady-state PK profile and the product's potential effect on surrogate biomarkers for the disease.

On January 8, 2016, we provided an update on the Company's corporate progress as it related to a number of initiatives, including ongoing clinical programs and 2016 revenue guidance. We announced that we would be submitting a Special Protocol Assessment (SPA) for once-nightly Micropump sodium oxybate in the first quarter of 2016 and upon approval would commence patient recruitment likely in the second quarter. We also announced that we had requested a meeting with FDA in the first quarter of 2016 to discuss continued development of FT227 related to Trigger Lock and expect to initiate licensing discussions for the technology in early 2016. Additionally, we announced our plans to move the first two LiquiTime products, ibuprofen and guaifenesin, into pivotal testing in 2016. Finally, we provided product revenue guidance for 2016 in the range of $100 to $120 million.

On February 8, 2016, we announced the acquisition of FSC Holdings, LLC, together with its wholly owned subsidiaries FSC Pediatrics, Inc., FSC Therapeutics, LLC, and FSC Laboratories, Inc. from Deerfield CSF, LLC, an affiliate of Deerfield Management, one of the Company's major shareholders. (see Note 19: Subsequent Events to the consolidated financial statements within Part II, Item 8 of this Annual Report on Form 10-K.). FSC is a Charlotte, NC-based specialty pharmaceutical company that markets three pediatric pharmaceutical products indicated for infection, allergy, gastroesophageal disease (GERD), and a medical device for the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. Under the terms of the acquisition, Flamel will pay $20.25 million over a five year period to Deerfield for all of its equity interests in FSC Holdings. Specifically, Flamel will pay $1.05 million annually for five years and will make a final payment in January 2021 of $15.0 million. Flamel will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to $12.5 million for a period not exceeding ten years.

Lead Products

Bloxiverz® (neostigmine methylsulfate injection), Flamel's first NDA approval. Bloxiverz'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 was 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. On January 8, 2015 and December 28, 2015, the FDA approved Fresenius Kabi USA ("Fresenius")'s NDA for neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths) and an ANDA submitted by Eurohealth International, an affiliate of West-Ward Pharmaceuticals Corp., neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths), respectively. In 2014, we recognized a total amount of $10.2 million as revenues from product sales and $150.3 million in 2015 (for more details, see "– Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K). In the future, the volume of sales of Bloxiverz is dependent upon the competitive market dynamics between Flamel, APP, West-Ward and any subsequent ANDA approvals that may occur. Additionally, an alternative product marketed by Merck, Bridion (sugammadex), was approved in early 2016 and will likely reduce the size of the neostigmine market.

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, 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. The volume of sales of Vazculep is dependent upon the competitive landscape in the marketplace.

Karbinal™ER (carbinoxamine maleate extended-release oral suspension). Karbinal ER is an H1 receptor antagonist (antihistamine) indicated for children two years of age and older, is the only first generation extended release oral suspension antihistamine available in U.S. Karbinal ER provides physicians with a new, effective and easy to use treatment option for children with seasonal and perennial allergic rhinitis that need symptomatic relief for runny nose, sneezing, itchy nose or throat and itchy and watery eyes. Karbinal ER was launched in 2015 and is exclusively licensed from Tris Pharma.

AcipHex® Sprinkle™ (rabeprazole sodium). AcipHex Sprinkle is a delayed-release capsule, in dosages of 5 mg and 10 mg, indicated for the treatment of GERD in children 1 to 11 years of age for up to 12 weeks. AcipHex Sprinkle can be sprinkled on a small amount of soft food (e.g., applesauce, fruit or vegetable based baby food, or yogurt) or the capsule granules can be emptied into a small amount of liquid (e.g., infant formula, apple juice, or pediatric electrolyte solution). The U.S. marketing rights for this product were acquired from Eisai Inc. and the product was launched in 2015.

Cefaclor for Oral Suspension, 125 mg/5 mL, 250 mg/5 mL and 375 mg/5 mL. Cefaclor is indicated for the treatment of otitis media, lower respiratory infections, pharyngitis and tonsillitis, urinary tract infections, and skin and skin structure infections, caused by susceptible organisms. It is a second generation cephalosporin antibiotic used to treat certain infections, caused by susceptible bacteria. Cefaclor was launched in 2015.

Flexichamber ™. Flexichamber is a collapsible holding chamber for use by patients under the care or treatment of a licensed healthcare professional to administer aerosolized medication from most pressurized Metered Dose Inhalers (MDI), is a prescription medical device. Flexichamber is comprised of antistatic materials to help improve delivery of medication from MDIs to the patient, while minimizing the adherence of the medication to the walls of the chamber. Flexichamber can be used with or without a mask. FSC received FDA 510(k) clearance for Flexichamber in October 2014 and the product is expected to be launched in 2016.

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 was 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. Until 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 "– Strategic Alliances" in this Part I, Item 1, and Note 17: Discontinued Operations to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

Other Products Under Development

Additional Unapproved Marketed Drug Products. The Company still intends to develop and seek NDA or ANDA approval for select products that are currently marketed in the U.S. but are currently not approved by the FDA. One of the Company's principle criteria is previously, well established efficacy. This strategy should create opportunities, to have the only approved version of products in niche markets, potentially enjoying a period of defacto exclusivity through the 505(b)(2) approval pathway. However, this strategy has a limited number of opportunities where a meaningful return on investment is possible. Through Éclat, Flamel has acquired additional opportunities beyond Bloxiverz and Vazculep:

- Flamel filed one of these products in mid-2015 and received a Prescription Drug User Fee Act (PDUFA) date of April 30, 2016 from the U.S. Food and Drug Administration (FDA). Based on IMS and other third-party data, the Company estimates that current U.S. market sales of the unapproved versions of this drug are in the range of $100 million per year.
- Another UMD Product is currently being reviewed internally and the Company anticipates its development in 2016.

Proprietary Pipeline Products. Five product development opportunities (*i.e.* four using Micropump or LiquiTime or Trigger Lock, and one 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, as is required with JAZZ's Xyrem® product. 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. Prior to commencement of clinical studies, the Company plans to submit to the FDA, a Special Protocol Assessment (SPA) for once-nightly Micropump sodium oxybate in the first quarter of 2016. SPAs serve as a way to reduce the risks associated with clinical studies, as the acceptance represents general agreement by the FDA of a pivotal trial's design, endpoints and analyses. Upon acceptance and approval of the SPA by the FDA, we plan to commence patient recruitment. The clinical trial is expected to run through early to mid-2017. It is expected to be a placebo-controlled efficacy study of approximately 200-300 patients and will be conducted at between 50 and 60 clinical sites in North America and Europe. In conjunction with the SPA, we expect to file for Investigational Medicinal Product Dossier (IMPD) approval in the EU. Any additional studies, such as pivotal pharmacokinetic (PK) studies, needed for a New Drug Application (NDA) approval will be run simultaneously, and the target for trial completion is mid-2017. Ultimately, we believe we will be able to demonstrate improved efficacy, improved safety and improved patient satisfaction over the standard of care, JAZZ's Xyrem®, a twice nightly sodium oxybate formulation, which generated approximately $955 million in revenues in 2015.

- **Ibuprofen**, LiquiTime-based formulation for twice-daily dosing for the treatment of pain. Flamel's pharmacokinetic 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. In October 2015, we entered into a license agreement with Elan Pharma International Limited ("Elan") for the U.S. OTC rights to LiquiTime including our ibuprofen product (see "– Products In Development With Partners in this Part I, Item 1 of this Annual Report on Form 10-K). In consultation with Elan, Flamel anticipates a US regulatory filing in 2017. Additionally, Flamel may follow such filing with a later filing in the European Union, either by itself or with another licensing partner. LiquiTime ibuprofen opens the door to the 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 pharmacokinetic 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. Our guaifenesin product was also part of the license agreement with Elan. We plan, in consultation with Elan, to begin pivotal testing in 2016. This second product will expand our twice-daily oral suspension offerings for the OTC market in the near future.

- **Exenatide**, a once a week Medusa-based injectable formulation of exenatide (FT228), 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 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. In 2015, we completed a Phase 1a clinical trial in healthy volunteers of a once weekly subcutaneous injection formulation of exenatide. The trial was conducted in two periods. The first, a 2-arm study of 20 healthy volunteers in each arm, evaluated the safety and PK profiles of FT228 versus Byetta®, a twice daily injection of exenatide marketed by Astra Zeneca, at a total dose of 10 mcg. The second, a 2-arm study of 20 healthy volunteers in each arm, evaluated the safety and PK profiles of FT228 at total doses of 70 mcg and 140 mcg. The safety profile of FT228 was favorable in healthy volunteers up to a dose of 140 mcg, with an extremely low incidence of the gastrointestinal side effects commonly related to twice daily subcutaneous administration of exenatide (nausea, vomiting, abdominal discomfort, loss of appetite), in addition to a low incidence of mild injection site reactions. Two subjects dropped out of the study prior to completion of the 140 mcg dosing for reasons unrelated to the clinical trial. The study achieved all safety and pharmacokinetic (PK) assessment objectives throughout ascending single dose administrations of FT228. We initiated a Phase 1b study of FT228 in Type 2 Diabetes Mellitus patients in the first quarter of 2016. One dose per week of FT228 is being administered for a one month period at two different doses in order to assess safety in patients, the steady-state PK profile and the product's potential effect on surrogate biomarkers for the disease.

- **Hydromorphone**. Flamel also has a Trigger Lock-based abuse-deterrent, extended-release, oral hydromorphone product (FT227) in development. Hydromorphone is used for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time. We announced in June 2015, positive results from two pilot pharmacokinetic (PK) studies in healthy volunteers of FT227. The PK studies were intended to provide sufficient data for the Company to select a preferred prototype formulation to move forward into pivotal studies. The studies compared three FT227 prototypes to the comparator product Jurnista© (sold as Exalgo© in the United States) in both fasted and fed conditions at a dose of 32mg. Under fasted conditions, comparing the AUC and the Cmax of FT227 to Jurnista in 16 subjects, the results identified a FT227 formulation that met the bioequivalence criteria for both parameters. Under fed conditions (14 subjects), the same formulation was bioequivalent in terms of AUC to Jurnista but outside of the Cmax bioequivalence criterion at the lower confidence interval level. Comparing the effect of food on the PK parameters of the FT227 prototypes across the two studies, no notable difference is seen in either AUC or Cmax in fed and fasted conditions. This suggests that administration of FT227 will not be subject to a clinically relevant food effect. In both studies FT227 was well tolerated and no serious adverse events were reported. In addition, Flamel has generated substantial in vitro data comparing the abuse deterrence properties of FT227 compared to other marketed abuse-deterrent opioid products. The Company is confident that Trigger Lock is a robust platform for opioids that will set a high standard in terms of abuse deterrence. Further in vitro data have been generated on FT227 by an independent contract research organization which confirmed the excellent abuse deterrent properties of the product. FT227 is designed to be filed as a 505(b)(2) New Drug Application (NDA). We recently requested a meeting with the FDA to discuss the further development of FT227 and expect to initiate licensing discussions for the technology in early 2016.

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, as described below under the caption "Proprietary Intellectual Property.", 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 above "– Lead Products" in this Part I, Item 1, and below "– Strategic Alliances" in this Part I, Item 1 and "– Manufacturing" in this Part I, Item 1 of this Annual Report on Form 10-K).

We entered into an Exclusive License Agreement on September 30, 2015, with Elan Pharma International Limited, a subsidiary of Perrigo Company plc, for the U.S. rights to our LiquiTime drug delivery platform for the U.S. (OTC) drug market. Under the multi-product license agreement, we received an upfront payment of $6.0 million and will be eligible for at least $50 million in approval and launch milestones. In addition, we will receive mid-single digit royalties on net sales of the products. Flamel and Elan believe there is a large market opportunity for other OTC extended release liquid drug formulations, including products containing active ingredient combinations for the US cough/cold market, which analysts have estimated between $6 billion to $8 billion annually.

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**®	Anesthesia	Marketed in the U.S.	
	UMD#3 (Undisclosed or "UD")**[2]**	UD	NDA filing in 2015 with PDUFA date of April 30, 2016	
	UMD #4 (UD)	UD	Development beginning in 2016 with anticipated filing in 2017	
Pediatrics	**Karbinal ER**	Allergy/Antihistamine	Marketed in the U.S.	FSC Pediatrics
	AchipHex Sprinkle	GERD	Marketed in the U.S.	
	Cefaclor Oral Suspension	Infections	Marketed in the U.S.	
	Flexichamber [4]	Asthma	Marketed in the U.S.	
Micropump®	Sodium oxybate	CNS (narcolepsy)	2 clinical studies completed SPA to be submitted in early 2016 (pivotal clinical study initiation expected as early as 2016)	To be determined**[3]**
LiquiTime®	Ibuprofen	Pain	FIM clinical study completed (pivotal clinical study initiation expected in 2016)	LiquiTime®-based product(s) out-licensed
	Guaifenesin	Respiratory	Proof of concept FIM clinical study completed (pivotal clinical study initiation expected in 2016)	
Trigger Lock™	Hydromorphone	Pain	PK study completed in 2015 (pivotal clinical study initiation expected in 2016)	To be determined**[3]**
Medusa™	Exenatide (once-a-week)	Diabetes	Phase 1(a) study completed in 2015 (Phase 1(b) study initiated Q1 2016)	

[1] Company's Unapproved Marketed Drug Products.

[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 are expected to be licensed to partners for completion of development and commercialization.

[4] Medical device

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 differentiated 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) has been accelerated by the demand for less expensive pharmaceutical products. As a result, the pricing power of pharmaceutical companies will be more tightly controlled in the future.

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 and specialty pharmaceutical 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.

Just as Flamel has undertaken a strategy of developing and commercializing its own products, 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. A few examples include Alkermes, Depomed, Ethypharm and Octoplus.

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

Flamel's Drug Delivery Platforms	Competition category*	Selected Competitive Companies*
Micropump® (oral)	**Solid sustained release**	Alkermes plc; COSMO Pharmaceuticals SpA; Depomed, Inc.; Durect Corp.; Supernus Pharmaceuticals, 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.; Altus Formulation, Cima (Cephalon); Collegium Pharmaceutical, Inc.; Durect Corp.; Egalet Corporation; Elite Pharmaceuticals, Inc.; Ethypharm; Grünenthal Group; Intellipharmaceutics International, Inc.; QRx Pharma, Ltd.; KemPharm, Inc.
Medusa™ (injectable)	**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.

Flamel's Specialty Pharma model (focusing on optimized re-formulations development capabilities) competes with a number of companies, based upon the product being developed. Examples of companies with whom we or future partners would compete, given our current pipeline, include Jazz Pharmaceuticals, Purdue Pharma, Tris Pharma and others. 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, and direct commercialization of drugs.

Market Opportunities

Drug delivery platforms are of particular interest for managing the life cycle of pharmaceutical products, as they offer many advantages:

- improvements in bioavailability
- pharmacokinetic improvements
- enhanced efficacy
- reduction of adverse events
- improved patient compliance

Drug delivery capabilities also provide companies the ability to protect the improved drugs by allowing patent protection to the differentiated drugs the technologies provide. Market exclusivity can also be granted for improvements to existing drugs. BCC Research estimated the global drug delivery market to worth an estimated $188 billion in 2014 and that the market grew to $194 billion in 2015. 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 2015, FDA's Center for Drug Evaluation and Research ("CDER") approved 41 novel new drugs, 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). Additionally, the FDA approved 82 "first time generic drugs" (FDA, ANDA (Generic) Drug Approvals in 2015, www.fda.gov).

Market opportunities for its current proprietary pipeline are estimated by Flamel to be worth at least several hundred million dollars each. For example, Xyrem® (sodium oxybate) recorded $955 million in sales in the U.S. for 2015 (source: Jazz press release Full Year And Fourth Quarter 2015 Financial Results, February 23, 2016); OTC ibuprofen products recorded sales in the U.S. beyond $480 million including combination products in 2015 (source: IMS). The U.S. cough, cold, pain and allergy markets targeted by our LiquiTime-based products, is estimated between $6 billion and $8 billion annually – (source: Nielsen Data Trend). Sales of GLP-1 drugs exceeded $3 billion in 2015 according to IMS and the U.S. market for prescription painkillers exceeded $7 billion in 2015 (source: IMS).

The industry faces many challenges. There are four main forces currently affecting all pharmaceutical and drug delivery companies and forcing the industry to adapt and to change: (i) the rise of generics; (ii) the rise in costs for new product development; (iii) the commoditization and acquisition of drug delivery technologies; (iv) the integration of the drug delivery-based formulation development occurs at much earlier stage in the overall pharmaceutical development; and (v) the higher regulatory and reimbursement hurdles.

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. Alternatively, 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. 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 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, is a competitive advantage. 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 through 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.

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

Flamel's Micropump platform permits either extended or delayed 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 Cmax 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 "– Lead Products") in this Part I, Item 1 of this Annual Report on Form 10-K. Flamel currently has additional Micropump-based internal products in development including sodium oxybate for narcolepsy, which has been successfully tested in two Phase 1 clinical studies; see "– Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K).

Micropump (and related products) is patent protected (see "– Proprietary Intellectual Property"). Coreg CR® Micropump-based microparticles are now being manufactured for GSK by Recipharm (see "– Strategic Alliances" in this Part I, Item 1 and "– Manufacturing" in this Part I, Item 1 of this Annual Report on Form 10-K).

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

The U.S. sales of drugs (Rx and OTC) in liquid form for oral administration exceeded $5.8 billion for the year 2015 (source: IMS). Amongst marketed "extended release" (twice-a-day or once-daily) liquid products are Tussionex® (hydrocodone polistirex and chlorpheniramine polistirex) and its branded and generic alternatives, Delsym® and Delsym Children® (dextromethorphan polistirex developed and sold by Reckitt Benckiser plc.) and Quillivant XR marketed by Pfizer. These products totaled $249 million sales in 2015 (source: IMS).

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. 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. 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 described two LiquiTime-based products in development: ibuprofen LiquiTime and guaifenesin LiquiTime both successfully tested in FIM clinical studies. The rights to these products along with the LiquiTime technology has been licensed to Elan Pharm International Limited for U.S. OTC rights. The first pivotal clinical study could be expected to be initiated as early as in the end of 2016 with respect to these products (see "Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K).

LiquiTime (and related products) is patent protected (see "– Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

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 2015, the U.S. sales of oral opioid drugs (hydrocodone, hydromorphone, morphine, oxycodone and oxymorphone, including combination products) exceeded $6.4 billion (source: IMS).

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, hydromorphone, under development for which certain PK and independent in-vitro abuse resistance data was gathered in 2015; a pivotal clinical study is expected to be initiated in 2016 (see "– Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K).
- Trigger Lock (and related products) is patent protected (see "– Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

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

U.S. sales for injectable products in 2015 were $132 billion, including nearly $16 billion for "long-acting" products (source: IMS). Conversely, global sales of biologics were between $190 to $222 billion in 2014 according to various analysts, and are expected to exceed $386 billion by 2019 (source: 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. 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 was completed in 2014 in order to update the Type IV Drug Master File ("DMF") filed with the FDA in February 2011.

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 Cmax 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 (Cmax 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 one Medusa-based internal product in development (see "– Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K). Flamel completed a Phase 1(a) study of its once-a-week Medusa exenatide product in 2015 and initiated a Phase 1(b) study in Q1 2016.

Medusa is patent protected until June 2031 in the United States (see "– Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

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 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. As of December 31, 2015, we owned the following patent and patent applications:

	US	EUROPE	ROW*	TOTAL
Granted patents	15	170	99	284
Pending patent applications	12	14	42	68
Patents granted in 2015	1	2	16	19
Patent applications filed in 2015	5	1	9	15

* ROW: Rest of the World

The Company's granted patents protecting its drug delivery platforms have the following latest dates of expiration by technology platform:

Drug Delivery Platforms	Date of expiration of granted patents	
	U.S.	Europe
Micropump®	July 2027	May 2030
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026
Medusa™	June 2031	November 2024

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 3 continuation application are pending in the U.S.

- **Trigger Lock™ platform** is protected by 7 (seven) Flamel's patent application families. Within these patent families, 12 (twelve) patents are granted in the U.S., Europe and Japan; and, 20 (twenty) 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 (see "Note 17: Discontinued Operations to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). 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. Additionally, 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.

In 2014 about 41% of our revenues came from partnerships. Today, however, the Company's business is financially less dependent on its need to work with partners to develop products using our drug delivery platforms. By design, we now have revenue generating marketed products and products in late stage development that are not dependent on these partnerships (see "– Lead Products" in this Part I, Item 1 and "– Other Products Under Development" in this Part I, Item 1 of this Annual Report on Form 10-K).

Nonetheless, 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 marketing unit, 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"). 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.

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 Vazculep, the FDA has required the Company to conduct post-marketing clinical and non-clinical studies to be completed between 2016 and 2019.

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.

Item 1A. 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 10-K, 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 products or customers could reduce our revenues significantly.

We derive a majority of our revenues from sales of two 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. Three customers, AmeriSource Bergen, Cardinal and McKesson accounted for approximately 95% of revenues from sales of these products in 2015. 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, and any such inability could have a material adverse effect on our business, results of operations, financial condition and prospects.

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 Trigger Lock based-hydromorphone and Medusa based-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, as we did with respect to the license to Elan for the OTC rights for LiquiTime (see "– Products In Development With Partners" in this Part I, Item 1 of this Annual Report on Form 10-K).

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 additional 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, development of products that utilize our drug delivery platforms, and the continued development and marketing of the products we obtained in the FSC acquisition in February 2016. If any of the UMDs products, products incorporating our drug delivery platforms, or FSC products fail to reach the commercial market, our future revenues would be adversely affected.

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

- the 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 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 2015, we spent $25.6 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 "Business – Information on the Company" in this Part I, Item 1 of this Annual Report on Form 10-K. 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 all of our drug products. 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 "Business – Competition and Market Opportunities" in this Part I, Item 1 of this Annual Report on Form 10-K). 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.

With respect to our UMD drug products, the FDA could approve generic versions or previously filed NDAs of our marketed products, as was the case with the approval of APP's (a division of Fresenius Kabi USA, LLC) and Eurohealth International's (an affiliate of West-Ward Pharmaceuticals Corp.) neostigmine methylsulfate products, competitive products to Bloxiverz in January and December 2015 respectively.

With respect to our pediatric products acquired from FSC, we have competitors selling products in both the OTC and the prescription markets. Many of these competitors have greater market shares for their products and have leverage in the physician's office and in the retail distribution channel. As a result of these dynamics, we could have competitors with a greater share of voice in the market, which would impede our ability to grow the FSC products.

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 third party payors choose not to reimburse the use of our pediatric products our sales and profitability could suffer.

Because several of the categories in which we participate are available on an over-the-counter basis (OTC) some insurance programs may drive consumers to those products by requiring large co-pays for our products. In some cases this could require a patient failure with OTCs before our products are allowed to be used. Additionally, some health plans may prefer generic alternatives in our therapeutic categories, which is manifested by requiring higher copays for our products. Other health plans could omit coverage for our products altogether. Any of these types of dynamics could negatively impact the sale of our products.

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 pursue our business strategy.

Our business strategy is to obtain FDA approval and commercialize certain UMD product candidates, continue to develop and commercialize our drug delivery platforms, develop and market the FSC products and identify and acquire additional businesses or new product opportunities. There can be no assurance that we will be successful in any of these objectives; and a failure in any of these objectives could negatively impact our business and operating results.

In particular, we may be unable to successfully identify attractive acquisition candidates or complete any acquisitions, or successfully integrate any acquired business, product or technology or retain any key employees of acquired businesses. 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.

The impact of the acquisition of FSC on our financial results may be worse than the assumptions we have used.

Even if the integration of the FSC business is successful, we have made certain assumptions relating to the impact on our financial results in respect of the acquisition. These assumptions relate to numerous matters, including:

- the amount of intangible assets that will result from the acquisition;
- the impact of fair value adjustments to contingent acquisition consideration payable as a result of changes in estimated probability and timing of achieving the targets;
- acquisition costs, including transaction and integration costs;
- the impact of impairment and other charges if the FSC products are unsuccessful; and
- other financial and strategic risks of the acquisition.

Irrespective of our assumptions, we may incur higher than expected operating, transaction and integration costs, and we may encounter general economic and business conditions that adversely affect us following the acquisition. If one or more of these assumptions are incorrect, it could have an adverse effect on our business and operating results, and the perceived benefits from the acquisition may not be realized.

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, or competitors may obtain patents that may have an adverse effect on our ability to conduct business or discover ways 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, as well as 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, 2015, we derived 100% of our total revenues from continuing operations from transactions in U.S. dollars, but have 24% of our cash and cash equivalents, and 28% 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.

We may not maintain an effective system of internal control over financial reporting, which could harm our business and financial results.

During its evaluation of the effectiveness of internal control over financial reporting as of December 31, 2015, our management identified material weaknesses related to: lack of sufficient personnel, resulting in, among other things, a failure to implement a proper segregation of duties; ineffective controls over the revenue, income tax, and financial close processes; ineffective controls over information technology and key spreadsheets used in preparing financial statements; and ineffective monitoring of our internal control systems. See Item 9A. Disclosure Controls and Procedures. While we have begun to implement measures that we believe are necessary and appropriate to address these material weaknesses, we cannot assure you that our efforts will prove wholly successful in remediating these material weaknesses. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of these material weaknesses, actual expenses may exceed our current estimates and may be material. In addition, we cannot assure you that we have identified all these material weaknesses, or that we will not identify other these material weaknesses in the future. If we are unable to successfully identify and remediate any material weakness that may exist in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements and applicable stock exchange listing requirements regarding timely filing of periodic reports, our stock price may decline, and we could be subject to shareholder litigation.

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, or other members of our senior executive team, 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 Vazculep, the FDA has required the Company to conduct post-marketing non-clinical and clinical studies to be completed between 2016 and 2019.

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 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 on 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 €10 million and product liability and recall insurance with a limit of €10 million. 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, 2015, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $11.50 to $25.69. 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. 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.

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

Prior to 2015, we had a history of operating losses and have accumulated aggregate net loss from our inception of approximately $281.5 million through December 31, 2015. 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 businesses. 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, develop new products, or acquire additional products and businesses. 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 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 ADSs) 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 impracticable 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.

As of February 16, 2016, Broadfin Capital and certain of its affiliates beneficially owned approximately 10.85% of our outstanding shares (in the form of ADRs), Janus Capital Management, LLC and certain of its affiliates beneficially owned 10.72% of our outstanding shares (in the form of ADRs) and Deerfield Capital and certain of its affiliates beneficially owned approximately 10.06% of our outstanding shares (in the form of ADRs). 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 1B. Unresolved Staff Comments

None.

Item 2. Properties

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 expired in 2015 and is expected to be renewed. 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.

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 Note 17: Discontinued Operations to the consolidated financial statements in Item II, Part 8 of this Annual Report on Form 10-K).

We have commercial and administrative activities located in Chesterfield, Missouri. In November 2015, we relocated to new office space in Chesterfield, Missouri. The office space consists of 12,100 square feet, and the lease expires in 2020. We still maintain the lease on our former office space which expires in 2018. Additionally, we have commercial and administrative activities located in Charlotte, North Carolina. This office space consists of 6,300 square feet, and the lease expires in 2020

We have intellectual property, clinical, quality, regulatory, and supply chain activities located in Dublin, Ireland. The office space consists of 5,059 square feet and the lease expires in 2025.

During 2015, we expended $1.6 million on property and equipment essentially limited to maintenance and investment in a global ERP.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K for more information regarding our investment activities and principal capital expenditures over the last three years.

Item 3. 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Common Stock Data (per share) (Unaudited):

The principal trading market for the Company's securities in ADSs is the NASDAQ Global Market. There is no foreign trading market for the Company's ordinary shares, ADSs or any other equity security issued by the Company. Each ADS represents one ordinary 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 March 7, 2016, there were 40,234,506 ADSs outstanding, and the closing stock price of the Company was $8.67 per share.

The following table reports the high and low trading prices of the ADSs on the NASDAQ Market for the periods indicated.

	2015 Price Range		2014 Price Range	
	High	Low	High	Low
First Quarter	$ 18.47	$ 11.50	$ 14.70	$ 8.15
Second Quarter	22.32	13.88	15.17	9.94
Third Quarter	25.69	15.37	15.78	13.21
Fourth Quarter	19.27	12.21	18.89	11.76

Holders

As of March 7, 2016 there were 30 holders of record of our Ordinary Shares or ADSs. Because almost all of our ordinary shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of individual shareholders represented by these record holders.

Dividends

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.

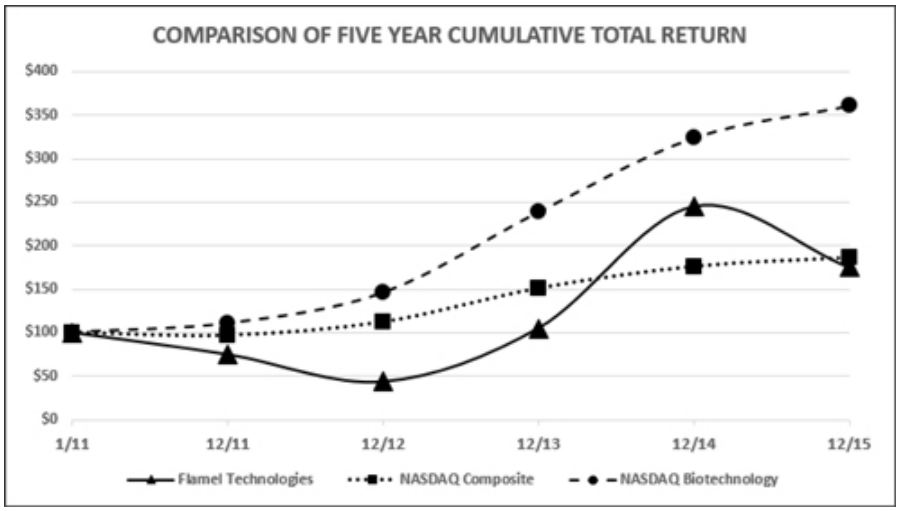
Securities authorized for issuance under equity compensation plans

Information regarding our equity compensation plans is presented below as of December 31, 2015 (in thousands, except per share data).

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Stock options	2,326	$ 13.84	97
Warrants	668	$ 16.97	45
Free share awards	226	n/a	250

Stock performance graph

The following graph compares the cumulative 5-year return provided to stockholders of Flamel's ADSs relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. We believe these indices are the most appropriate indices against which the total shareholder return of Flamel should be measured. The NASDAQ Biotechnology Index has been selected because it is an index of U.S. quoted biotechnology and pharmaceutical companies. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our ADSs and in each of the indexes on January 1, 2011 and its relative performance is tracked through December 31, 2015. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, nor intended to forecast, the potential future performance of our stock.



Notwithstanding anything to the contrary set forth in any of our filings under the Securities Act of 1933, or the Exchange Act that might incorporate future filings, including this annual report on Form 10-K, in whole or, in part, the performance graph presented above shall not be incorporated by reference into any such filings.

Item 6. Selected Financial Data (in thousands, except per share amounts)

Annual Financial Data:

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes and Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II of this Report.

	2015	2014	2013	2012	2011
Statement of Income Data:					
Revenues	**$ 173,209**	$ 14,775	$ 4,179	$ 7,534	$ 9,238
Gross profit (a)	**162,288**	11,392	3,617	20,241	26,316
Operating income (loss)	**71,447**	(93,857)	(53,700)	(8,363)	(9,583)
Net income (loss) from continuing operations	**40,659**	(88,924)	(46,509)	(4,740)	(11,449)
Net income (loss) from discontinued operations	-	4,018	3,584	1,512	2,675
Net income (loss)	**40,659**	(84,906)	(42,925)	(3,228)	(8,774)
Earnings (loss) per share - Basic:					
Continuing operations	**1.00**	(2.45)	(1.83)	(0.19)	(0.46)
Discontinued operations	-	0.11	0.14	0.06	0.11
Net income (loss)	**1.00**	(2.34)	(1.69)	(0.13)	(0.36)
Earnings (loss) per share - Diluted:					
Continuing operations	**0.93**	(2.45)	(1.83)	(0.19)	(0.46)
Discontinued operations	-	0.11	0.14	0.06	0.11
Net income (loss)	**0.93**	(2.34)	(1.69)	(0.13)	(0.36)

(a) Gross margin is computed by subtracting cost of products and services sold from total revenues.

	2015	2014	2013	2012	2011
Balance Sheet Data:					
Cash and cash equivalents	**$ 65,064**	$ 39,760	$ 6,636	$ 2,742	$ 3,456
Marketable securities	**79,738**	53,074	401	6,413	21,035
Goodwill	**18,491**	18,491	18,491	18,491	-
Intangible assets, net	**15,825**	28,389	40,139	41,589	-
Total assets	**214,977**	174,205	116,252	117,311	69,402
Long-term debt (incl. current portion)	**1,118**	3,717	30,249	10,409	3,715
Long-term contingent consideration payable (incl. current portion)	**122,693**	114,750	55,265	26,220	-

Quarterly Financial Data (Unaudited):

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2015 and 2014. Year-to-date Earnings (loss) per share amounts may be different than the sum of the applicable quarters due to differences in weighted average shares outstanding for the respective periods.

	March 31	June 30	September 30	December 31
2015:				
Revenues	$ 32,726	$ 49,795	$ 47,320	$ 43,368
Gross profit (a)	29,096	47,039	45,233	40,920
Operating income (loss)	10,214	(1,177)	(14,479)	76,889
Net income (loss)	11,647	(17,400)	(29,685)	76,097
Net income (loss) per share - Basic	0.29	(0.43)	(0.73)	1.85
Net income (loss) per share - Diluted	0.27	(0.43)	(0.73)	1.75
2014:				
Revenues	$ 4,578	$ 4,318	$ 2,913	$ 2,966
Gross profit (a)	3,805	3,811	2,206	1,570
Operating loss	(24,231)	(19,399)	(16,739)	(33,488)
Net loss from continuing operations	(26,861)	(20,200)	(9,980)	(31,883)
Net income (loss) from discontinued operations	223	(873)	(66)	4,734
Net loss	(26,638)	(21,073)	(10,046)	(27,149)
Earnings (loss) per share - Basic:				
Continuing operations	(0.95)	(0.53)	(0.26)	(0.81)
Discontinued operations	0.01	(0.02)	-	0.12
Net income (loss)	(0.94)	(0.55)	(0.26)	(0.69)
Earnings (loss) per share - Diluted:				
Continuing operations	(0.95)	(0.53)	(0.26)	(0.81)
Discontinued operations	0.01	(0.02)	-	0.12
Net income (loss)	(0.94)	(0.55)	(0.26)	(0.69)

(a) Gross margin is computed by subtracting cost of products and services sold from total revenues.

The quarter ended September 30, 2015 includes the unfavorable correction to revenue of $1,193, which should have been recorded in the second quarter of 2015, and is due to the fact that the Company incorrectly recorded revenue in the second quarter of 2015 as a result of improper reconciliation to revenue data communicated by service providers.

The quarter ended December 31, 2015 includes the unfavorable correction to revenue of $1,200 with respect to the Company’s rebate calculations which should have been recorded in the third quarter of 2015.

The quarter ended December 31, 2015 includes the favorable correction to net income (loss) of $1,969 with respect to tax benefits from stock-based compensation which should have been recorded in prior periods ($359 in 2012, $333 in 2013, $(692) in the first quarter of 2014, and $618, $814 and $537 in the first, second and third quarter of 2015 respectively).

The impact of these errors was not material to any prior periods. In addition, the cumulative impact of the corrections was not material to the Company's consolidated financial statements for the quarter ended September 30, 2015, the quarter ended December 31, 2015 or the year ended December 31, 2015.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Management's Discussion And Analysis
(In Thousands, Except Per Share Data)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 7 together with our consolidated financial statements and the related notes appearing elsewhere in this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Disclosure Regarding Forward-Looking Statements" set forth immediately following the Table of Content of this annual report on Form 10-K for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section of this annual report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this annual report on Form 10-K.

Overview

We are a specialty pharmaceutical company utilizing core competencies in drug delivery and formulation to develop safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. Flamel has a balanced business model consisting of a successful previously Unapproved Marketed Drugs ("UMDs") business with two marketed products in the USA, Bloxiverz and Vazculep, and a branded development business, focusing on the development of products utilizing Flamel's proprietary drug delivery platforms. The branded products are based on proprietary drug delivery platforms and target high-value solid oral and alternative dosage forms using 505(b)(2) and Biosimilar pathways where the Company can develop strong intellectual property positions and deliver meaningful patient benefits. Flamel's business model allows the Company to select, develop, seek approval for, and commercialize niche branded and generic products, initially targeted for the U.S. market. The Company is able to self-fund the development of most product development opportunities.

Strategy

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

- ***Unapproved Marketed Drug Development***: The Company now derives cash flow and profitability from the sales of two of its UMD products. During 2015 the Company generated $172,488 of sales from the UMD products compared to $11,993 in 2014. The first UMD product, Bloxiverz, which had sales of $150,283 in 2015 was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S. The second UMD product, Vazculep, which had sales of $20,251 in 2015, 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. These sales were derived from the acquisition of Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) regulatory pathway. Through our acquisition of Éclat we obtained marketing and licensing knowledge of the commercial and regulatory process in the U.S. and EU. We believe this knowledge has enhanced our ability to identify product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and license and market products in the U.S and EU. The revenues from these UMD products are now generating cash flow which we can use to fund our second strategy, the development and commercialization of our drug delivery products.

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

    - **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.

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

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

The key elements of our pipeline strategy include:

- 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;
- Developing and validating additional drug delivery platforms utilizing our current drug delivery platforms

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

Key Business Trends and Highlights

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

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

Highlights of our consolidated results for the year ended December 31, 2015 are as follows:

- Revenue was $173,209 for the year ended December 31, 2015 compared to $14,775 in the same period last year. This substantial increase was the result of product launches in 2014 which had a full year’s worth of revenues in 2015.
- Operating income was $71,447 compared to an operating loss of ($93,857) in 2014.
- Net Income was $40,659 compared to a net loss of ($84,906) in 2014.
- Diluted net income per share was $0.93, compared to diluted net loss of ($2.34) in 2014.
- Cash and marketable securities increased $51,968 to $144,802 from $92,834 at December 31, 2014.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. Actual results could differ from those estimates under different assumptions or conditions.

The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

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

Product Sales and Services

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

For generic products and branded products sold in mature and stable markets where changes in selling price are rare, the Company recognizes revenues upon shipment. For products where market conditions remain volatile and selling price is subject to changes, which is the Company's situation in 2015, 2014 and 2013, the Company delays revenue recognition until the wholesaler sells the product to its customers. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, 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.

License and Research Revenue

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

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

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

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

- 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.

When Flamel receives revenue under signed feasibility study agreements, revenue is then recognized over the term of the agreement as services are performed.

R&D. Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development costs. Clinical study and outside services costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third party fees. Personnel expenses relate primarily to salaries, benefits and stock-based compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred.

The Company recognizes R&D tax credits received from the French government for spending on innovative R&D as an offset of R&D expenses.

The Company does not track fully-burdened research and development expenses on a project-by-project basis. We manage our R&D expense by identifying the research and development activities we anticipate will be performed during a given period and then prioritizing efforts based on scientific data, probability of successful development, market potential, available human and capital resources and other similar considerations. We continually review our pipeline and the development status of product candidates and, as necessary, reallocate resources among the research and development portfolio that we believe will best support the future growth of our business.

Long-Lived Assets. Long-lived assets include fixed assets and intangible assets. 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.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant unanticipated changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. There were no indications of impairment as of December 31, 2015 or 2014.

Contingent Consideration. The acquisition-related contingent consideration payable arising from the acquisition of Éclat Pharmaceuticals are accounted at fair-value (see Note 8 : Long-Term Contingent Consideration Payable). The fair value of warrant consideration is estimated on a quarterly basis using a Black-Scholes option pricing model, and the fair value of earn-out payment consideration is estimated on a quarterly basis using a discounted cash flow model based on probability-adjusted annual gross profit of the specified Éclat Pharmaceuticals products at an appropriate discount rate. Changes in fair value are recorded in the consolidated statements of operations within operating expenses as changes in fair value of related party acquisition-related contingent consideration.

The Company elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the Deerfield and Broadfin Royalty Agreements (see Note 8 : Long-Term Contingent Consideration Payable). The fair value of royalty agreement consideration is estimated on a quarterly basis using a discounted cash flow model based on probability-adjusted annual revenues of the specified Éclat Pharmaceuticals products at an appropriate discount rate. Changes in fair value are recorded in the consolidated statements of operations as Interest expense - changes in fair value of related party financing-related contingent consideration.

Discontinued Operations. The Company followed the guidance in Financial 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 of the Pessac facility. In 2014, the Company opted to early adopt the provisions of ASU 2014-08 as management believed that all criteria for presenting the disposal of Pessac Facility and its business as a discontinued operation were met, and that presenting the disposal as a discontinued operation would better reflect the ongoing operations of the entity.

The divestiture of the Pessac facility represented a strategic shift that had and will have a major effect on the Company’s operations and financial results. Since 2012, the Company’s business model of combining novel, high-value internally developed products with its leading drug delivery capabilities and commercializing 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 of the Pessac facility 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 was 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 is considered to be 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 consolidated statements of operations. The assets and liabilities of the discontinued operation have been reported separately in the asset and liability sections of the consolidated statements of financial position for the periods presented in the statement. Note 17: Discontinued Operations contains 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 consolidated statements of operations, financial position and cash flows relative to the disposal group.

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

Results of Operations

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

	Years Ended December 31,			Increase / (Decrease) 2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Product sales and services	**$ 172,488**	$ 11,993	$ 1,153	$ 160,495	1,338.2%	$ 10,840	940.2%
License and research revenue	**721**	2,782	3,026	(2,061)	(74.1)%	(244)	(8.1)%
Total revenues	**173,209**	14,775	4,179	158,434	1,072.3%	10,596	253.6%
Cost of products and services sold	**10,921**	3,383	562	7,538	222.8%	2,821	502.0%
Research and development expenses	**25,608**	17,298	15,966	8,310	48.0%	1,332	8.3%
Selling, general and administrative expenses	**21,712**	15,698	13,216	6,014	38.3%	2,482	18.8%
Intangible asset amortization	**12,564**	11,749	-	815	6.9%	11,749	*n/a*
Changes in fair value of acquisition-related contingent consideration	**30,957**	57,491	28,135	(26,534)	(46.2)%	29,356	104.3%
Loss on early repayment of related party acquisition-related note	**-**	3,013	-	(3,013)	(100.0)%	3,013	*n/a*
Total operating expenses	**101,762**	108,632	57,879	(6,870)	(6.3)%	50,753	87.7%
Operating income (loss)	**71,447**	(93,857)	(53,700)	165,304	176.1%	(40,157)	(74.8)%
Investment Income	**2,651**	963	254	1,688	175.3%	709	279.1%
Interest Expense	**(1,415)**	(5,747)	(2,602)	4,332	75.4%	(3,145)	(120.9)%
Interest Expense - changes in fair value of financing-related contingent consideration	**(4,883)**	(3,525)	(1,990)	(1,358)	(38.5)%	(1,535)	(77.1)%
Foreign exchange gain (loss)	**10,594**	11,871	(288)	(1,277)	(10.8)%	12,159	4,221.9%
Income (loss) before income taxes	**78,394**	(90,295)	(58,326)	168,689	186.8%	(31,969)	(54.8)%
Income tax provision (benefit)	**37,735**	(1,407)	(11,244)	39,142	2,781.9%	9,837	87.5%
Net income (loss) from continuing operations	**40,659**	(88,888)	(47,082)	129,547	145.7%	(41,806)	(88.8)%
Net income from discontinued operations	**-**	4,018	3,584	(4,018)	(100.0)%	434	12.1%
Net income (loss)	**$ 40,659**	$ (84,870)	$ (43,498)	$ 125,529	147.9%	$ (41,372)	(95.1)%
Earnings (loss) per share - Diluted	**$ 0.93**	$ (2.34)	$ (1.69)	$ 3.28	139.8%	$ (0.66)	(39.0)%

Revenues

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

	Years Ended December 31,			Increase / (Decrease) 2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Bloxiverz	**$ 150,283**	$ 10,211	$ -	$ 140,072	1,371.8%	$ 10,211	*n/a*
Vazculep	**20,151**	-	-	20,151	*n/a*	-	-
Dextroamphetamine	**1,946**	1,643	-	303	18.4%	1,643	*n/a*
Other	**108**	139	1,153	(31)	(22.3)%	(1,014)	(87.9)%
Total product sales and services	**172,488**	11,993	1,153	160,495	1,338.2%	10,840	940.2%
License and research revenue	**721**	2,782	3,026	(2,061)	(74.1)%	(244)	(8.1)%
Total revenues	**$ 173,209**	$ 14,775	$ 4,179	$ 158,434	1,072.3%	$ 10,596	253.6%

2015 Compared to 2014

Product sales and services revenues were $172,488 for the year ended December 31, 2015, compared to $11,993 for the prior year. This represents a $160,495 increase in 2015 from 2014. The primary driver of growth was higher sales of Bloxiverz® of $140,072 resulting from volume increases due to market share gains and, to a lesser degree, higher net selling prices. Bloxiverz® was launched in 2014. Additional sales volume resulting from the 2015 launch of Vazculep® also contributed to the sales increase and generated $20,151 of higher sales when compared to the same period last year.

License and research revenues were $721 for the year ended December 31, 2015, compared to $2,782 for the prior year. This represents a $2,061 decrease in 2015 from 2014, largely driven by the termination of remaining development partnership contracts as the Company continues to pursue its strategy of depending less on the development activities performed by partners, and more on the development of its own, self-funded, products.

2014 Compared to 2013

Product sales and services revenues were $11,993 for the year ended December 31, 2014, compared to $1,153 for the prior year. This represents a $10,840 increase in 2014 from 2013. The primary driver of growth was additional sales volume of $10,211 resulting from the 2014 launch of Bloxiverz®.

License and research revenues were fairly consistent between the years ended December 31, 2014 and 2013.

Cost of Products and Services Sold

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Cost of products and services sold	**$ 10,921**	$ 3,383	$ 562	$ 7,538	222.8%	$ 2,821	502.0%
Percentage of sales	**6.3%**	22.9%	13.4%				

Cost of products and services sold increased $7,538 during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to increases in respective product sales and services. As a percentage of sales, cost of products sold decreased to 6.3% in 2015 compared to 22.9% in 2014 due primarily to higher sales volumes and a favorable change in product mix.

Cost of products and services sold increased $2,821 during the year ended December 31, 2014 as compared to the same period in 2013 primarily due to increases in respective product sales and services. As a percentage of sales, cost of products sold increased to 22.9% in 2014 compared to 13.4% in 2013 primarily due to an unfavorable change in product mix.

Research and Development Expenses

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Research and development expenses	**$ 25,608**	$ 17,298	$ 15,966	$ 8,310	48.0%	$ 1,332	8.3%
Percentage of sales	**14.8%**	117.1%	382.1%				

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

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Salaries and employee benefits	**$ 9,466**	$ 12,420	$ 8,395	$ (2,954)	(23.8)%	$ 4,025	47.9%
Clinical studies and outside services	**17,196**	6,844	9,211	10,352	151.3%	(2,367)	(25.7)%
Other	**4,258**	4,049	4,591	209	5.2%	(542)	(11.8)%
Government grants and R&D tax credit	**(5,312)**	(6,015)	(6,231)	703	11.7%	216	3.5%
Total research and development expenses	**$ 25,608**	$ 17,298	$ 15,966	$ 8,310	48.0%	$ 1,332	8.3%

Research and development expenses increased $8,310 or 48.0% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to higher clinical studies and outside services costs including a $2,300 filing fee for the third Éclat product and the Company's overall continued investment in its pipeline products. These costs were partially offset by a decrease in salaries and employee benefits which were driven largely by changes in foreign exchange rates and a decrease in certain employee benefits in 2015 relative to 2014.

Research and development expenses increased $1,332 or 8.3% during the year ended December 31, 2014 as compared to the same period in 2013 primarily due primarily to increases in certain employee benefits, partially offset by approximately $2,000 for Vazculep filing fees made in 2013 that did not repeat in 2014.

Selling, General and Administrative Expenses

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Selling, general and administrative expenses	**$ 21,712**	$ 15,698	$ 13,216	$ 6,014	38.3%	$ 2,482	18.8%
Percentage of sales	**12.5%**	106.2%	316.2%				

Selling, general and administrative expenses increased $6,014 or 38.3% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to higher stock-based compensation expenses of $4,356 and additional employee recruitment costs associated with the Company's efforts to reinforce its management team.

Selling, general and administrative expenses increased $2,482 or 18.8% during the year ended December 31, 2014 as compared to the same period in 2013 primarily due to increased 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 the Company's intellectual property from our French entity to our Irish-based entity.

Intangible Asset Amortization

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Intangible asset amortization	**$ 12,564**	**$ 11,749**	**$ -**	$ 815	6.9%	$ 11,749	*n/a*
Percentage of sales	**7.3%**	79.5%	-				

Intangible asset amortization expense increased $815 or 6.9% during the year ended December 31, 2015 as compared to the same period in 2014 due to the commencement of amortization related to the acquired In-Process R&D ("IPR&D") Vazculep intangible asset upon the product's launch in 2015.

Intangible asset amortization expense increased $11,749 during the year ended December 31, 2014 as compared to the same period in 2013 due to the commencement of amortization related to the acquired IPR&D Bloxiverz intangible asset upon the product's launch in 2014.

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

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Changes in fair value of related party acquisition-related contingent consideration	**$ 30,957**	$ 57,491	$ 28,135	$ (26,534)	(46.2)%	$ 29,356	104.3%
Percentage of sales	**17.9%**	389.1%	673.2%				

Changes in fair value of related party acquisition-related contingent consideration decreased $26,534 or 46.2% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to decreases in the changes in fair value of warrants of $37,970 driven by a reduction in the Company's stock price, which were partially offset by increases in the changes in fair value of the earn-out payments liability of $11,436 due to changes in the associated long-term product sales forecasts.

Changes in fair value of related party acquisition-related contingent consideration increased $29,356 or 104.3% during the year ended December 31, 2014 as compared to the same period in 2013 primarily due to increases in the changes in fair value of the earn-out payments liability of $18,642 driven by changes in the associated long-term product sales forecasts and increases in the fair value of warrants of $15,075 driven largely by an increase in the Company's stock price.

Income Taxes

	Years Ended December 31,			Increase / (Decrease)			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Income tax provision (benefit)	**$ 37,735**	$ (1,407)	$ (11,244)	$ 39,142	2,781.9%	$ 9,837	87.5%
Percentage of income (loss) before income taxes	**48.1%**	1.6%	19.5%				

The items accounting for the difference between the income tax provision (benefit) computed at the French statutory rate and the Company's effective tax rate are as follows for the years ended December 31:

	2015	2014	2013
Statutory tax rate	**33.3%**	33.3%	33.3%
Non-deductible changes in fair value of contingent consideration	**13.8%**	(24.7)%	(16.6)%
Change in valuation allowance	**(9.5)%**	5.2%	(4.5)%
Income tax deferred charge	**-**	(16.9)%	-
International tax rates differential	**10.9%**	6.7%	6.2%
Other	**(0.4)%**	(2.0)%	1.1%
Effective income tax rate	**48.1%**	1.6%	19.5%
Income tax provision (benefit) - at Statutory tax rate	**$ 26,105**	$ (30,080)	$ (19,232)
Non-deductible changes in fair value of contingent consideration	**10,835**	22,326	9,592
Change in valuation allowance	**(7,425)**	(4,732)	2,616
Income tax deferred charge	**-**	15,273	-
International tax rates differential	**8,559**	(6,026)	(3,609)
Other	**(339)**	1,832	(611)
Income tax provision (benefit) - at Effective income tax rate	**$ 37,735**	$ (1,407)	$ (11,244)

The Company's effective tax rates for the years ended December 31, 2015, 2014 and 2013 were 48.1%, 1.6% and 19.5%, respectively. Increased expenses reported during 2015, 2014 and 2013 due to changes in fair value of contingent consideration are not deductible for income tax purposes, and therefore unfavorably impact the Company's effective income tax rate. In 2013, valuation allowances were placed against the deferred tax assets generated by pre-tax losses in France. In 2014, the Company entered into an intra-entity transaction to transfer intellectual property from France to Ireland which resulted in a charge of $15,273 after utilization of net operating loss carryforwards that were previously fully reserved with a valuation allowance. In 2015 certain valuation allowances were reversed with respect to pre-tax income of our U.S. and French operations as the Company had sufficient taxable income to utilize net operating losses. These rates also reflect the additional tax impacts of the Company's significant U.S. operations at a higher statutory tax rate than the French statutory tax rate, and in 2015 are additionally unfavorably impacted by losses incurred at our Irish entity at a lower statutory tax rate.

Net Income From Discontinued Operations

	Years Ended December 31,			*Increase / (Decrease)*			
				2015 vs. 2014		2014 vs. 2013	
	2015	2014	2013	$	%	$	%
Net income from discontinued operations	**$ -**	$ 4,018	$ 3,584	$ (4,018)	(100.0)%	$ 434	12.1%

On December 1, 2014, Flamel divested its Pessac Facility to Recipharm AB ("Recipharm"). Under the divestiture agreement, Recipharm paid the Company $13,200. 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. As part of the divestiture agreement, as of December 1, 2014 the Company transferred to Recipharm the Supply Agreement and the associated royalties pertaining to Coreg CR® under the License agreement with GSK to Recipharm. 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 17 – Discontinued Operations to the Consolidated Financial Statements in "Item 8. Financial Statements").

The divestiture of the Pessac Facility has been classified as Discontinued Operations for the twelve months ended December 31, 2015, 2014 and 2013, with net income attributable to such Discontinued Operations of $0, $4018 and $3,584, respectively. The gain on sale of the Pessac Facility in 2014 amounted to $5,007.

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

	2015	2014	2013
Revenues	**$ -**	$ 14,967	$ 18,265
Operating income (loss)	-	(875)	3,667
Gain on disposal	-	5,007	-
Interest Expense	-	(4)	(9)
Income tax provision (benefit)	-	110	74
Net income from discontinued operations	**$ -**	**$ 4,018**	**$ 3,584**

Liquidity and Capital Resources

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

				Increase / (Decrease)			
	Years Ended December 31,			**2015 vs. 2014**		**2014 vs. 2013**	
	2015	**2014**	**2013**	**$**	**%**	**$**	**%**
Net cash provided by (used in):							
Operating activities	**$ 84,293**	$ (10,618)	$ (20,676)	$ 94,911	893.9%	$ 10,058	48.6%
Investing activities	**(31,730)**	(43,083)	6,045	11,353	26.4%	(49,128)	(812.7)%
Financing activites	**(23,751)**	95,995	18,274	(119,746)	(124.7)%	77,721	425.3%

Operating Activities

Net cash provided by operating activities of $84,293 for the year ended December 31, 2015 increased $94,911 from the same prior year period. The primary driver of this growth was a $96,574 increase in net income after adjusting for non-cash changes in fair value of contingent consideration and depreciation and amortization expenses.

Net cash used in operating activities of $10,618 for the year ended December 31, 2014 decreased $10,058 from the same period in 2013. The primary driver of this for this decrease in the use of cash related to proceeds in 2014 of $13,210 from the French Government for R&D credits for the reimbursement of a portion of R&D expenses.

Investing Activities

Cash used in investing activities of $31,730 for the year ended December 31, 2015 decreased $11,353 compared to the same prior year period. This decrease was primarily driven by lower use of cash for net purchases of marketable securities of $24,496, which was partially offset by $13,242 of proceeds from the sale of the Pessac facility in 2014 that did not repeat in 2015.

Cash used in investing activities of $43,038 for the year ended December 31, 2014 increased $49,128 compared to the same period in 2013. This increase was primarily driven by higher net purchases of marketable securities of $60,664 after implementing a revised investment strategy to leverage cash received from the Company’s 2014 capital raise. These outflows were partially offset by $13,242 of proceeds from the sale of the Pessac facility in 2014.

Financing Activities

Cash used in financing activities of $23,751 for the year ended December 31, 2015 increased $119,746 compared to $95,995 of cash provided by financing activities in the same period of 2014. This increase was primarily driven by significant 2014 activity that did not repeat in 2015, consisting of $132,260 of proceeds from the 2014 capital raise that were partially offset by $34,392 of 2014 debt repayments, each of which are specifically addressed in the below description of 2014 activity. The increase in cash used in financing activities during 2015 was further increased by $23,169 of additional earn-out payments paid to Deerfield driven by higher 2015 gross profit earned on sales of the related Éclat products.

Cash provided by financing activities of $95,995 for the year ended December 31, 2014 increased $77,721 compared to the same period in 2013. This increase was primarily driven by $132,260 of proceeds from the 2014 capital raise, comprised of the issuance of ordinary shares and warrants primarily in connection with the underwriter public offering fulfilled in March 2014 and issuance of shares to Recipharm in December 2014. These inflows were partially offset by $34,392 of debt repayments, which primarily consisted of:

- $12,000 to Deerfield, a related party, to repay an acquisition liability note originally incurred as part of the consideration for the Company’s acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012,
- $15,000 to Deerfield, a related party, to repay a facility agreement originally borrowed as part of a February 2013 debt financing transaction, and
- $5,000 to Broadfin, a related party, to repay a facility agreement originally borrowed as part of a December 2013 debt financing transaction.

The increase in cash provided by financing activities in 2014 compared to 2013 was also partially offset by $20,000 of loan proceeds in 2013 related to the above $15,000 and $5,000 from Deerfield and Broadfin, respectively, which did not repeat in 2014.

Liquidity and Risk Management

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

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

Other Matters

Litigation

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

Material Commitments

The Company has commitments to purchase services from Recipharm Pessac for a total of $22,500 for a five-year period commencing January 1, 2015 (disclosed in Note 17- Discontinued Operations) and to purchase one batch per year for the next five years of the generic pharmaceutical product it markets for $46 per year. During the year ended December 31, 2015, the Company recorded $4,089 of research and development expenses, and cash outflows of $5,679, related to this commitment to Recipharm

The Company and its subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense was $752, $844 and $759 in 2015, 2014, and 2013, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2015 are as follows:

2016	**$ 784**
2017	**472**
2018	**463**
2019	**389**
2020	**310**
Thereafter	-
Total	**$ 2,418**

Other than the above commitments to Recipharm and for operating leases, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, long-term contingent consideration payable, and post-retirement benefit plan obligations which are disclosed in Note 7 - Long-Term Debt , Note 8 – Long-term Contingent Consideration Payable, and Note 10 – Post-Retirement Benefit Plans, respectively.

Aggregate Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2015:

		Payments due by period			
	Total	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Statement of Income Data:					
Long-term debt	**$ 1,118**	$ 434	$ 539	$ 145	$ -
Long-term contingent consideration payable (undiscounted)	**155,155**	20,981	41,011	28,849	64,314
Recipharm purchase commitment	**18,220**	4,250	9,110	4,860	-
Operating leases	**2,418**	784	935	699	-
Other	**184**	46	92	46	-
Total contractual cash obligations	**$ 177,095**	$ 26,495	$ 51,687	$ 34,599	$ 64,314

See Note 7 : Long-Term Debt and Note 8 : Long-Term Contingent Consideration Payable to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the respective items within the above table. Obligations relative to the Deerfield warrant-based contingent consideration of $20,617 are not included within the above table. The Company’s long-term debt does not bear interest and therefore no interest is included in the above table.

See Note 17 – Discontinued Operations to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the Company's Recipharm and other obligations within the above table.

See Note 10 : Post-Retirement Benefit Plans to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the Company's post-retirement benefit plans. Obligations of $2,170 related to the post-retirement benefit plans are not included within the above table.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

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

Foreign Exchange Risk

We have significant operations in Europe as well as in the U.S. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in Euro. A 10% strengthening/(weakening) in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in the euro would have increased/(decreased) net income for the year ended December 31, 2015 by approximately $9,500.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign currency gain (loss) in the consolidated statements of income. As of December 31, 2015, our primary exposure to transaction risk related to euro net monetary liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were $10,594 for the year ended December 31, 2015.

Item 8. Financial Statements and Supplementary Data.

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

	Years ended December 31,		
	2015	**2014**	**2013**
Revenues:			
Product sales and services	**$ 172,488**	$ 11,993	$ 1,153
License and research revenue	**721**	2,782	3,026
Total	**173,209**	14,775	4,179
Operating expenses:			
Cost of products and services sold	**10,921**	3,383	562
Research and development expenses	**25,608**	17,298	15,966
Selling, general and administrative expenses	**21,712**	15,698	13,216
Intangible asset amortization	**12,564**	11,749	-
Changes in fair value of related party acquisition-related contingent consideration	**30,957**	57,491	28,135
Loss on early repayment of related party acquisition-related note	-	3,013	-
Total	**101,762**	108,632	57,879
Operating income (loss)	**71,447**	(93,857)	(53,700)
Investment Income	**2,651**	963	254
Interest Expense	**(1,415)**	(5,747)	(2,602)
Interest Expense - changes in fair value of related party financing-related contingent consideration	**(4,883)**	(3,525)	(1,990)
Foreign exchange gain (loss)	**10,594**	11,871	(288)
Other income (expense)	-	**(36)**	573
Income (loss) before income taxes	**78,394**	(90,331)	(57,753)
Income tax provision (benefit)	**37,735**	(1,407)	(11,244)
Net income (loss) from continuing operations	**40,659**	(88,924)	(46,509)
Net income from discontinued operations	-	4,018	3,584
Net income (loss)	**$ 40,659**	$ (84,906)	$ (42,925)
Earnings (loss) per share - Basic:			
Continuing operations	**$ 1.00**	$ (2.45)	$ (1.83)
Discontinued operations	-	0.11	0.14
Net income (loss)	**$ 1.00**	$ (2.34)	$ (1.69)
Earnings (loss) per share - Diluted:			
Continuing operations	$ 0.93	$ (2.45)	$ (1.83)
Discontinued operations	-	0.11	0.14
Net income (loss)	$ 0.93	$ (2.34)	$ (1.69)
Weighted average number of shares outstanding - Basic	40,580	36,214	25,450
Weighted average number of shares outstanding - Diluted	43,619	36,214	25,450

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2015	**2014**	**2013**
Net income/(loss)	**$ 40,659**	$ (84,906)	$ (42,925)
Other comprehensive income/(loss), net of tax:			
Foreign currency translation gain/(loss), net	**(15,087)**	(18,040)	562
Unrealized gain/(loss) on marketable securities	**(147)**	(198)	-
Total other comprehensive income/(loss), net of tax	**(15,234)**	(18,238)	562
Total comprehensive income/(loss)	**$ 25,425**	$ (103,144)	$ (42,363)

See accompanying notes to consolidated financial statements.

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

	December 31,	
	2015	**2014**
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 65,064**	$ 39,760
Marketable securities	**79,738**	53,074
Accounts receivable (net of allowance of $35 and $127 at December 31, 2015 and 2014 respectively)	**6,978**	1,679
Inventories	**4,155**	6,729
Research and development tax credit receivable - current portion	**2,382**	5,932
Prepaid expenses and other current assets	**7,989**	4,418
Current assets held for sale	**-**	730
Total current assets	**166,306**	112,322
Property and equipment, net	**2,616**	1,776
Goodwill	**18,491**	18,491
Intangible assets, net	**15,825**	28,389
Income tax deferred charge	**11,581**	13,102
Other	**158**	125
Total assets	**$ 214,977**	$ 174,205
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	**$ 434**	$ 2,440
Current portion of long-term related party contingent consideration payable	**28,614**	39,892
Accounts payable	**10,565**	8,024
Deferred revenue	**5,121**	1,336
Accrued expenses	**3,598**	5,667
Income taxes	**323**	7,643
Other	**133**	5,672
Current liabilities held for sale	**-**	168
Total current liabilities	**48,788**	70,842
Long-term debt, less current portion	**684**	1,277
Long-term related party contingent consideration payable, less current portion	**94,079**	74,858
Deferred taxes	**1,351**	-
Other	**2,210**	2,333
Total liabilities	**147,112**	149,310
Shareholders' equity:		
Ordinary shares, nominal value of 0.122 euro per share; 53,198 shares authorized; 41,241 and 40,191 issued and outstanding at December 31, 2015 and 2014, respectively	**6,331**	6,188
Additional paid-in capital	**363,984**	346,582
Accumulated deficit	**(279,793)**	(320,452)
Accumulated other comprehensive loss	**(22,657)**	(7,423)
Total shareholders' equity	**67,865**	24,895
Total liabilities and shareholders' equity	**$ 214,977**	$ 174,205

See accompanying notes to consolidated financial statements.

Flamel Technologies S.A.
Consolidated Statements of Shareholders' Equity
(In Thousands)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity
	Shares	Amount				
Balance, December 31 2012	25,416	$ 3,714	$ 209,158	$ (192,621)	$ 10,253	$ 30,504
Net loss	-	-	-	(42,925)	-	(42,925)
Other comprehensive income	-	-	-	-	562	562
Subscription of warrants	-	-	(27)	-	-	(27)
Exercise of stock options or warrants	50	8	391	-	-	399
Vesting of free shares	147	24	(24)	-	-	-
Stock-based compensation expense	-	-	1,975	-	-	1,975
Balance, December 31 2013	25,613	$ 3,746	$ 211,473	$ (235,546)	$ 10,815	$ (9,512)
Net loss	-	-	-	(84,906)	-	(84,906)
Other comprehensive loss	-	-	-	-	(18,238)	(18,238)
Subscription of warrants	-	-	351	-	-	351
Exercise of stock options or warrants	1,001	164	5,861	-	-	6,025
Vesting of free shares	151	24	(24)	-	-	-
Stock-based compensation expense	-	-	2,894	-	-	2,894
Public offering	12,400	2,099	113,133	-	-	115,232
Shares granted to Recipharm AB	1,026	155	12,894	-	-	13,049
Balance, December 31 2014	40,191	$ 6,188	$ 346,582	$ (320,452)	$ (7,423)	$ 24,895
Net income	-	-	-	40,659	-	40,659
Other comprehensive income	-	-	-	-	(15,234)	(15,234)
Subscription of warrants	-	-	601	-	-	601
Exercise of stock options or warrants	899	123	6,266	-	-	6,389
Vesting of free shares	151	20	(20)	-	-	-
Stock-based compensation expense	-	-	7,741	-	-	7,741
Excess tax benefit from stock-based compensation	-	-	2,814	-	-	2,814
Balance, December 31 2015	**41,241**	**$ 6,331**	**$ 363,984**	**$ (279,793)**	**$ (22,657)**	**$ 67,865**

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2015	**2014**	**2013**
Cash flows from operating activities:			
Net income (loss)	**$ 40,659**	$ (84,906)	$ (42,925)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	**13,132**	14,141	3,062
Loss (gain) on disposal of property and equipment	**-**	(4,952)	14
Loss (gain) on sale of marketable securities	**779**	-	-
Unrealized exchange gain	**(8,969)**	(6,252)	-
Grants recognized in research and development expenses and operating income	**(1,498)**	(589)	(676)
Remeasurement of related party acquisition-related contingent consideration	**30,957**	60,503	28,135
Remeasurement of related party financing-related contingent consideration	**4,883**	3,319	1,990
Imputed interest on long-term debt	**-**	-	712
Change in deferred tax and income tax deferred charge	**1,420**	(2,806)	(11,320)
Stock-based compensation expense	**7,741**	2,690	2,029
Increase (decrease) in cash from:			
Accounts receivable	**(8,108)**	3,426	(511)
Inventories	**2,547**	(3,112)	(2,186)
Prepaid expenses and other current assets	**(610)**	(2,330)	315
Research and development tax credit receivable	**2,975**	13,210	665
Accounts payable & other current liabilities	**(3,887)**	8,090	800
Deferred revenue	**3,815**	(55)	(14)
Accrued expenses	**(1,617)**	(265)	1,211
Other long-term assets and liabilities	**74**	(10,730)	(1,977)
Net cash provided by (used in) operating activities	**84,293**	(10,618)	(20,676)
Cash flows from investing activities:			
Purchases of property and equipment	**(1,629)**	(1,728)	(1,029)
Proceeds from disposal of property and equipment	**-**	13,242	1,007
Proceeds from sales of marketable securities	**20,490**	13,678	7,152
Purchase of marketable securities	**(50,591)**	(68,275)	(1,085)
Net cash provided by (used in) investing activities	**(31,730)**	(43,083)	6,045
Cash flows from financing activities:			
Reimbursment of loans	**(4,911)**	(34,186)	-
Reimbursment of conditional R&D grants	**(747)**	(355)	(475)
Proceeds from loans or conditional R&D grants	**-**	-	19,333
Principal payments on capital lease obligations	-	(161)	(77)
Earn-out payments for related party acquisition-related contingent consideration	**(24,526)**	(1,357)	(907)
Royalty payments for related party financing-related contingent consideration	**(3,371)**	(206)	-
Excess tax benefit from stock-based compensation	**2,814**	-	-
Cash proceeds from issuance of ordinary shares and warrants	**6,990**	132,260	400
Net cash provided by (used in) financing activities	**(23,751)**	95,995	18,274
Effect of exchange rate changes on cash and cash equivalents	**(3,508)**	(9,170)	251
Net increase in cash and cash equivalents	**25,304**	33,124	3,894
Cash and cash equivalents at January 1	**39,760**	6,636	2,742
Cash and cash equivalents at December 31	**$ 65,064**	$ 39,760	$ 6,636
Supplemental disclosures of cash flow information:			
Income tax paid	$ 42,121	$ 403	$ 153
Interest paid	$ 4,738	$ 4,431	$ 1,701
Supplemental schedule of non-cash investing and financing activities:			
Income tax paid Grants recognized in research and development expenses and operating income	$ (1,498)	$ -	$ -

See accompanying notes to consolidated financial statements.

NOTE 1 : Summary of Significant Accounting Policies

Nature of Operations. 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 utilizing core competencies in drug delivery and formulation development to create safer and more efficacious pharmaceutical products to address unmet medical needs and/or reduce overall healthcare costs. The Company is headquartered in Lyon, France and has operations in St. Louis, Missouri, and Charlotte, NC, USA, and Dublin, Ireland.

Basis of Presentation. These Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The consolidated financial statements include the accounts of the Company and all majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Reclassifications. The accompanying consolidated financial statements for prior years contain certain reclassifications to conform to the presentation used in 2015.

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

Product Sales and Services

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

For generic products and branded products sold in mature and stable markets where changes in selling price are rare, the Company recognizes revenues upon shipment. For products where market conditions remain volatile and selling price is subject to changes, which is the Company’s situation in 2015, 2014 and 2013, the Company delays revenue recognition until the wholesaler sells the product to its customers. For new product launches the Company recognizes revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. Net product sales of wholesalers to their customers are determined using sales data from an independent, 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.

License and Research Revenue

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

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

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

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

- 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.

When Flamel receives revenue under signed feasibility study agreements, revenue is then recognized over the term of the agreement as services are performed.

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

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 an offset to R&D expense. 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.

R&D. Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development costs. Clinical study and outside services costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third party fees. Personnel expenses relate primarily to salaries, benefits and stock-based compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred.

The Company recognizes R&D tax credits received from the French government for spending on innovative R&D as an offset of R&D expenses.

Stock-based Compensation. The Company accounts for Stock-based compensation based on grant-date fair value estimated in accordance with ASC 718. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models (“Black-Scholes model”). The term used within the Black-Sholes valuation models is determined using a simplified method, as historical data was considered insufficient and irrelevant relative to the grant of stock-options and warrants to a limited population. The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes. The provision for income taxes is based on pretax income reported in the consolidated statements of income and currently enacted tax rates for each jurisdiction. 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 and liabilities are adjusted for the effects of changes in the tax laws and rates on the date of enactment. The Company regularly reviews its deferred tax assets for recoverability and establishes a valuation allowance when it believes it is more likely than not that such assets may not be recovered, taking into consideration historical operating results, expectations of future earnings, changes in its operations and the expected timing of the reversals of existing temporary differences.

Discontinued Operations. The Company followed the guidance in Financial 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 of the Pessac facility. In 2014, the Company opted to early adopt the provisions of ASU 2014-08 as management believed that all criteria for presenting the disposal of Pessac Facility and its business as a discontinued operation were met, and that presenting the disposal as a discontinued operation would better reflect the ongoing operations of the entity.

The divestiture of the Pessac facility represented a strategic shift that had and will have a major effect on the Company’s operations and financial results. Since 2012, the Company’s business model of combining novel, high-value internally developed products with its leading drug delivery capabilities and commercializing 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 of the Pessac facility 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 was 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 is considered to be 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 consolidated statements of operations. The assets and liabilities of the discontinued operation have been reported separately in the asset and liability sections of the consolidated statements of financial position for the periods presented in the statement. Note 17: Discontinued Operations contains 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 consolidated statements of operations, financial position and cash flows relative to the disposal group.

Cash and Cash Equivalents. Cash and cash equivalents consist of cash on hand, cash on deposit and fixed term deposits which are highly liquid investments with original maturities of less than three months.

Marketable Securities. Marketable securities consist of investments in available-for-sale marketable equity securities and are recorded at fair value.

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. A majority of accounts receivable is due from three significant customers which are disclosed in Note 16: Company Operations by Product, Customer and Geographic Area.

Inventories. Inventories consist of raw materials and finished products, which are stated at lower of cost or market 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.

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

Goodwill. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. The Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Company relies upon projections of future discounted 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 potential associated impairment. The Company has determined that no impairment of goodwill existed at December 31, 2015 or 2014.

Long-Lived Assets. Long-lived assets include fixed assets and intangible assets. 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.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant unanticipated changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. The Company has determined that no indications of impairment existed at December 31, 2015 or 2014.

Contingent Consideration. The acquisition-related contingent consideration payable arising from the acquisition of Éclat Pharmaceuticals are accounted at fair-value (see Note 8 : Long-Term Contingent Consideration Payable). The fair value of warrant consideration is estimated on a quarterly basis using a Black-Scholes option pricing model, and the fair value of earn-out payment consideration is estimated on a quarterly basis using a discounted cash flow model based on probability-adjusted annual gross profit of the specified Éclat Pharmaceuticals products at an appropriate discount rate. Changes in fair value are recorded in the consolidated statements of operations within operating expenses as changes in fair value of related party acquisition-related contingent consideration.

The Company elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the Deerfield and Broadfin Royalty Agreements, both of whom are related parties (see Note 8: Long-Term Contingent Consideration Payable). The fair value of royalty agreement consideration is estimated on a quarterly basis using a discounted cash flow model based on probability-adjusted annual revenues of the specified Éclat Pharmaceuticals products at an appropriate discount rate. Changes in fair value are recorded in the consolidated statements of operations as interest expense - changes in fair value of related party financing-related contingent consideration.

Fair Value Measurement. The Company is often required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value extensively when accounting for and reporting of certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business combination.

ASC 820, *Fair Value Measurements and Disclosures* defines fair value as a market-based measurement that should be determined based on the assumptions that marketplace participants would use in pricing an asset or liability. When estimating fair value, depending on the nature and complexity of the asset or liability, we may generally use one or each of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.

- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

As a basis for considering the assumptions used in these techniques, the standard establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Quoted prices for identical assets or liabilities in active markets (Level 1 inputs).

- Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means (Level 2 inputs).

- Unobservable inputs that reflect estimates and assumptions (Level 3 inputs).

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

Use of Estimates. The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. Actual results could differ from those estimates under different assumptions or conditions.

NOTE 2 : Effect of New Accounting Standards

In July 2015, the FASB issued ASU 2015-14 *Revenue from Contracts with Customers: Deferral of the Effective Date* (ASU 2015-14) which deferred the effective date for ASU No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), by one year. ASU 2014-09 will supersede the revenue recognition requirements in Revenue Recognition (Topic 605) and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is now effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which for the Company is January 1, 2018. Early adoption is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period.. The new standard can be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of the change recognized at the date of the initial application in retained earnings. The Company is currently evaluating the potential impact the adoption of ASU 2014-09 will have on its consolidated financial statements and has not yet selected a transition method.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* (ASU 2015-11), which requires an entity to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The effective date for the standard is for fiscal years beginning after December 15, 2016, which for the Company is January 1, 2017. Early adoption is permitted. The new standard is to be applied prospectively. The Company does not expect ASU 2015-11 to have a material impact on its consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Simplifying the Accounting for Measurement-Period Adjustments* (ASU 2015-16). The amended guidance requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments are effective prospectively for the fiscal years, and the interim reporting periods within those years, beginning on or after December 15, 2015 and early adoption is permitted. The Company has elected not to early adopt ASU 2015-16.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17), which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU is effective for the Company in its first quarter of fiscal 2017, with early application permitted and, upon adoption, may be applied either prospectively or retrospectively. The Company early adopted the provisions of ASU 2015-17 for the year ended December 31, 2015 on a prospective basis.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which supersedes ASC 840 "*Leases*" and creates a new topic, ASC 842 "*Leases*." This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the effect of this update on its consolidated financial statements.

NOTE 3 : Marketable Securities

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

The value at cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale marketable securities are summarized below as of December 31:

	2015	2014
Value at cost	**$ 79,885**	$ 53,272
Gross unrealized holding gains	**-**	-
Gross unrealized holding losses	**(147)**	(198)
Fair value	**$ 79,738**	$ 53,074

NOTE 4 : Inventories

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

	2015	2014
Finished Goods	**$ 2,545**	$ 5,068
Raw Materials	**1,610**	1,661
Total	**$ 4,155**	$ 6,729

NOTE 5 : Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2015 and 2014 are as follows:

	2015	2014
Laboratory equipment	**$ 9,963**	$ 9,801
Office and computer equipment	**2,968**	3,288
Furniture, fixtures and fittings	**4,315**	4,544
Less - accumulated depreciation	**(14,630)**	(15,857)
Total	**$ 2,616**	$ 1,776

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was $568, $681 and $774, respectively.

NOTE 6 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2015 and 2014 are as follows:

	2015			2014		
	Gross Value	Accumulated Amortization	Net Book Value	Gross Value	Accumulated Amortization	Net Book Value
Amortizable intangible assets:						
Acquired IPR&D - Bloxiverz	**$ 35,248**	**$ (23,498)**	**$ 11,750**	$ 35,248	$ (11,749)	$ 23,499
Acquired IPR&D - Vazculep	**12,061**	**(7,986)**	**4,075**	12,061	(7,171)	4,890
Total amortizable intangible assets	**$ 47,309**	**$ (31,484)**	**$ 15,825**	$ 47,309	$ (18,920)	$ 28,389
Unamortizable intangible assets:						
Goodwill	**19,035**	**(544)**	**18,491**	19,035	(544)	18,491
Total unamortizable intangible assets	**$ 19,035**	**$ (544)**	**$ 18,491**	$ 19,035	$ (544)	$ 18,491

The Company recorded amortization expense related to amortizable intangible assets of $12,564, $11,749 and $0 for the years ended December 31, 2015, 2014 and 2013, respectively. Accumulated amortization in the above tables includes an impairment charge of $7,171 which was recognized during the year ended December 31, 2012 relative to the Acquired IPR&D – Vazculep intangible asset.

Amortizable intangible assets are amortized over their estimated useful lives, which range from three to six years, using the straight-line method. Total future amortization of intangible assets for the next five years is as follows:

Years ending December 31,	Estimated Amortization Expense
2016	$ 12,565
2017	815
2018	815
2019	815
2020	815
Total	**$ 15,825**

During the years ended December 31, 2015 and 2014, the Company did not acquire any intangible assets or goodwill.

NOTE 7 : Long-Term Debt

French government agencies provide financing to French companies for research and development. At December 31, 2015 and 2014, the Company had outstanding loans of $1,118 and $3,717, 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. Potential repayment is scheduled to occur from 2015 through 2019.

During the years ended December 31, 2015, 2014 and 2013, the Company repaid $747, $355 and $475, of loans associated with specific research projects, respectively. In addition, during 2015 the Company received waivers of repayment for the remaining portion of certain loans of $1,498 on the basis of limited commercial and technical success. Amounts waived are reported as reductions to R&D expenses in the Company’s consolidated statements of income. No such waivers were received during 2014 or 2013.

NOTE 8 : Long-Term Contingent Consideration Payable

Long-term contingent consideration payable and related activity are reported at fair value and consist of the following at December 31, 2015 and 2014:

		Activity During Year Ended December 31, 2015			
			Changes in Fair Value of Contingent Consideration		
	Balance, December 31, 2014	Payments to Related Parties	Operating Expense; Acquisition-Related	Interest Expense; Financing-Related	**Balance, December 31, 2015**
Acquisition-related:					
Warrants - Éclat Pharmaceuticals (a)	**$ 34,542**	$ -	$ (13,925)	$ -	**$ 20,617**
Earn-out payments - Éclat Pharmaceuticals (b)	**70,112**	(24,526)	44,882	-	**90,468**
Financing-related:					
Royalty agreement - Deerfield (c)	**6,837**	(2,282)	-	3,307	**7,862**
Royalty agreement - Broadfin (d)	**3,259**	(1,089)	-	1,576	**3,746**
Total contingent consideration	**$ 114,750**	$ (27,897)	$ 30,957	$ 4,883	**$ 122,693**
Less: Current portion	**(39,892)**				**(28,614)**
Total long-term contingent consideration payable	**$ 74,858**				**$ 94,079**

Each of the above items is associated with related parties as further described in Footnote 18 – Related Parties.

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

The fair value of the warrants is estimated on a quarterly basis using a Black-Scholes option pricing model with the following assumptions as of December 31, 2015 and 2014:

	2015	**2014**
Weighted average exercise price per share	$ 8.63	$ 8.63
Expected term (years)	2.63	3.63
Expected volatility	64.54%	54.80%
Risk-free interest rate	0.93%	1.25%
Expected dividend yield	-	-

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

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

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

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

Expected dividend yield: The expected dividend yield is based on the Company's authorized periodic dividend and the Company's expectation for dividend yields over the expected term. The Company has not distributed any dividends since its inception, and has no plan to distribute dividends in the foreseeable future.

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

(b) As part of the consideration for the Company's acquisition of Éclat Pharmaceuticals, LLC in March 2012, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat Pharmaceuticals products. These payments will continue in perpetuity.

(c) As part of a February 2013 debt financing transaction conducted with Deerfield Management, a related party and current shareholder, the Company received cash of $2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat Pharmaceuticals products until December 31, 2024.

(d) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Company received cash of $2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat Pharmaceuticals products until December 31, 2024.

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

NOTE 9 : Income Taxes

The components of income (loss) before income taxes consist of the following for the years ended December 31:

	2015	2014	2013
United States	**$ 101,241**	$ (89,939)	$ (53,864)
France	**6,622**	(392)	(3,889)
Ireland	**(29,469)**	-	-
Total income (loss) before income taxes	**$ 78,394**	$ (90,331)	$ (57,753)

The income tax provision (benefit) consists of the following for the years ended December 31,:

	2015	2014	2013
Current:			
United States - Federal	**$ 33,748**	$ -	$ -
United States - State	**980**	-	-
France	**1,657**	1,400	76
Total current	**36,385**	1,400	76
Deferred:			
United States - Federal	**1,830**	(2,457)	(9,905)
United States - State	**1,267**	(350)	(1,415)
France	**(1,747)**	-	-
Total deferred	**1,350**	(2,807)	(11,320)
Income tax provision (benefit)	**$ 37,735**	$ (1,407)	$ (11,244)

The items accounting for the difference between the income tax provision (benefit) computed at the French statutory rate and the Company's effective tax rate are as follows for the years ended December 31,:

	2015	2014	2013
Statutory tax rate	**33.3%**	33.3%	33.3%
Non-deductible changes in fair value of contingent consideration	**13.8%**	(24.7)%	(16.6)%
Change in valuation allowance	**(9.5)%**	5.2%	(4.5)%
Income tax deferred charge	-	(16.9)%	-
International tax rates differential	**10.9%**	6.7%	6.2%
Other	**(0.4)%**	(2.0)%	1.1%
Effective income tax rate	**48.1%**	1.6%	19.5%
Income tax provision (benefit) - at Statutory tax rate	**$ 26,105**	$ (30,080)	$ (19,232)
Non-deductible changes in fair value of contingent consideration	**10,835**	22,326	9,592
Change in valuation allowance	**(7,425)**	(4,732)	2,616
Income tax deferred charge	-	15,273	-
International tax rates differential	**8,559**	(6,026)	(3,609)
Other	**(339)**	1,832	(611)
Income tax provision (benefit) - at Effective income tax rate	**$ 37,735**	$ (1,407)	$ (11,244)

The Company's effective tax rates for the years ended December 31, 2015, 2014 and 2013 were 48.1%, 1.6% and 19.5%, respectively. Increased expenses reported during 2015, 2014 and 2013 due to changes in fair value of contingent consideration are not deductible for income tax purposes, and therefore unfavorably impact the Company’s effective income tax rate. In 2013, valuation allowances were placed against the deferred tax assets generated by pre-tax losses in France. In 2014, the Company entered into an intra-entity transaction to transfer intellectual property from France to Ireland which resulted in a charge of $15,273 after utilization of net operating loss carryforwards that were previously fully reserved with a valuation allowance. In 2015 certain valuation allowances were reversed with respect to pre-tax income of our U.S. and French operations as the Company had sufficient taxable income to utilize net operating losses. These rates also reflect the additional tax impacts of the Company's significant U.S. operations at a higher statutory tax rate than the French statutory tax rate, and in 2015 are additionally unfavorably impacted by losses incurred at our Irish entity at a lower statutory tax rate.

Deferred Tax Assets (Liabilities)

Deferred income tax provisions reflect the effect of temporary differences between consolidated financial statement and tax reporting of income and expense items. The net deferred tax assets/liabilities at December 31, 2015 and 2014 resulted from the following temporary differences:

	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	**$ 44,587**	$ 66,167
Stock based compensation	**1,767**	-
Fair value royalty agreements	**2,435**	2,130
Other	**1,025**	1,039
Total deferred tax assets	**49,814**	69,336
Valuation allowances	**(45,516)**	(57,980)
Net deferred tax assets	**4,298**	11,356
Deferred tax liabilities:		
Amortization of IPR&D	**(5,649)**	(11,356)
Total deferred tax liabilities	**(5,649)**	(11,356)
Net deferred tax assets (liabilities)	**$ (1,351)**	$ -

The net operating loss carryforwards at December 31, 2015 relate primarily to Irish and French operations. While these net operating losses have no expiration in France or Ireland, in France they are limited to annual utilization of €1,000 plus fifty per cent (50%) of any taxable income in excess of €1,000. The company continually reviews the adequacy of the valuation allowance. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. The Company has provided valuation allowances covering 100% of these deferred tax assets as of December 31, 2015.

At December 31, 2015, the Company has no unremitted earnings outside of France as measured on a US GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may be different for tax purposes, these earnings, which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the Company were to sell its stock in the subsidiaries. It is not practicable to estimate the amount of deferred tax liability on such earnings.

The Company and its subsidiaries file income tax returns in France, Ireland and U.S. federal and various state jurisdictions. The Company is no longer subject to, with limited exceptions, French income tax examinations by tax authorities for years prior to 2013. Any other tax period or jurisdiction in which the Company files remains subject to potential tax examination by the respective tax authorities.

Certain vested and exercised employee equity compensation awards have resulted in tax deductions in excess of previously recorded tax benefits based on the value of such equity compensation awards at the time of grant, and have been recorded as additional paid-in capital. The excess tax benefit from stock-based compensation recognized in 2015 is $2,814.

Research and Development Tax Credits Receivable

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 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, 2015, the Company's net Research tax credit receivable amounts to $2,382 and represents a gross research tax credit of $3,720, partially offset by current income tax payable of $1,338.

Income Tax Deferred Charge

On December 16, 2014, the Company transferred all of its intangible intellectual property from its French entity to its Irish entity as a part of a global reorganization. The intellectual property includes patents on drug delivery platforms, clinical data sets and other intangible assets related to the pipeline of proprietary products in development. This intra-entity transaction resulted in a charge of $14,088 of related taxes to the French government in December 2014. As this represents an intra-entity transaction, no deferred tax asset has been recognized, but rather was originally recorded as $986 of prepaid expenses and $13,102 of a long-term Income tax deferred charge asset in accordance with ASC 740-10-25-3 (e). This income tax deferred charge asset is amortized over the tax life of the asset at a rate of 7% per year and will result in tax relief in Ireland of $8.5 million from 2016 to 2029. At December 31, 2015, the balance of these respective accounts was classified as prepaid expenses of $842 and Income tax deferred charge asset of $11,581. This deferred charge asset will not be changed by future events other than the sale or amortization, including market write-down or impairment measured on a pretax basis, of the related asset in Ireland. No impairment has been identified in connection with the impairment test performed as of December 31, 2015.

NOTE 10 : Post-Retirement Benefit Plans

Post-Retirement Benefit Contributions to French Government Agencies

The Company is required by French law to deduct specific monthly payroll amounts to support post-retirement benefit programs sponsored by the relevant government agencies in France. As the ultimate obligation is maintained by the French government agencies, there is no additional liability recorded by the Company in connection with these plans. Expenses recognized for these plans were $573 in 2015, $719 in 2014, and $701 in 2013.

Retirement Indemnity Obligation – France

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. The retirement indemnity has been actuarially calculated on the assumption of voluntary retirement at a government-defined retirement age. Benefits do not vest prior to retirement. Any actuarial gains or losses are recognized in the Company's consolidated statements of income in the periods in which they occur.

The benefit obligation is calculated as the present value of estimated future benefits to be paid, using the following assumptions:

	Years Ended December 31,		
	2015	**2014**	**2013**
Compensation rate increase	**3.00%**	3.00%	3.00%
Discount rate	**2.03%**	1.49%	3.25%
Employee turn-over	---------- Actuarial standard and average of the last 5 years ----------		
Average age of retirement	----- 60 to 65 years actuarial standard based on age and professional status -----		

Certain actuarial assumptions, such as discount rate, have a significant effect on the amounts reported for net periodic benefit cost and accrued retirement indemnity benefit obligation amounts. The discount rate is determined annually by benchmarking a published long-term bond index using the iBoxx € Corporates AA 10+ index.

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

	2015	2014
Retirement indemnity benefit obligation, beginning of year	**$ 2,350**	$ 2,142
Service cost	**117**	99
Interest cost	**20**	36
Plan amendments	**-**	-
Benefits paids	**(46)**	(87)
Actuarial loss (gain)	**(27)**	460
Exchange rate changes	**(244)**	(300)
Retirement indemnity benefit obligation, end of year	**$ 2,170**	$ 2,350

The lump sum retirement indemnity is accrued on the Company's Consolidated Balance Sheets within non-current other liabilities, excluding the current portion. As these are not funded benefit plans, there are no respective assets recorded.

The future expected benefits to be paid over the next five years and for the five years thereafter is as follows:

	Retirement indemnity benefit obligation
Expected benefit payments for year ending December 31,:	
2016	$ -
2017	-
2018	-
2019	11
2020	-
Next five years	221

NOTE 11 : Other Assets and Liabilities

Various other assets and liabilities are summarized as follows for the year ending December 31,:

	2015	2014
Prepaid expenses and other current assets		
Valued-added tax recoverable	**$ 1,099**	$ 1,077
Prepaid expenses	**2,846**	3,225
Advance to suppliers and other current assets	**518**	116
Income tax receivable	**3,526**	-
Total	**$ 7,989**	$ 4,418

	2015	2014
Accrued expenses		
Accrued compensation	**$ 1,888**	$ 3,792
Accrued social charges	**1,710**	1,875
Total	**$ 3,598**	$ 5,667

	2015	2014
Other current liabilities		
R&D credit tax financing short term	**$ -**	$ 5,382
Provision for retirement indemnity short term	**-**	55
Other	**133**	235
Total	**$ 133**	$ 5,672

	2015	2014
Other non-current liabilities		
Provision for retirement indemnity	**$ 2,170**	$ 2,295
Other	**40**	38
Total	**$ 2,210**	$ 2,333

NOTE 12 : Contingent Liabilities and Commitments

Litigation

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At December 31, 2015 and 2014, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

Material Commitments

The Company has commitments to purchase services from Recipharm Pessac for a total of $22,500 for a five-year period commencing January 1, 2015 (disclosed in Note 17- Discontinued Operations) and to purchase one batch per year for the next five years of the generic pharmaceutical product it markets for $46 per year.

The Company and its subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense was $752, $844 and $759 in 2015, 2014, and 2013, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2015 are as follows:

2016	**$ 784**
2017	**472**
2018	**463**
2019	**389**
2020	**310**
Thereafter	-
Total	**$ 2,418**

Other than the above commitments to Recipharm and for operating leases, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, long-term contingent consideration payable, and post-retirement benefit plan obligations which are disclosed in Note 7 - Long-Term Debt , Note 8 – Long-term Contingent Consideration Payable, and Note 10 – Post-Retirement Benefit Plans, respectively.

NOTE 13 : Equity Instruments and Stock Based Compensation

Compensation expense included in the Company's Consolidated Statements of Income for all stock-based compensation arrangements was as follows:

	2015	2014	2013
Cost of products and services sold	**$ -**	$ 38	$ 20
Research and development expenses	**1,587**	1,027	779
Selling, general and administrative expenses	**6,154**	1,798	1,230
Total stock-based compensation expense	**$ 7,741**	$ 2,863	$ 2,029

As of December 31, 2015, the Company expects $13,297 of unrecognized expense related to granted, but nonvested stock-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 1.7 years.

The Company recognized a tax benefit related to stock-based compensation of $1,767 for the year ended December 31, 2015.

Upon exercise of stock options or warrants, or upon the issuance of free share awards, the Company issues new shares.

Determining the Fair Value of Stock Options and Warrants

The Company measures the total fair value of stock options and warrants on the grant date using the Black-Scholes option-pricing model and recognizes each grant's fair value as compensation cost over the period that the option or warrant vests. Options are granted to employees of the Company and generally become exercisable within four years following the grant date and expire ten years after the grant date. Warrants are typically issued to the Company's Board of Directors as compensation for services rendered and generally become exercisable within one year following the grant date, and expire four years after the grant date.

The weighted-average assumptions under the Black-Scholes option-pricing model for stock option and warrant grants are as follows:

	2015	2014	2013
Stock Option grants:			
Expected term (years)	6.25	6.25	6.25
Expected volatility	58.59%	59.00%	58.15%
Risk-free interest rate	1.89%	1.79%	1.66%
Expected dividend yield	-	-	-
Warrant grants:			
Expected term (years)	2.50	2.50	2.50
Expected volatility	55.00%	58.00%	54.00%
Risk-free interest rate	0.89%	0.75%	0.47%
Expected dividend yield	-	-	-

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

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

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

Expected dividend yield: The expected dividend yield is based on the Company's authorized periodic dividend and the Company's expectation for dividend yields over the expected term. The Company has not distributed any dividends since its inception, and has no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Company's stock option plans for the year ended December 31, 2015 is as follows:

	Number of Stock Options	Wtd. Avg. Exercise Price per Share	Wtd. Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Stock options outstanding, January 1, 2015	2,498	$ 11.45		
Granted	934	16.71		
Exercised	(708)	8.75		
Forfeited	(398)	14.59		
Stock options outstanding, December 31, 2015	**2,326**	**$ 13.84**	**8.26 years**	**$ 6,426**
Stock options exercisable, December 31, 2015	**798**	**$ 10.80**	**6.12 years**	**$ 4,880**

The aggregate intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was $10,063 and $3,789, respectively. There were no options exercised in 2013.

The weighted average grant date fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was $9.38, $9.19 and $3.36 per share, respectively.

At December 31, 2015, there were 97 shares authorized for stock option grants in subsequent periods.

Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2015 is as follows:

	Number of Warrants	Wtd. Avg. Exercise Price per Share	Wtd. Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Warrants outstanding, January 1, 2015	553	$ 10.47		
Granted	305	21.67		
Exercised	(190)	5.57		
Forfeited	-	-		
Warrants outstanding, December 31, 2015	**668**	**$ 16.97**	**2.90 years**	**$ 687**
Warrants exercisable, December 31, 2015	**363**	**$ 13.04**	**2.41 years**	**$ 687**

The aggregate intrinsic value of warrants exercised during the years ended December 31, 2015, 2014 and 2013 was $2,698, $3,107 and $2, respectively.

The weighted average grant date fair value of warrants granted during the years ended December 31, 2015, 2014 and 2013 was $5.92, $3.90 and $1.50 per share, respectively.

At December 31, 2015, an additional 3,300 warrants were outstanding and exercisable relative to consideration paid for the Company’s acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012. These warrants are not considered stock-based compensation and are therefore excluded from the above tables, and instead are addressed within Note 8 - Long-Term Contingent Consideration Payable.

At December 31, 2015, there were 45 shares authorized for warrant grants in subsequent periods.

Free Share Awards

Free share awards represent Company shares issued free of charge to employees of the Company as compensation for services rendered. The Company measures the total fair value of free share awards on the grant date using the Company's stock price at the time of the grant. Free share awards generally cliff vest at the end of a four year vesting period, and are expensed over this vesting period.

A summary of the Company's free share awards as of December 31, 2015, and changes during the year then ended, is reflected in the table below.

	Number of Free Share Awards	Wtd. Avg. Grant Date Fair Value
Nonvested free share awards outstanding, January 1, 2015	**402**	$ 11.29
Granted	-	-
Vested	**(151)**	7.36
Forfeited	**(25)**	10.95
Nonvested free shares awards outstanding, December 31, 2015	**226**	**$ 13.95**

The weighted average grant date fair value of free share awards granted during the years ended December 31, 2014 and 2013 was $16.30 and $7.36, respectively. There were no free share awards granted in 2015.

At December 31, 2015, there were 250 shares authorized for free share award grants in subsequent periods.

NOTE 14 : Earnings (Loss) Per Share

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

A reconciliation of basic and diluted earnings (loss) per share, together with the related shares outstanding in thousands for the years ended December 31, is as follows:

	2015	2014	2013
Net income (loss) from continuing operations	**$ 40,659**	$ (88,924)	$ (46,509)
Net income (loss) from discontinued operations	-	4,018	3,584
Net income (loss)	**$ 40,659**	**$ (84,906)**	**$ (42,925)**
Weighted average shares:			
Basic shares	**40,580**	36,214	25,450
Effect of dilutive securities—options and warrants outstanding	3,039	-	-
Diluted shares	**43,619**	**36,214**	**25,450**
Earnings (loss) per share - Basic:			
Continuing operations	**$ 1.00**	$ (2.45)	$ (1.83)
Discontinued operations	-	0.11	0.14
Net income (loss)	**$ 1.00**	$ (2.34)	$ (1.69)
Earnings (loss) per share - Diluted:			
Continuing operations	**$ 0.93**	$ (2.45)	$ (1.83)
Discontinued operations	-	0.11	0.14
Net income (loss)	**$ 0.93**	$ (2.34)	$ (1.69)

Potential common shares of 635, 6,753, and 7,753 were excluded from the calculation of weighted average shares for the years ended December 31, 2015, 2014 and 2013, because their effect was considered to be anti-dilutive. For the years ended December 31, 2014 and 2013, the effects of dilutive securities were entirely excluded from the calculation of earnings per share as a net loss was reported in these periods.

NOTE 15 : Comprehensive Income (Loss)

The following table shows the components of accumulated other comprehensive income (loss) for the twelve months ended December 31, 2015, 2014, and 2013 net of immaterial tax effects:

	Foreign Currency Translation Adjustment Income (Loss), Net	Unrealized Gain (Loss) on Marketable Securities, Net	Total
Balance - January 1, 2013	$ 10,253	$ -	**$ 10,253**
Other comprehensive income	562	-	**562**
Balance - December 31, 2013	10,815	-	**10,815**
Other comprehensive loss	(18,040)	(198)	**(18,238)**
Balance - December 31, 2014	(7,225)	(198)	**(7,423)**
Other comprehensive loss	(15,087)	(147)	**(15,234)**
Balance - December 31, 2015	$ (22,312)	$ (345)	**$ (22,657)**

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

NOTE 16 : Company Operations by Product, Customer and Geographic Area

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

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

	Years Ended December 31,		
	2015	**2014**	**2013**
Bloxiverz	**$ 150,283**	$ 10,211	$ -
Vazculep	**20,151**	-	-
Dextroamphetamine	**1,946**	1,643	-
Other	**108**	139	1,153
Total product sales and services	**172,488**	11,993	1,153
License and research revenue	**721**	2,782	3,026
Total revenues	**$ 173,209**	$ 14,775	$ 4,179

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

	Years Ended December 31,		
	2015	**2014**	**2013**
Customer A	**$ 60,620**	$ 3,659	$ 354
Customer B	**53,988**	3,937	541
Customer C	**43,434**	3,563	(124)
Other	**14,446**	834	382
Total product sales and services	**172,488**	11,993	1,153
License and research revenue	**721**	2,782	3,026
Total revenues	**$ 173,209**	$ 14,775	$ 4,179

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

	2015	**2014**	**2013**
Revenues, for the years ended December 31,			
United States	**$ 172,379**	$ 14,302	$ 3,368
France	**89**	473	811
Ireland	**741**	-	-
Total	**$ 173,209**	$ 14,775	$ 4,179
Long-lived assets, as of December 31,			
United States	**$ 34,515**	$ 47,077	$ 58,868
France	**2,317**	1,704	2,307
Ireland	**258**	-	-
Total	**$ 37,090**	$ 48,781	$ 61,175

NOTE 17 : Discontinued Operations

On December 1, 2014, the Company signed an Asset Purchase Agreement with Recipharm AB (“Recipharm”) to divest its development and manufacturing facility and associated business 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, as well as 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®, which was Flamel’s lead product at the time, using its Micropump drug delivery platform and manufactured in the Pessac Facility.

The aggregate consideration received for the divested assets and business was $13,200, plus the value of divested inventory as determined using inventory valuation methodology as defined by the two parties. All cash and receivables pertaining to the Pessac Facility business prior to the sale were retained by the Company. A contribution of $700 was made by the Company 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 the Company’s consolidated financial statements for all applicable years presented. The Company recognized a $5,007 gain on disposal, which was included in our income from Discontinued Operations, in fiscal year 2014. Concurrently with the above, Recipharm made an investment of $13,000 in newly issued Flamel shares, the purchase price of which was based on the average of the trailing 20 days’ trading prices of the Company’s shares prior to the closing date.

In connection with the Asset Purchase Agreement, the Company also 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 $22,500 as follows:

Year 1	$	4,250
Year 2	$	4,250
Year 3	$	4,250
Year 4 & 5 (each)	$	4,860

During the year ended December 31, 2015, the Company recorded $4,089 of research and development expenses, and cash outflows of $5,679, related to this commitment to Recipharm.

Option Agreement

Recipharm has a first option (right of first refusal) to discuss and negotiate licenses of the Company's intellectual property rights for the sale of certain products in Europe. Upon exercise of the option, Recipharm and the Company shall agree in good faith on terms and conditions of the 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. The Company received no compensation related to the option agreement.

Summary results of operations for the divested Pessac business were as follows for the years ended December 31,:

	2015	2014	2013
Revenues	**$ -**	$ 14,967	$ 18,265
Operating income (loss)	-	(875)	3,667
Gain on disposal	-	5,007	-
Interest Expense	-	(4)	(9)
Income tax provision (benefit)	-	110	74
Net income from discontinued operations	**$ -**	**$ 4,018**	**$ 3,584**

Carrying amounts of major classes of assets and liabilities classified as held for sale in the Consolidated balance sheets are as follows as of December 31,:

	2015	2014
Accounts receivable, net	**$ -**	$ 730
Total assets of the disposal group classified as held for sale	-	**730**
Accounts payable	-	**168**
Total liabilities of the disposal group classified as held for sale	**$ -**	**$ 168**

The major cash flows related to Discontinued Operations as included in the Consolidated statements of cash flows are as follows for the years ended December 31,:

	2015	2014	2013
Capital expenditures	**$ -**	$ 1,271	$ 872
Depreciation and amortization	-	1,709	1,751
Operating and investing non-cash elements	-	(740)	(676)

NOTE 18 : Related Party Transactions

In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. (“Breaking Stick”, formerly Éclat Holdings), an affiliate of Deerfield Capital L.P (“Deerfield”), a significant shareholder of the Company. As of December 31, 2015 and 2014, the remaining consideration obligations for this transaction consisted of two warrants to purchase a total of 3,300 shares of Flamel and commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the “Products”). Breaking Stick is majority owned by Deerfield, with a minority interest owned by Mr. Michael Anderson, the Company’s CEO, and certain other current and former employees. The original consideration for the acquisition of Éclat also included a $12 million senior note payable to the majority owners of Breaking Stick, which was fully repaid in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

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

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

NOTE 19 : Subsequent Event

On February 8, 2016, the Company entered into an agreement to acquire FSC Holdings, LLC (“FSC”), a Charlotte, NC-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a related party. Under the terms of the acquisition, which was completed on February 8, 2016, the Company will pay $1,050 annually for five years with a final payment in January 2021 of $15,000 for a total of $20,250 to Deerfield for all of the equity interests in FSC. The Company will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to $12,500 for a period not exceeding ten years. The Company is in the initial stages of allocating the purchase price to the acquired net assets of FSC.

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 income/(loss), of comprehensive income/(loss), of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Flamel Technologies SA and its subsidiaries at December 31, 2015 and December 31, 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) because material weaknesses in internal control over financial reporting existed as of that date.

The material weaknesses related to 1) an insufficient complement of personnel with an appropriate level of knowledge, experience and training commensurate with the Company's financial reporting requirements, 2) a lack of effective controls over segregation of duties and restricted access for processes, including an assessment of incompatible management responsibilities at its US subsidiary relating to a) journal entries as the Company has not designed or maintained effective controls over the review, approval and documentation related to journal entries recorded, b) third party vendors and third party payments as the Company has not designed or maintained effective controls over the review, approval, ongoing maintenance of third party vendor contracts and vendor payments, c) cash payments as the Company does not have an adequate process to ensure the safeguarding of the Company's assets, d) payroll and related accounts as the Company has not designed or maintained effective controls over the payroll process, 3) revenue as the Company has not designed or maintained effective controls over product pricing and rebate arrangements and the use of service providers in the revenue process, 4) income taxes as the Company has not designed or maintained effective controls related to the completeness, accuracy and valuation of income taxes process, 5) information technology general controls and key spreadsheets as the Company has not designed or maintained effective controls over information technology general controls and key spreadsheets, 6) financial close process as the Company has not designed or maintained effective controls over the financial close process, 7) monitoring controls as the Company did not maintain an internal audit function sufficient to monitor control activities.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses referred to above are described in Management's Report on Internal Control Over Financial Reporting, appearing under Item 9a. We considered these material weaknesses in determining the nature, timing, and extent of audit tests applied in our audit of the December 31, 2015 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements. The Company's management is responsible for these financial statements and financial statement schedule, 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 referred to above. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for the classification of deferred income tax balances in 2015.

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,
March 15, 2016

PricewaterhouseCoopers Audit

Represented by
/s/ Frédéric Charcosset
Frédéric Charcosset

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

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

Management, including our Chief Executive Officer and Chief Financial Officer, believes the consolidated financial statements included in this annual report on Form 10-K fairly present in all material respects our financial condition, results of operations and cash flows at the end of and for the periods presented in accordance with U.S. GAAP.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO, or persons performing similar functions, and effected by the Company's board of directors, management and other personnel 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, 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.

Management of the Company has assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. In making its assessment of internal control over financial reporting, management used the criteria described in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Management has identified the following control deficiencies that constituted material weaknesses in our internal control over financial reporting as of December 31, 2015:

- **Lack of sufficient personnel**: We did not maintain a sufficient number of personnel with an appropriate level of knowledge, experience and training in internal control over financial reporting commensurate with our financial reporting requirements.

- **Segregation of duties**: As a consequence of the above weakness we have not designed or maintained effective controls over segregation of duties and restricted access for processes, including an assessment of incompatible management responsibilities relating to the following:

    - Journal entries: We have not designed or maintained effective controls over the review, approval and documentation related to journal entries recorded in the US.

    - Third party vendors and third party payments: We have not designed or maintained effective controls in the US over the review, approval, ongoing maintenance of third party vendor contracts and vendor payments.

    - Cash payment process: We have not designed or maintained effective controls over the cash payment process in the US. We do not have an adequate process to ensure the safeguarding of the Company's assets to support the proper functioning of internal controls.

    - Payroll and related accounts: We have not designed or maintained effective controls over the US payroll process.

- **Revenue**: We have not designed or maintained effective controls over the revenue process. Specifically, we have not designed or maintained effective controls over the review and approval of product prices and subsequent changes to customer prices, the authorization, review and accounting for rebate arrangements included in customer contracts and the company's use of service providers in the revenue process.

- **Income taxes**: We have not designed or maintained effective controls over the income tax process. Specifically, we have not designed or maintained effective controls related to the income tax process on a quarterly or year-end basis, including deferred tax reconciliations, valuation allowances, review of state income taxes and related apportionment, review of tax returns and return to provision differences, review of information provided to and received from the outsourced tax provider, review of effective income tax rates and any uncertain tax positions.

- **Information technology general controls and key spreadsheets**: We have not designed or maintained effective controls over information technology general controls and key spreadsheets used within certain processes and management's controls to support account balances or in the preparation of the financial statements.

- **Financial close process**: We have not designed or maintained effective controls over the financial close process.

- **Monitoring controls**: We did not design and maintain effective monitoring controls related to the design and operational effectiveness of our internal controls. Specifically, we did not maintain an internal audit function sufficient to monitor control activities.

These control deficiencies could result in misstatements that could be pervasive to the financial statements and disclosures which would result in a material misstatement of the consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that these control deficiencies constitute material weaknesses.

Because of these material weaknesses, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2015, based on criteria in Internal Control-Integrated Framework (2013) issued by the COSO.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by PricewaterhouseCoopers Audit, our independent registered public accounting firm. Their report appears in Item 8. Financial Statements and Supplementary Data of this annual report on Form 10-K.

Remediation Plan and Status

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

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

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

Changes in Internal Control Over Financial Reporting

As described above under "Remediation Plan and Status", there were changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the most recent fiscal quarter and annual period that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this annual report on Form 10-K because we intend to file our definitive proxy statement for our 2016 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2016 Proxy Statement"), not later than 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and certain information to be included in our Definitive 2016 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding Directors, Executive Officers and Corporate Governance is hereby incorporated by reference to our Definitive 2016 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2015.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2016 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2015.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters is hereby incorporated by reference to our Definitive 2016 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2015.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information regarding Certain Relationships and Related Transactions, and Director Independence is hereby incorporated by reference to our Definitive 2016 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2015.

Item 14. Principal Accountant Fees and Services.

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2016 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2015..

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents Filed as Part of this Report:

1. ***Financial Statements*** See Item 8 - Financial Statements and Supplementary Data of Part II of this Report

2. ***Financial Statement Schedules*** See below for Schedule II: Valuation and Qualifying Accounts. All other schedules are omitted as they are not applicable, not required or the information is included in the consolidated financial statements or related notes to the consolidated financial statements

Schedule II
Valuation and Qualifying Accounts
(in thousands)

	Balance at beginning of period	Additions: Charges to expense (a)	Deductions (b)	Other changes (c)	**Balance at end of period**
Deferred tax asset valuation allowance:					
2015	**$ 57,980**	$ 4,312	$ (11,737)	$ (5,039)	**$ 45,516**
2014	**69,939**	8,453	(13,185)	(7,227)	**57,980**
2013	**64,356**	2,616	-	2,967	**69,939**

a) Additions to the deferred tax asset valuation allowance relate to movements on certain French, Irish and U.S. deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.

b) Deductions to the deferred tax asset valuation allowance include movements relating to utilization of NOLs and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns.

c) Other changes to the deferred tax asset valuation allowance relate primarily to currency translation adjustments recorded directly in equity.

3. ***Exhibits*** The exhibits listed on the following Index to Exhibits are filed as part of this annual report on Form 10-K.

Index to Exhibits

Number	Description
3.1	Revised *Statuts* or ByLaws of the Company **(1)**
4.1	Guaranty of Note made by Flamel Technologies S.A. in favor of Éclat Holdings, LLC, dated March 13, 2012 **(2)**
4.2	Warrant to purchase 2,200,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. **(2)**
4.3	Warrant to purchase 1,100,000 American Depositary Shares, each representing one Ordinary Share of Flamel Technologies S.A. **(2)**
10.1	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) **(3)**
10.2*	Note Agreement among Flamel Technologies S.A., Flamel US Holdings, Inc. and Éclat Holdings, LLC, dated March 13, 2012 **(2)**
10.3	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC, dated March 13, 2012 **(2)**
10.4	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 **(4)**
10.5*	Royalty Agreement among Eclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P dated December 31, 2012 **(4)**
10.6*	Security Agreement between Éclat Pharamaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl, dated February 4, 2013 **(4)**
10.7	Broadfin Facility Agreement, effective as of December 3, 2013 **(5)**
10.8*	Broadfin Royalty Agreement, dated as of December 3, 2013 **(5)**
10.9	Asset Purchase Agreement by and among Flamel Technologies and Recipharm Pessac, dated November 26, 2014 **(1)**
10.10	Master Agreement on Supply of Services and Products by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 **(1)**
10.11	Service Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 **(1)**
10.12	Supply Agreement by and between Flamel Technologies and Recipharm Pessac, dated December 1, 2014 **(1)**
10.13*	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 **(1)**
10.14*	License Agreement by and between Elan Pharma International Limited and Flamel Ireland Limited, dated September 30, 2015 (Filed herewith)
10.15	Lease Agreement by and between Nine East, LLC and Eclat Pharmaceuticals LLC, dated July 23, 2013 (Filed herewith)
10.16	Lease Agreement by and between Grove II LLC and Eclat Pharmaceuticals LLC, dated October 5, 2015 (Filed herewith)
10.17	Lease Agreement by and between Channor Limited, Blanchardstown Corporate Park Management Limited, Flamel Ireland Limited, and Flamel Technologies S.A., dated July 3, 2015 (Filed herewith)

10.18‡	Employment Agreement by and between Flamel Technologies S.A. and Sandra Hatten, dated July 8th, 2015 (Filed herewith)
10.19‡	Employment Agreement by and between Flamel Technologies S.A. and Phillandas T. Thompson, dated July 7th, 2015 (Filed herewith)
10.20	Membership Interest Purchase Agreement dated as of February 5, 2016, by and among James Flynn, Peter Steelman, Deerfield CSF, LLC, FSC Holding Company, LLC, FSC Therapeutics, LLC, FSC Laboratories, Inc., Flamel Technologies SA, and Flamel US Holdings, Inc. (Filed herewith)
10.21‡	Rules Governing the Free Share Plan – December 2014 (Filed herewith)
10.22‡	Rules Governing the Free Share Plan – December 2014 (Filed herewith)
10.23‡	June 2015 Stock Warrant Rules (Filed herewith)
10.24‡	Subscription Form of Stock Warrant (Filed herewith)
10.25‡	December 2015 Stock Option Rules (Filed herewith)
10.26‡	Form of Stock Option Grant Letter (Filed herewith)
14.1	Code of Ethics for CEO (*Directeur Général*), Delegated Managing Directors (*Directeurs Généraux Délégués*) and Senior Financial Officers **(6)**
21.1	List of Subsidiaries (Filed herewith)
23.1	Consent of PricewaterhouseCoopers Audit (Filed herewith)
31.1	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)
31.2	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)
32.1	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)
32.2	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)
101.INS	XBRL Instant Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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(1) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015.

(2) Incorporated by reference to the Company's Current Report on Form 6-K, filed March 21, 2012.

(3) Incorporated by reference to the Company's registration statement on Form F-6 filed February 12, 2014, as amended (No. 333-193892).

(4) 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.

(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.

(6) Incorporated by reference to the Company's Annual Report on Form 20-F for the year ended December 31, 2003, filed on April 26, 2004.

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

‡ Management contract or compensatory plan or arrangement filed pursuant to Item 15(b) of Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

FLAMEL TECHNOLOGIES S.A.

Dated: March 15, 2016

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of each of Craig R. Stapleton, Guillaume Cerutti, Francis J.T. Fildes, Benoit Van Assche and Christophe Navarre, by their respective signatures below, irrevocably constitutes and appoints Michael S. Anderson and Phillandas T. Thompson, and each of them individually acting alone without the other, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Michael S. Anderson Michael S. Anderson	Chief Executive Office (Principal Executive Officer) and Director	March 15, 2016
/s/ Michael F. Kanan Michael F. Kanan	Chief Financial Officer (Principal Financial Officer)	March 15, 2016
/s/ David P. Gusky David P. Gusky	Corporate Controller (Principal Accounting Officer)	March 15, 2016
/s/ Craig R. Stapleton Craig R. Stapleton	Non-Executive Chairman of the Board and Director	March 15, 2016
/s/ Guillaume Cerutti Guillaume Cerutti	Director	March 15, 2016
/s/ Francis J.T. Fildes Francis J.T. Fildes	Director	March 15, 2016
/s/ Benoit Van Assche Benoit Van Assche	Director	March 15, 2016
/s/ Christophe Navarre Christophe Navarre	Director	March 15, 2016

Exhibit 10.14

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 COPY

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "Agreement") is dated as of September 30, 2015 (the "Effective Date"), and is by and between ELAN PHARMA INTERNATIONAL LIMITED, a company organized under the laws of the Republic of Ireland, with offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland ("Elan") and FLAMEL IRELAND LIMITED, a company organized under the laws of the Republic of Ireland, with offices located at 2nd Floor, Block 10, Unit 1 Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Flamel").

RECITALS

A. Flamel has technology called LiquiTime® that may be used for developing modified/controlled release oral pharmaceutical products in a liquid suspension formulation.

B. Elan has substantial experience in developing, selling and marketing pharmaceutical products in the over-the counter, non-prescription ("OTC") pharmaceutical markets.

C. Flamel has begun working on developing extended release versions utilizing LiquiTime® of Ibuprofen liquid suspension (the "Ibuprofen Product") and Guaifenesin liquid suspension (the "Guaifenesin Product" and collectively with the Ibuprofen Product, the "Initial Products" and each an "Initial Product").

D. For the Initial Products and certain additional extended release OTC products identified by the Parties in the future, each utilizing LiquiTime® (each an "Additional Product" and collectively the "Additional Products" and collectively with the Initial Products the "Products" and each a "Product"), Flamel will develop and obtain marketing authorizations for the Products, transfer the marketing authorizations for these Products to Elan upon their approval and be paid a royalty by Elan on its sales of the Products; all on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions.

As used in this Agreement, the following terms have the meanings indicated below:

"Additional Product" or "Additional Products" has the meaning set forth in the Recitals hereof.

"Additional Product Requirement" has the meaning set forth in Section 5.4 hereof.

"Act" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

"Affiliate" means, with respect to any Person, any other Person directly or indirectly controlled by, controlling, or under common control with such Person. For such purposes, the term "control" means, whether used as a noun or a verb, the possession, directly or indirectly, of the power to affirmatively direct, or affirmatively cause the direction of, the management and policies of an entity, whether through the ownership of voting securities, by contract or otherwise (which would include the ownership, directly or indirectly, of more than 50% of the voting stock or equity interest of the subject Person, or such other relations as, in fact, result in the right to direct the management and policies of the subject Person).

"Agreement" has the meaning set forth in the Preamble hereof.

"cGMP" means those current Good Manufacturing Practices required by the FDA to be followed in connection with the manufacturing, handling, storing and controlling of pharmaceutical products in the United States, as defined from time to time by the Act, as amended, or any successor laws or any regulations related thereto.

"Clinical and Regulatory Activities" has the meaning set forth in Section 4.2 hereof.

"Coated API" has the meaning set forth in Section 5.5 hereof.

"Coated API Agreement" has the meaning set forth in Section 5.5 hereof.

"Commercial Manufacturing Scale-Up Activities" has the meaning set forth in Section 4.3 hereof.

"Commercial Launch Date" means, with respect to each Product, the date of Elan's first sale of such Product to Third Parties on a commercial basis in the Territory, which date shall be no later than (i) sixty (60) days following delivery to Elan of the commercial launch quantities of the Ibuprofen Product; and (ii) sixty (60) days after FDA approval of the Regulatory Filing for the Guaifenesin Product and each Additional Product.

"Competing Product" means, with respect to any Product, any extended release liquid product containing the same active pharmaceutical ingredient, in the same strength as such Product in the case of monotherapy products or the same combination of active pharmaceutical ingredients as such Product in the case of combination therapy products such that such product would reasonably be considered as substitutable for such Product.

"Confidential Information" means all proprietary materials, data or other information (whether or not patentable) regarding a Person's knowhow, products, business information or objectives, that are designated as confidential in writing by the disclosing party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such material, data or other information is disclosed by such Person to the recipient. Notwithstanding the foregoing, materials, data or other information that are disclosed by a Person in writing without an appropriate letter, stamp or legend, or that are orally, electronically or visually disclosed by a Person, also constitute Confidential Information of such Person if (i) within thirty (30) calendar days after such disclosure, such Person delivers to the recipient a written document or documents describing the materials, data or other information indicating that such materials, data or other information constitute Confidential Information, and referencing the place and date of such oral, visual, electronic or written disclosure and the names of the persons to whom such disclosure was made, or (ii) such materials, data or other information are of the type that are customarily considered to be confidential information by Persons engaged in activities that are substantially similar to the activities being engaged in by the Persons exchanging such information. Confidential Information does not include any information that is (i) already known to the recipient prior to the date of disclosure to the recipient as evidenced by the recipient's written records made prior to such date, (ii) publicly known prior to or after disclosure other than through unauthorized acts or omissions of the recipient, (iii) disclosed in good faith to the recipient by a Third Party lawfully and contractually entitled to make such disclosure or (iv) developed by or for the recipient without the use of any Confidential Information of the disclosing party, as evidenced by the recipient's written records.

"Contract Year" means each one (1) year period during the Term with the first such one (1) year period commencing on the Effective Date and ending on the day immediately preceding the one (1) year anniversary of the Effective Date, and each subsequent one (1) year period commencing on the subsequent anniversary of the Effective Date.

"Damages" has the meaning set forth in Section 7.1 hereof.

"Effective Date" has the meaning set forth in the Preamble hereof.

"Elan" has the meaning set forth in the Preamble hereof.

"Elan Fiscal Quarter" means each of the four (4) fiscal quarters used by Elan for financial reporting purposes.

"Elan Indemnitees" has the meaning set forth in Section 7.1 hereof.

"Elan Net Sales" means, with respect to the aggregate amount of each Product sold by Elan or its Affiliates, the gross sales (for purposes of determining whether a given sale occurs during a computation period, such Product will be considered sold as of the date of shipment by Elan or its Affiliates to its customers), less the sum of the following (to the extent actually incurred or accrued): (i) any and all credits for such Product returns during such period, including, but not limited to, credits for returned, unsold, or short-dated Product, allowances granted or included in the invoice, reasonable cash discounts, customer program accruals (overbills, administrative fees, third party rebates, sales brokerage, and volume rebates), other adjustments and rebates, including but not limited to Medicaid and other state or governmental rebates, charge backs, floor stock adjustments, and similar items that may be estimated in accordance with GAAP to the extent actually incurred or accrued; (ii) shipping costs, sales and excise Taxes, other consumption Taxes, or other governmental charges to the extent actually included in gross sales; and (iii) the amount of any receivables that have been included in gross sales and are deemed to be uncollectible according to Elan's or it Affiliates' internal accounting principles and GAAP, with such bad debt deduction applied against gross sales in the period in which such receivables are written off and shall be exclusive of any bad debt or uncollectible receivables of Elan or its Affiliates unrelated to any such Product sold by Elan or its Affiliates.

"Elan Subcontractor" has the meaning set forth in Section 4.2 hereof.

"FDA" means the United States Food and Drug Administration.

"Field" means the OTC pharmaceutical markets.

"Flamel" has the meaning set forth in the Preamble hereof.

"Flamel Indemnitees" has the meaning set forth in Section 7.2 hereof.

"Flamel Know-How" means all trade secrets, knowledge, technology, specifications, inventions, assays, means, methods, processes, controls, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, manufacturing procedures, test procedures and purification and isolation techniques, quality controls, the identity and amounts of ingredients, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form, and all improvements, whether to the foregoing or otherwise, and other discoveries, developments and inventions; in each case, applying or pertaining to (i) Flamel's LiquiTime® technology for developing modified/controlled release oral pharmaceutical products in a liquid suspension formulation; and (ii) the Laboratory Development Activities, the Clinical and Regulatory Activities and the Commercial Manufacturing Scale-Up Activities of Flamel for each Product.

"Flamel Patents" means (i) the issued patent identified as UD 7,906,145 and any extensions, reissues or reexaminations thereof; and (ii) any patent applications throughout the world claiming priority of patent applications identified in US 7,906,145 and any patents that may issue therefrom.

"Flamel Patents Termination Date" means the earlier of (i) the date the Flamel Patents expire in the Territory; or (ii) the date the Flamel Patents are revoked by the United States Patent and Trademark Office.

"Flamel Technology" means, collectively, the Flamel Patents and the Flamel Know-How.

"Force Majeure Event" has the meaning set forth in Section 11.7 hereof.

"GAAP" means generally accepted accounting principles applied in a consistent manner in the United States of America.

"Governmental Body" means any national, state, provincial, or other political subdivision thereof or any governmental or regulatory entity or agency with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions in the Territory or the jurisdiction in which Product is manufactured.

"Guaifenesin Product" has the meaning set forth in the Recitals hereof.

"Ibuprofen Product" has the meaning set forth in the Recitals hereof.

"Indemnified Party" has the meaning set forth in Section 7.3 hereof.

"Indemnifying Party" has the meaning set forth in Section 7.3 hereof.

"Initial Product" or "Initial Products" has the meaning set forth in the Recitals hereof.

"Insolvent" means, with respect to any Person, such Person (i) making an assignment for the benefit of creditors; (ii) filing or having filed against it a petition in bankruptcy; (iii) having a receiver appointed for its assets; or (iv) being dissolved or liquidated.

"Intellectual Property Rights" means, collectively, all of the following intangible legal rights in the Territory, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: (i) patents, patent disclosures, patent rights, including any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, utility model, industrial designs and design patents or any extensions thereof; (ii) rights associated with works of authorship, including without limitation, copyrights, copyright applications and copyright registrations; (iii) rights in trademarks, trademark registrations and applications therefor, trade names, service marks, service names, logos, or trade dress; (iv) rights relating to the protection of formulae, trade secrets, know-how and Confidential Information; and (v) all other intellectual or proprietary rights in the Territory.

"Laboratory Development Activities" has the meaning set forth in Section 4.1 hereof.

"License Conversion Event" means the earlier to occur of the following: (i) the Flamel Patents Termination Date; or (ii) the termination of this Agreement by Elan pursuant to Section 10.2(a) hereof.

"OTC" has the meaning set forth in the Recitals hereof.

"Party" or "Parties" means, individually or collectively, as the case may be, Elan and Flamel.

"Person" means any natural person, partnership, limited liability, company, trust, joint venture, joint stock company, association, unincorporated organization, government or agency or political subdivision thereof, or other entity, whether acting in an individual, fiduciary or other capacity.

"Product" or "Products" has the meaning set forth in the Recitals hereof.

"Reasonable Commercial Efforts" means, with respect to the subject Party, the level of efforts and resources equivalent to those employed by the subject Party to market and distribute a product of similar market potential at a similar stage in its product life to each Product, taking into account the establishment of such Product in the marketplace, the competitiveness of alternative products in the marketplace, the conditions or prospects of regulatory approval, the profitability of such Product and other relevant factors.

"Regulatory Filing" means a New Drug Application filed pursuant to Section 505(b)(2) of the Act.

"Royalty" means, with respect to each Product, the amount computed under the following royalty rates for that Product:

Time Period	Marginal Royalty Rate
First five (5) years after Commercial Launch Date of Product	[***]% of Elan Net Sales
Thereafter, until the expiration of the Term	[***]% of Elan Net Sales

"Special Damages" has the meaning set forth in Section 7.4 hereof.

"Tax" means any tax, levy, impost, duty or other charge or withholding of a similar nature (including any penalty or interest payable in connection with any failure to pay or any delay in paying any of the same).

"Tax Deduction" means any deduction or withholding for or on account of a Tax from any payment under this Agreement.

"Technology Transfer" has the meaning set forth in Section 4.4 hereof.

"Term" has the meaning set forth in Section 10.1 hereof.

"Territory" means the United States, including its territories and possessions.

[***] Confidential treatment requested for deleted portion.

"Third Party" means any Person other than the Parties and their Affiliates.

"UK Rx Markets" has the meaning set forth in Section 2.2 hereof.

"VAT" means (i) the value added Tax as provided for in the Value-Added Tax Consolidation Act 2010 (as amended) of Ireland; (ii) any Tax imposed in compliance with the Council Directive of 28 November 2006 on the common system of value added Tax (EC Directive 2006/112); and (iii) any other Tax of a similar nature, whether imposed in a member state of the European Union in substitution for, or levied in addition to, such Tax referred to in clause (i) and (ii) above, or imposed elsewhere.

2. Terms of License.

2.1 Grant of License. During the Term, Flamel hereby grants to Elan, and Elan hereby accepts from Flamel, an exclusive (even as to Flamel except for Flamel, its Affiliates or its subcontractors solely to perform their obligations and duties hereunder or in connection therewith), sublicensable, license solely in the Field in the Territory to use the Flamel Technology, including all Intellectual Property Rights pertaining thereto, to sell and market the Products and otherwise exploit the Regulatory Filings for the Products in the Field in the Territory and after the Flamel Patents Termination Date to also develop and register additional pharmaceutical products in the Field in the Territory. Elan acknowledges and agrees that the exclusivity granted to Elan in this license will, prior to any License Conversion Event, be contingent on Elan continuing to satisfy the Additional Product Requirement and the Competing Product Requirement.

2.2 Expansion of Field and Territory. Flamel hereby acknowledges Elan's interest in commercializing the Flamel Technology in the Rx markets in the United Kingdom, which markets are outside of the Field and the Territory (the "UK Rx Markets"). Flamel agrees to discuss the UK Rx Markets in good faith with Elan prior to offering this business to any Third Party.

2.3 License Conversion Event. Upon the occurrence of any License Conversion Event, (i) the license to the Flamel Technology will become perpetual, fully-paid and irrevocable in the Field and in the Territory, and (ii) Elan's obligation to pay Royalties will cease; in each case, with respect to each Product impacted by the circumstances giving rise to such License Conversion Event (but not for any Products not so impacted).

3. Financial Provisions

The sole and exclusive consideration payable to Flamel by Elan for the license granted above, Flamel's development work described below and all other obligations of Flamel under this Agreement or services performed by Flamel, its Affiliates or subcontractors in connection with the Initial Products is as follows:

3.1 License Fee. Elan shall pay to Flamel a one-time, license fee of Six Million Dollars ($6,000,000) within thirty (30) days after the Effective Date.

3.2 Milestone Payments. With respect to each Initial Product Elan shall pay to Flamel the following milestone Payments within thirty (30) days after the occurrence of each event described below with respect to such Initial Product:

- [***] Dollars ($[***])– upon submission of the NDA transfer letter by Flamel to the FDA notifying the FDA of the transfer of the Regulatory Filing to Elan after FDA approval of such Initial Product.

- [***] Dollars ($[***]) – upon Commercial Launch Date of such Initial Product.

3.3 Royalty. Within ten (10) days after the end of each Elan Fiscal Quarter, Elan shall provide Flamel with an initial estimate of the Royalties due to Flamel for such Elan Fiscal Quarter. Elan shall pay the Royalty to Flamel in respect of Product sales taking place during that Elan Fiscal Quarter within sixty (60) days after the end of that Elan Fiscal Quarter.

3.4 Recordkeeping and Audit Right. Elan shall maintain complete and accurate records pertaining to its computation of the Royalty payable under this Agreement during Term and for a period of two (2) years after the termination or expiration of this Agreement. On an annual basis or more frequently for good cause shown, during the Term and the retention period noted above, upon reasonable advance notice Flamel may appoint at its own expense an independent public accounting firm to audit the relevant records of Elan supporting its computation of the Royalty. Flamel shall be entitled to any amounts determined by the independent public accounting firm to have been underpaid by Elan, within forty-five (45) calendar days after demand therefor has been received by Elan, which demand shall include the complete audit report prepared by the independent public accounting firm. The determination by the independent public accounting firm will be binding on the Parties absent manifest error. The fees of the independent public accounting firm shall be borne by Flamel unless the report of the independent public accounting firm shows an underpayment by Elan of more than 10% in which case Elan shall be responsible for payment of the independent public accounting firm's fees.

4. Product Development and Technology Transfer.

4.1 Laboratory Development Activities. With respect to each Initial Product and upon mutual agreement of the Parties with respect to the Additional Products, Flamel, or one of its Affiliates or subcontractors, will be responsible for Product formulation, method validation, pilot studies and all other activities necessary to create a lab-scale version of such Product (the "Laboratory Development Activities").

4.2 Clinical and Regulatory Activities. With respect to each Initial Product and upon mutual agreement of the Parties with respect to the Additional Products, Flamel, or one of its Affiliates or subcontractors, will be responsible for performing all clinical studies, including any bio-equivalence studies, and for making the Regulatory Filing and obtaining approval of the Regulatory Filing (collectively, the "Clinical and Regulatory Activities").

[***] Confidential treatment requested for deleted portion.

4.3 Commercial Manufacturing Scale-Up Activities. With respect to the Initial Products and upon mutual agreement of the Parties with respect to each Additional Product, Flamel, or one of its Affiliates or subcontractors, will also be responsible for scaling up such Product for commercial production, manufacturing exhibit batches for pivotal studies (conducted by Flamel as part of the Clinical and Regulatory Activities) and producing exhibit batches for stability testing (the "Commercial Manufacturing Scale-Up Activities"). Although Flamel will be responsible for all Commercial Manufacturing Scale-Up Activities, it will engage Elan or one of its Affiliates as a subcontractor (the "Elan Subcontractor") to perform the Commercial Manufacturing Scale-Up Activities for each Product (except for the Ibuprofen Product for which Flamel has engaged another subcontractor to perform the Commercial Manufacturing Scale-Up Activities as of the Effective Date). Flamel and the Elan Subcontractor will enter into a separate agreement covering the legal and commercial terms governing the Commercial Manufacturing Scale-Up Activities for each Product; provided that such agreement will provide that Elan's fees for the Commercial Manufacturing Scale-Up Activities for each Product shall be charged to Flamel at Elan's fully-allocated cost and when added together with the cost of the Technology Transfer as described in Section 4.4 below may not exceed [***] Dollars ($[***]) per Product, provided further, that such agreement will also provide that such limitation to will not apply to any work required due to Product reformulation, test failures, specification changes or any other factor that is not under Elan's reasonable control. Notwithstanding the foregoing, in the event that Elan or the Elan Subcontractor cannot successfully perform the Commercial Manufacturing Scale-Up Activities for a Product within a reasonable period of time, Flamel shall have the right to engage a Third Party to perform such Commercial Manufacturing Scale-Up Activities and to manufacture and supply such Product to Elan on a commercial basis until such time as Elan or the Elan Subcontractor can successfully perform such activities at a price to Elan of no more than cost plus [***] percent ([***]%).

4.4 Technology Transfer; Commercial Manufacturing - Ibuprofen Product. To effect the transition of the Commercial Manufacturing Scale-Up Activities to Elan, Flamel, or one of its Affiliates or subcontractors, will transfer to Elan all Flamel Know How for that Product obtained in performing the Laboratory Development Activities and the Clinical and Regulatory Activities (the "Technology Transfer"). In the case of the Ibuprofen Product, the Technology Transfer will occur upon FDA approval of the Regulatory Filing for that Product. Furthermore, the Parties acknowledge and agree that in the case of the Ibuprofen Product, Flamel, its Affiliates or its subcontractor will be responsible for the commercial supply of the Ibuprofen Product to Elan at Flamel's cost or Flamel's acquisition cost of the Ibuprofen Product until the completion of the Technology Transfer and Elan or the Elan Subcontractor has received FDA approval to manufacture commercial supplies of the Ibuprofen Product. In the event that Flamel terminates this Agreement pursuant to Section 10.2, Elan shall immediately transfer back to Flamel all of the Flamel Know-How referenced above in this Section 4.4.

4.5 Regulatory Process and Transfer of Regulatory Filing. For each Product, Flamel, or one of its Affiliates or subcontractors, will submit the Regulatory Filing in Flamel's or its Affiliate's name and conduct all communications with the FDA. Elan will provide assistance to Flamel in connection with preparing, and obtaining approval of, the Regulatory Filing, provided that any such assistance will be performed on a time and materials basis unless within the scope of the Commercial Manufacturing Scale-Up Activities. Flamel, or one its Affiliates or subcontractors, will transfer the Regulatory Filing to Elan upon the earlier of the approval of the applicable Regulatory Filing or the termination of this Agreement; provided that Flamel shall have a right to reference and use any data (clinical or otherwise) with respect to the Products; and provided further that in the event of a termination of the Agreement by Flamel pursuant to Section 10.2, Elan shall immediately transfer the Regulatory Filing and any related data, back to Flamel.

[***] Confidential treatment requested for deleted portion.

4.6 Intellectual Property Rights. Subject to the license granted by Flamel to Elan under Section 2.1, all Intellectual Property Rights and intellectual property, arising as a result of the activities and services performed by Flamel under this Agreement shall be the sole and exclusive property of Flamel. Additionally, Elan agrees that Flamel shall have a royalty free, fully paid up, sublicensable license to any intellectual property and Intellectual Property Rights developed by Elan, the Elan Subcontractor or its Affiliates derived from the Flamel Technology.

5. Elan's Marketing, Sale and Distribution of Product.

5.1 Elan's Responsibilities. Elan shall use Reasonable Commercial Efforts to market and sell Product to customers that are located in the Field in the Territory. Under this Agreement, Elan shall not be permitted to (i) sell Product to, or solicit orders for sale of Product from, any existing or prospective customer located outside the Territory, (ii) deliver or tender (or cause to be delivered or tendered) Product outside the Territory, (iii) sell Product to, or solicit any sale of Product from, a customer in the Territory for which Elan knows or has reason to know intends to resell Product outside the Territory; or (iv) prior to any License Conversion Event, bundle any Product with another product of Elan or one of its Affiliates where such bundling results in any discount applied to such Product being proportionally greater than the discount applied to any other products.

5.2 Expenses. Elan is responsible for paying all its expenses in performing its sales and marketing obligations set forth in this Article 5.

5.3 Elan's Selling Price of Product. Subject to Section 5.1(iv) above, Elan has sole discretion over establishing the price at which it sells Product and is responsible for invoicing customers.

5.4 Exclusivity; Additional Product Requirement; Competing Product Requirement. Elan will be the exclusive licensee for the Flamel Technology in the Field in the Territory. Further, Flamel agrees that it will not, on its own or through an Affiliate, use the Flamel Technology in the Field in the Territory for any commercial purpose other than to perform its obligations and duties under this Agreement. The exclusivity granted by Flamel to Elan in this Section 5.4 will terminate in the event that Elan fails to satisfy the Additional Product Requirement or the Competing Product Requirement (as each is defined below). Elan will designate an Additional Product to be developed by Flamel during each of the first five (5) Contract Years on terms and conditions reasonably acceptable to the Parties (the "Additional Product Requirement"). In the event that the Parties cannot agree on the terms and conditions to satisfy the Additional Product Requirement, then, at Elan's option and decision, Flamel or its Affiliates or subcontractors shall either (A) develop the Additional Product for Elan and Elan shall pay Flamel, when due and payable, Flamel's or its Affiliates' fully-allocated cost (including the costs associated with any activities performed by any subcontractor) associated with performing the services) plus [***] percent ([***]%) and Elan shall pay Flamel (i) milestone payments of: (x) $[***] upon submission of the Regulatory Filing transfer letter to FDA notifying the FDA of the transfer of the of the Regulatory Filing to Elan after FDA approval of such Additional Product and (y) $[***] upon commercial launch of such Additional Product and (ii) the same Royalty as the Royalty paid for the Initial Products; or (B) develop and commercialize such Additional Product with a Third Party on commercial terms no less favorable to Flamel than the commercial terms set forth in clause (A) above. Elan acknowledges and agrees that in the case of clause (B) in the preceding sentence where such Additional Product is developed by a Third Party, Elan shall still have the obligation to designate a replacement Product for such Contract Year. Furthermore, as an additional condition to retaining the exclusivity set forth in this Section 5.4, during the Term, Elan agrees that it shall not directly or through an Affiliate or with a Third Party, manufacture, sale, market or distribute a Competing Product. Elan further agrees and acknowledges that Elan in addition to forgoing the exclusivity by selling a Competing Product, Elan shall pay Flamel, a royalty (in the same percentage and for the same time period) that is equal to the Royalty on the Products as set forth herein for any Competing Product sold.

5.5 Key Commercial Terms. Not later than six (6) months prior to the expected date of approval of the Regulatory Filing for each Product, the Parties will enter a commercial agreement for the supply by Flamel or one of its Affiliates or subcontractors to Elan of the extended release active pharmaceutical ingredient for such Product, coated by Flamel or one of its Affiliates or subcontractors with extended-release beads using the Technology ("Coated API"). The commercial agreement for Flamel's or one of its Affiliates' or subcontractors' supply of Coated API to Elan (the "Coated API Agreement") will include the terms set forth in **Schedule 5.5** attached hereto and other terms agreed upon by the Parties.

6. Representations and Warranties.

Each Party represents and warrants to the other Party that (i) it is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, (ii) the execution, delivery and performance of this Agreement by such Party has been duly authorized, and this Agreement is a valid and binding obligation of such Party enforceable against such Party in accordance with its terms, (iii) the execution, delivery and performance of this Agreement by such Party will not result in any breach of its organizational documents or any breach or violation of any agreement or instrument to which it is a party or bound or of any law, regulation, order or decree to which it is subject or by which its assets are bound, (iv) such Party has full power and authority to perform its obligations and grant the rights it has granted to the other Party as provided in this Agreement, (iv) none of its employees, officers, directors, or agents has been: (a) debarred, or convicted of a crime for which a Person can be debarred, under Section 306(a) of the United States Federal Generic Drug Enforcement Act of 1992, as amended, or (b) to the best of its knowledge, have been threatened with debarment or indictment for such a crime by a Governmental Body.

[***] Confidential treatment requested for deleted portion.

If any debarment or conviction occurs while this Agreement is in force and effect, the Party involved with such debarment or conviction shall promptly provide notification to the other Party.

EXCEPT AS PROVIDED IN THIS ARTICLE 6, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

7. Patent Indemnification and Excluded Damages.

7.1 Patent Indemnification. Except in the case of Elan's gross negligence or willful misconduct, Flamel shall defend, indemnify and hold Elan, including its Affiliates and their respective directors, officers, shareholders, employees, servants and agents harmless (the "Elan Indemnitees") from and against any and all losses, liabilities, damages, costs and expenses, including reasonable attorneys' fees and disbursements in connection with any and all Third-Party suits, investigations, claims or demands (collectively, "Damages"); in each case, resulting from or in connection with the Flamel Patents, except, in each case, for those Damages for which Elan has an obligation to indemnify the Flamel Indemnitees pursuant to Section 7.2, as to which Damages each Party shall indemnify the other Party to the extent of its respective liability for such Liabilities.

7.2 Commercialization Indemnification. Except in the case of Flamel's gross negligence or willful misconduct, Elan shall defend, indemnify and hold Flamel, including its Affiliates and their respective directors, officers, shareholders, employees, servants and agents harmless (the "Flamel Indemnitees") from and against any Damages from or in connection with Elan's manufacturing, sale, marketing and distribution of the Products; except, in each case, for those Damages for which Flamel has an obligation to indemnify the Elan Indemnitees pursuant to Section 7.1, as to which Damages each Party shall indemnify the other Party to the extent of its respective liability for such Damages.

7.3 Indemnification Procedures. Upon the occurrence of any event giving rise to a right to seek indemnification hereunder, Elan or Flamel, as the case may be (the "Indemnified Party") shall give notice of such claim, action or proceeding to the other Party (the "Indemnifying Party") within ten (10) calendar days after it becomes known to Elan, except that the failure to give such notice shall not relieve the Indemnifying Party of its obligations to indemnify unless such failure materially and adversely affects the defense of such action or increases the liability of the Indemnifying Party. Within ten (10) calendar days after receipt of such notice, the Indemnifying Party shall notify the Indemnified Party as to whether or not the Indemnifying Party wishes to take over the defense of such action, and if the Indemnifying Party fails to provide such notice, the Indemnified Party shall be entitled to take over the defense of the action. Upon proper notification by the Indemnifying Party of its intention to defend the claim, the Indemnifying Party shall engage counsel reasonably satisfactory to the Indemnified Party to assume the investigation and defense of the claim and shall keep the Indemnified Party and its counsel currently informed as to all material aspects of the claim and its investigation and defense. The Indemnified Party may, in such case, engage counsel to assist in the investigation and defense of the claim but shall not be entitled to reimbursement for any expenses related to the engagement of such counsel. If the Indemnifying Party elects not to assume the investigation and defense of the claim, or fails to make any election within the time period herein provided, or if in the reasonable opinion of counsel to the Indemnified Party, the Indemnified Party has available to it defenses that are contrary to the interests of the Indemnifying Party in any such action, then the Indemnified Party may engage its own counsel for such investigation and defense and shall be entitled to full indemnification for the costs thereof.

7.4 Excluded Damages**.** EXCEPT IN THE CASE OF A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR A BREACH OF SECTION 9.1, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR OTHER SIMILAR DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF REVENUE OR LOSS OF PROFITS ("COLLECTIVELY, "SPECIAL DAMAGES"), EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH SPECIAL DAMAGES, PROVIDED THAT EITHER PARTY WILL BE LIABLE FOR SUCH SPECIAL DAMAGES TO THE EXTENT IT IS OBLIGATED TO INDEMNIFY THE OTHER PARTY UNDER THIS AGREEMENT IN RESPECT OF A THIRD-PARTY CLAIM AGAINST THE OTHER PARTY THAT INCLUDES SUCH SPECIAL DAMAGES.

8. Insurance.

8.1 General Requirements. Each of Flamel and Elan shall obtain and maintain at its expense during the Term and for a period of at least five (5) years after the termination or expiration of this Agreement, all insurance coverage required by law as well as appropriate insurance coverage to protect against any and all claims or liabilities that may arise directly or indirectly as a result of its performance of its obligations under this Agreement. Insurance shall be placed with a carrier with an A.M. Best rating of at least A- for financial strength and a size rating of at least VIII. Coverage shall be occurrence based, unless occurrence coverage is unavailable, in which case "claims made" coverage is acceptable, provided retroactive coverage is provided prior to the inception of the business relationship between Elan and Flamel. None of the requirements contained herein as to coverage types or limits of insurance required to be maintained by the Parties shall be construed to limit in any manner the liability of either Party to the other Party hereunder.

8.2 Proof of Insurance. Each Party shall deliver to the other Party, within thirty (30) calendar days after the execution of this Agreement, Certificates of Insurance evidencing the following: (i) the effective and expiration dates of the policies; (ii) for each of the policies, the limits of liability per occurrence and in the aggregate; (iii) that the other Party has been named as an additional insured under products liability and excess liability policies; and (iv) that the other Party shall be given thirty (30) calendar days advance notice prior to any cancellation, non-renewal or material change of any of the policies. Each Party shall provide to the other Party current Certificates of Insurance evidencing renewal of insurance throughout the Term promptly after any change or renewal of the policies.

8.3 Specific Minimum Coverages. At a minimum, each Party shall keep the following policies in place during the term of this Agreement:

Required Coverages and Minimum Policy Limit

Required Coverage	Policy Limit
Worker's Compensation	Statutory
General Liability: Bodily Injury & Property Damage	$ 5,000,000 (U.S. Combined Single Limit, per occurrence)
Product Liability	$ 10,000,000
Excess Liability	$ 5,000,000

9. Confidentiality.

9.1 Obligations of Confidentiality. Neither Party will use or disclose to Third Parties any Confidential Information of the other Party (except to comply with its obligations under this Agreement), except that each Party may disclose such Confidential Information to such of its managers, officers, directors, employees and agents (and to such of the managers, officers, directors, employees and agents of its Affiliates) as reasonably required it in connection with this Agreement and who agree in writing to be bound by confidentiality obligations not less restrictive than those contained in this Agreement, and each Party shall ensure that such managers, officers, directors, employees and agents comply with such obligations and shall be responsible for their failure to do so. Notwithstanding the foregoing, such information may be (i) disclosed to any Governmental Body where such Confidential Information may be required to be included in regulatory filings permitted under the terms of this Agreement or in patent applications filed within the United States Patent and Trademark Office or corresponding international patent offices, (ii) provided to a Party's employees, advisors and consultants under appropriate terms and conditions including confidentiality provisions substantially equivalent to those in this Agreement, for the purpose of such Party performing its obligations under this Agreement, (iii) published, if and to the extent such publication has been approved by disclosing Party, or (iv) disclosed to the extent required by applicable laws or regulations or as ordered by a court or other Governmental Body having competent jurisdiction. In each of the foregoing cases, the recipient shall use its reasonable commercial efforts to limit the disclosure and maintain confidentiality to the extent possible. In the case of a required disclosure under clause (iv) above, the Party required to make the disclosure shall promptly notify the original disclosing Party and shall provide reasonable assistance, if requested by the original disclosing party, to assist the original disclosing Party in its attempts to prevent or limit the disclosure at the original disclosing Party's cost and expense. If a Party is required by law or court order to provide a copy of this Agreement or any related document to any Third Party (except in confidence as permitted by this Agreement), such Party shall redact Confidential Information from such document, except as otherwise required by law. Each Party shall have the right to review and approve each redacted document prior to its submission to a Third Party. The reviewing Party shall have a period of ten (10) calendar days to review the redacted document, except that in the case of the order of a court or regulatory agency, the reviewing Party shall have the maximum reasonable amount of time.

9.2 Termination of Agreement. Upon the expiration or termination of this Agreement, each Party shall return to the disclosing Party or destroy all Confidential Information of the disclosing Party in tangible form in its possession; provided, that (i) the receiving Party may retain one (1) copy of Confidential Information of the disclosing Party in its legal files solely for the purpose of demonstrating the satisfaction of its continuing obligations of confidentiality under this Agreement, and (ii) if a License Conversion Event has occurred, Elan may retain any documents needed to continue to exercise its rights under its license.

9.3 Injunctive Relief. Each Party acknowledges that if it breaches any of the provisions of this Article 9, the other Party may not have an adequate remedy at law and may suffer irreparable damage and injury and that, in addition to any other available rights and remedies, the other Party shall be entitled to seek an injunction restricting the breaching Party from committing or continuing any violation of such provisions.

10. Term and Termination.

10.1 Term. This Agreement commences of on the Effective Date and will remain in effect, unless earlier terminated as set forth herein, with respect to each Product, until the Flamel Patents Termination Date (the "Term").

10.2 Termination.

(a) Either Party may terminate this Agreement or a particular Product from this Agreement by written notice to the other Party if the other Party materially breaches this Agreement and fails to cure the material breach within forty-five (45) calendar days after written notice of the material breach has been given to the breaching Party.

(b) Either Party may terminate this Agreement upon written notice to the other Party if the other Party becomes Insolvent.

(c) Either Party may terminate this Agreement upon thirty (30) days written notice in connection with a Force Majeure Event pursuant to Section 11.7 hereof.

10.3 Actions Upon Termination. Upon termination or expiration of this Agreement for any reason, Elan may sell Product in its inventory as of the date of termination, and, prior to any License Conversion Event, Elan shall pay to Flamel the Royalty for such sales in accordance with Section 3.3 hereof.

11. Miscellaneous.

11.1 Each Party Pays Own Costs. Except as expressly stated otherwise herein, each Party shall be responsible for the costs it incurs in performing its obligations under this Agreement.

11.2 Currency. All financial calculations and payments made by Elan to Flamel under this Agreement shall be made in U.S. Dollars. All other references to "dollars" or "$" shall indicate U.S. Dollars.

11.3 Taxes. All sums required to be paid under or in connection with this Agreement for Flamel Technology are to be treated as exclusive of VAT, and Elan shall pay to Flamel an amount in respect of VAT properly chargeable on any amounts due under this Agreement in addition to the sums otherwise payable. Flamel shall issue a valid VAT invoice in accordance with law. Elan shall make all payments to be made by it without any Tax Deduction, unless a Tax Deduction is required by law.

11.4 Independent Contractor. The relationship between Elan and Flamel is that of independent contractors, and nothing contained in this Agreement or otherwise shall be deemed to create any other relationship, including employment, partnership, agency or joint venture, between them. Neither Party shall have any authority to employ any Person as agent or employee for or on behalf of the other Party, or to bind, or attempt to bind, the other Party to any obligation with any Third Party. Each Party has and retains full control and supervision over the performance of its obligations hereunder and over the employment, direction, compensation and discharge of all employees, agents and subcontractors it utilizes in the performance of such obligations. Each Party is responsible for its acts and omissions and those of its employees, agents and subcontractors.

11.5 Advertising and Publicity. Neither Party shall use the name or any trademark, trade name, logo or symbol of the other Party or the other Party's Affiliates, or disclose any matters relating to this Agreement, in any advertising, promotion, press/publicity releases, written articles or communications without the prior consent of the other Party.

11.6 Cooperation. The Parties agree to meet regularly and keep one another updated with respect to the activities set forth in Article 4 and Article 5 and the development, manufacturing, marketing and sale of the Products.

11.7 Force Majeure. Neither Party shall be liable for delays in performance or nonperformance in whole or in part due to any causes that are beyond its reasonable control and not due to its acts or omissions, such as acts of God, fire, strikes, embargo, acts of the government, or other similar causes, but not acts that could be anticipated, such as raw material price increases, shortages of raw material or an increase in demand for Product (each a "Force Majeure Event"), provided that if any Force Majeure Event shall continue for a period of six (6) months or longer, then the Party whose performance has not been impacted by such Force Majeure Event shall have the right to terminate this Agreement without liability upon notice to the Party whose performance has been so impacted. Upon the occurrence of a Force Majeure Event, the Party delayed shall promptly give notice to the other Party.

11.8 Assignment and Subcontracting. Other than to one of its Affiliates and to subcontractors with respect to Article 4 and Section 5.4 hereof, neither Party may assign this Agreement or subcontract any of its obligations under this Agreement, in whole or in part, to any other Person without the prior consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. Notwithstanding any permitted assignment under this Section 11.8, the assigning party will remain jointly and severally liable for the obligations assigned.

11.9 Notices. Any notice, communication, consent, approval, request, demand or statement required or permitted to be given hereunder shall be in writing and deemed to have been sufficiently given when delivered in person or by registered or certified mail, postage prepaid, return receipt requested or by overnight courier service, addressed as follows:

To Flamel:

Flamel Ireland Limited
c/o Flamel Technologies, SA
702 Spirit 40 Park Drive, Suite 108
Chesterfield, Missouri 63005
Attention: Legal Department
Facsimile: +16364991850

To Elan:

Elan Pharma International Limited
c/o L. Perrigo Company
515 Eastern Avenue
Allegan, Michigan 49010
Attn: General Counsel
Facsimile: +12696731386

Any Party may, by notice to the other, change the addresses and names given above.

11.10 Non-Waiver. The failure of a Party to strictly enforce any of the terms or conditions of this Agreement shall not be considered as a waiver of any right hereunder nor shall it deprive that Party of the right at some other time to insist upon strict adherence to that term or condition or to any other terms or conditions.

11.11 Severability. If any article, section, subsection, sentence or clause of this Agreement shall be adjudged illegal, invalid or unenforceable, such illegality, invalidity or unenforceability shall not affect the legality, validity or enforceability of this Agreement as a whole or of any article, subsection, sentence or clause hereof not so adjudged, and the remaining terms and provisions of this Agreement will remain unimpaired and in full force and effect.

11.12 Section Headings. All section headings herein are for convenience only and are not to be construed as a limitation of the scope of the particular sections to which they refer.

11.13 Governing Law and Jurisdiction. The validity, interpretation and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to its principles of conflicts of law.

11.14 Successors and Assigns. This Agreement will apply to, inure to the benefit of and be binding upon the Parties hereto and upon their respective successors and permitted assigns.

11.15 Survival of Obligations. The termination or expiration of this Agreement shall not affect the survival and continuing validity of Section 2.3 (License Conversion Event); Article 3 (Financial Provisions); Article 7 (Indemnification and Excluded Damages); Article 8 (Insurance); Article 9 (Confidentiality); Section 10.3 (Actions Upon Termination); and Article 11 (Miscellaneous) or of any other provision that is expressly or by implication intended to continue in force after such termination or expiration.

11.16 Amendments. No modification, alteration or amendment of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto, as the case may be.

11.17 Entire Agreement. This Agreement, together with any documents attached hereto, constitutes the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect thereto, including but not limited to the Mutual Confidential Disclosure Agreement between Flamel and Perrigo Company plc dated as of December 3, 2014.

ELAN PHARMA INTERNATIONAL LIMITED

By: _____
Name: _____
Title: Authorized Signatory

FLAMEL IRELAND LIMITED

By: /s/ Phillandas T. Thompson
Name: Phillandas T. Thompson
Title: Authorized Signatory

SCHEDULE 5.5

KEY COMMERCIAL TERMS FOR COATED API AGREEMENT

Subject Matter	Term
Price for Coated API	Fully-allocated cost of Flamel to supply Coated API until the termination of Royalty payments under Agreement; thereafter, plus an agreed-upon percentage mark-up.
Indemnification	Elan would defend, indemnify and hold Flamel harmless for any Product defects not caused by defects with Coated API, Flamel Technology or Flamel's breach of its obligations under Coated API Agreement.
Term and Termination	May be terminated only upon termination of License and Development Agreement or due to either Party's material breach (which in the case of Elan would be limited to non-payment).
Exclusions on Damages	Except in the case of a Party's gross negligence or willful misconduct, in no event will either Party be liable to the other party for any special, indirect, incidental, consequential, punitive or other similar damages, including without limitation loss of revenue or loss of profits.
Responsibility For API Defects	Elan will source and be responsible for any defects with immediate release API; Flamel will source and be responsible for any defects with extended release API.
Warranties	Flamel will perform the API coating in accordance with cGMP and in a professional and workmanlike manner.
Governing Law	New York
Shipping Terms	FCA (Incoterms 2010) Allegan, Michigan.
Payment Terms	MSN 3
Recall Expenses	Each Party will be responsible for recalls to the extent of its fault.

Exhibit 10.15

LEASE

This Lease, entered into as of the 23rd day of July, 2013, between Nine East, LLC, hereinafter called "Landlord", and Eclat Pharmaceutical LLC, hereinafter called "Tenant".

WITNESSETH:

1. **Premises**. Landlord, for an in consideration of the rents, covenants and agreements hereinafter mentioned and hereby agreed to be paid, kept and performed by Tenant, does hereby lease with covenant for quiet enjoyment to Tenant, and Tenant hereby leases from Landlord office space in the building known and numbered as 702 Spirit 40 Park Drive, Chesterfield, Missouri 63005, located on ground in St. Louis County, Missouri, said space (hereinafter referred to as the "leased premises") being more particularly described as Suite 108, and set forth on Exhibit A attached hereto and by reference made a part hereof.

2. **Use of Premises**. The leased premises shall be used and occupied by Tenant, subject to the conditions herein contained, for general office purposes only. In no event shall the leased premises be used or occupied by the Tenant in any manner contrary to law, zoning regulations, or recorded restrictions, if any.

3. **Term**. The term of this lease shall be for five (5) years, commencing on November 1, 2013, and ending on October 31, 2018, both dates inclusive. Tenant agrees to make material and/or color selections (when applicable) within 15 days after being requested to do so by Landlord, failing which Landlord shall make such material and/or color selection without Tenant's participation. If the leased premises are not available or ready for occupancy at the stated commencement date, and such unavailability or unreadiness is not occasioned or caused by Tenant, then the commencement date shall be the first day of the month succeeding the month in which the leased premises are available and ready for occupancy, as evidenced by written notice given by Landlord to Tenant, and the termination date shall be extended accordingly. In the event the commencement and termination dates have been determined as aforesaid upon the demand of either the Landlord or the Tenant, the parties hereto agree to execute a written declaration expressing the specific commencement and termination dates. Subject to the availability of the leased premises, the Tenant shall have the right prior to the commencement date to enter upon the leased premises at reasonable times for the purpose of preparing the leased premises for their intended use. If, by mutual consent of the parties, Tenant takes possession of the leased premises prior to the commencement date, then during such pre-term period, Tenant shall pay rent as herein established on a pro rata basis and such occupancy shall be under all of the terms and conditions of this lease, but such pre-term occupancy shall not affect the lease term as herein otherwise established.

4. **Rent**. Tenant shall, without deduction, abatement or setoff of any nature whatsoever, pay to Landlord as fixed rent for the leased premises the sum of Eighty Four Thousand Six Hundred Sixty ($84,660.00) Dollars per annum, in equal monthly installments of Seven Thousand Fifty-Five ($7,055.00) Dollars each for the period November 1, 2013 through October 31, 2016, and the sum Ninety Five Thousand Two Hundred Forty Four ($95,244.00) Dollars per annum, in equal monthly installments of Seven Thousand Nine Hundred Thirty Seven ($7,937.00) Dollars each for the period November 1, 2016 through October 31, 2018, in advance and without demand on the first day of each and every month throughout the term of this lease. The rent shall be payable at the office of Landlord, or at such other place as Landlord may from time to time designate in writing. The third month's rent shall be due with the signing of this lease by Tenant. The first two months of Tenant's rent shall be abated.

5. **Rent Adjustments.**

a. The Tenant shall pay to Landlord, as additional rent, the proportionate part of any increases in real estate taxes levied, assessed or payable with respect to the land and building of which the leased premises are a part over and above the amount thereof levied, assessed or paid for the calendar year 2014 (Base Year). Such additional rent by reason of tax increases shall be payable by Tenant upon presentation to Tenant of copies of paid tax statements for the base year and for the year for which payment is demanded. The proportion of such increase payable by the Tenant shall be based on the ratio which the number of rentable square feet of area occupied by the Tenant in the building bears to the total number of rentable square feet of area in the entire building (Tenant's Proportionate Share). If the term of this lease shall commence or terminate other than on the first or last day of a calendar year, Tenant shall pay for said calendar year, that portion of such increases in taxes, if any, proportionate to the number of months of tenancy during such year. Tenant's proportionate share of such taxes shall be paid within thirty (30) days after receipt of an invoice from Landlord .

b. In the event that for any calendar year Landlord's Operating Expenses of the building (including interior and exterior common areas) of which the leased premises are a part shall exceed the Base Amount occurring during the calendar year 2014 as evidenced by a statement of actual Operating Expenses prepared by Landlord, Tenant shall pay Tenant's Proportionate Share (as defined in (a) above) of such excess over the Base Amount as follows. For expenses which Landlord has direct control over, in no event shall the total of such Landlord-controlled expense increases exceed 5% over the total of Landlord-controlled expenses for the previous year.

c. After the second calendar year, 2015, ending during the lease term, Tenant shall within thirty (30) days after receipt of Landlord's statement of Operating Expenses pay to Landlord in one lump sum, as additional rent, Tenant's Proportionate Share of the increase, if any, in Operating Expenses for such second calendar year over the Base Amount, prorated, however, on the basis of thirty (30) days to the month if the first calendar year of the lease term shall be less than twelve (12) months.

d. During the second and succeeding calendar years Tenant shall pay monthly in advance, as additional rent for each such calendar year (or to the expiration date of this lease, whichever first occurs), an amount per month equal to one-twelfth (1/12th) of Tenant's Proportionate Share of Landlord's estimated Operating Expenses for said calendar year over the Base Amount. The amount of such additional rent not determined at the beginning of any calendar year shall be brought current by Tenant with fifteen (15) days after the amount is determined. If by reason of such advance monthly payments Tenant shall have paid in excess of its Proportionate Share of excess Operating Expenses for the fiscal year, Landlord will, when the amount of Operating Expenses for such calendar year is determined, reimburse Tenant the amount of the excess paid. Should Landlord fail to pay Tenant the excess paid within thirty (30) days, then Tenant shall be entitled to credits in base rent until such time that the credit has been offset from base rent. If it is determined that Tenant has not paid Tenant's Proportionate Share in full by reason of such advance monthly payments, then Tenant will pay the difference in one lump sum within fifteen (15) days after receipt of Landlord's statement.

e. The Expenses shall mean all expenses and costs of operating the Building, including, without limitation, the following costs: (a) wages of all employees (including employment taxes and fringe benefits); (b) janitorial labor and materials applicable to the common areas; (c) costs of building security personnel and materials; (d) electricity, gas, sewer, water, trash disposal and other utilities; (e) maintenance and repairs (including maintenance and service contracts); (f) landscaping maintenance; (g) insurance premiums; (h) omitted; (i) reasonable expenses of Landlord in attempting to reduce or limit real estate and/or personal property taxes (any refunds to be credited against taxes in the year received); 0) capital improvements to the extent necessary to comply with applicable governmental rules and regulations, provided that said capital improvements are amortized over their useful life; (k) expense of building management fees customary in office buildings of comparable quality and location; (1) capital expenses which reduce any component costs of Expenses (such cost to be reasonably amortized by Landlord and Expenses to include only the cost as so amortized over their useful life by Landlord during the calendar year for which such computation is made; (m) legal and accounting fees. Expenses shall not include: (o) costs of alterations of any tenant's premises; (p) principal and interest payments on loans made on the security of the Building; (q) costs of capital expenditures (except as provided above in this section; and (r) leasing commissions and real estate broker's commissions.

f. The Base Amount shall be equal to the total operating expenses as defined herein for the calendar year 2014. The Base Amount, and all subsequent Lease years shall be adjusted to reflect a 95% occupancy and use of the building. All Operating Expenses shall be calculated by Landlord in accordance with Generally Accepted Accounting Principles.

g. For the purpose of determining Tenant's Proportionate Share under this Paragraph 5, it is agreed that the area contained in the leased premises is 5,291 rentable square feet and the rentable area of the building is 29,640 square feet and Tenant's Proportionate share is 17.85%.

6. Security Deposit. Tenant agrees to pay to Landlord the sum of Seven Thousand Two

Hundred Sixteen ($7,216.00) Dollars prior to the commencement of the lease term as security for the performance by the Tenant of the terms of this lease. Landlord may retain said funds as their own (without being liable for interest) and may use or apply the whole or any part thereof to the extent required for the payment of any rent, additional rent or other sum as to which the Tenant is in default under the lease, or for the payment of any amount which the Landlord may be required to expend by reason of the Tenant's default in respect of any of the terms of this lease. Upon Tenant's complying with all of the terms of this lease and delivering possession of the leased premises to Landlord at the termination of the lease term, Landlord shall pay over to Tenant the amount of such security payment not therefore used or applied as herein provided. In the event of a sale or transfer by Landlord of the building of which the leased premises are a part, Landlord shall be relieved of its obligation to return the security deposit if the purchaser or transferee of the building shall assume Landlord's obligations under this lease with respect of the security deposit. The Security Deposit is due with Tenant's signing of the Lease.

7. Services by Landlord. Landlord covenants and agrees:

a. To air condition and heat the leased premises 24 hours per day, 7 days per week to reasonable temperatures for normal occupancy and use.

b. All utility services are provided.

c. To provide water for lavatory and drinking purposes in places designated by the Landlord.

d. To provide maintenance services to keep the public areas of the building in good order.

No interruption or malfunction of any of the services to be furnished by Landlord hereunder shall constitute an eviction or disturbance of Tenant's use and possession of the leased premises, or a breach by the Landlord of any of its obligations hereunder, or render the Landlord liable for damages or entitle Tenant to be relieved of any of its obligations hereunder (including obligation to pay rent) or grant Tenant any right of setoff or recoupment. In the event of any such interruption or malfunction of such services, however, Landlord agrees to use best reasonable efforts to restore such service.

8. Utilities. Landlord shall pay for all electric service to the demised premises for lighting, appliances, and normal business machines.

9. Repairs and Maintenance. Landlord shall, at its own cost and expense, except as may be provided elsewhere herein, make all necessary repairs to the corridors, lobby and structural members of the building of which the leased premises is a portion, and to the equipment used to provide the services furnished by the Landlord hereunder, unless any such damage is caused by acts or omissions of Tenant, its officers, agents, employees or invitees, in which event, Tenant shall bear the cost of such repairs. Tenant shall not injure the leased premises or the building of the which the leased premises are a part, but shall maintain the leased premises in a clean, attractive condition and in good repair, except as to damage to be repaired by Landlord as provided above and except for the cleaning services to be rendered by Landlord as provided above. Tenant further covenants not to do or suffer any waste to the leased premises.

10. **Tenant's Improvements**. No alteration, addition, improvement, or refinishing of or to the leased premises shall be made by Tenant without the prior written consent of the Landlord, said consent will not be unreasonably withheld. Any alteration, addition or improvement made by the Tenant after such consent shall have been obtained, and any fixtures installed by Tenant (including wall-to-wall carpeting and wall paneling), shall become the property of the Landlord upon the expiration or other sooner termination of this lease, and Tenant shall reimburse Landlord for additional taxes and cleaning or maintenance expense, if any, resulting from any such items.

Tenant shall not permit any mechanics' lien to be filed against the fee of the leased premises or against the Tenant's leasehold interest in the premises by reason of work, labor, services or material supplied or claimed to have been supplied to the Tenant or anyone holding the leased premises through or under the Tenant, whether prior or subsequent to the commencement of the term hereof. If any such mechanics' lien shall at any time be filed against the leased premises and Tenant shall fail to remove same within thirty (30) days thereafter, it shall constitute a default under the provisions of this lease.

11. **Damage or Destruction**. The damage of, or destruction or injury to the leased premises or the building of which the leased premises comprise a part, by fire or the elements or other casualty which will render the premises unquestionable untenantable for more than ninety (90) days, shall cause a termination of this lease. Provided, however, that such damage, destruction or injury which will render the leased premises unquestionably untenantable for more than 20% of the unexpired term shall also, at the sole option of the Landlord, produce and work a termination of this lease. Provided, further, that if such damage, destruction, or injury to the premises shall be due to the act or negligence of Tenant, its officers, agents or employees, the Landlord alone shall have the option to produce and work a termination of this lease or to restore the premises to substantially the same condition in which they existed prior **to** such destruction, damage **or injury.**

Within thirty (30) days from the date of such damage, Landlord shall notify Tenant, in writing, of Landlord's reasonable estimation of the length of time within which material restoration can be made, and Landlord's determination shall be binding to Tenant. For purposes of this Lease, the Building or Premises shall be deemed "materially restored" if they are in such condition as would not prevent or materially interfere with Tenant's use of the Premises for the purpose for which it was being used immediately before such damage. If such repairs cannot be made within ninety (90) days, Landlord and Tenant shall each have the option of giving the other, at anytime within sixty (60) days after such damage, notice terminating this Lease as of the date of such damage.

If Landlord and Tenant cannot agree as to the number of days the building or leased premises are unquestionably untenantable, the fact shall be determined by arbitration; the Landlord and Tenant shall mutually choose an arbitrator within five (5) days after either has notified the other in writing of such damage. If it is determined by arbitration, or by agreement between the Landlord and Tenant, that said premises are not unquestionable untenantable for ninety (90) days or 20% of the unexpired term, whichever is applicable, then Landlord shall restore said premises to substantially the same condition in which they existed prior to such damage, at Landlord's own expense, with all reasonable speed and promptness, and in such case a just and proportionate part of said rental shall be abated until said premises have been restored, provided, however, that in the event the damage to said premises has not resulted in a termination of this lease under the above provisions and such damage is caused by the act of Tenant, as aforesaid, during such period of restoration or rebuilding there shall be no rent abatement hereunder. In determining what constitutes reasonable speed and promptness, consideration shall be given to delays caused by strikes, adjustment of insurance, and other causes beyond the Landlord's control. In no event shall the Landlord be required to restore any alterations, additions or improvements made by or for the Tenant and not required by this lease to be furnished by Landlord, nor any trade fixtures, furniture, equipment or other property belonging to Tenant.

12. **Liability.** Except for claims caused by Landlord's gross negligence and willful misconduct, Landlord shall not be responsible or liable to the Tenant for any injury or damage to person or property caused by gasoline, oil, steam, gas, electricity, hurricane, tornado, earthquake, flood, wind or similar storms and disturbances, nor water, rain or snow which may be upon any sidewalk or any entranceway or which may leak or flow from the roof, skylight, trap door, sewer, gas mains or any sub surface area or opening in the building of which the leased premises constitute a part; nor for loss resulting from theft or mysterious disappearance; nor from any interference with light or air. Except for claims caused by Landlord's gross negligence and willful misconduct Landlord shall not be liable for any personal injury to Tenant, its officers, agents, employees and invitees, nor any other occupant of any part of the leased premises, nor for any damages to any property of the Tenant or of any other occupant of any part of the leased premises, irrespective of how such injury or damage may be caused, whether from action of the elements or acts of negligence of the Landlord or occupants of adjacent properties.

13. **Waiver of Subrogation.** Notwithstanding anything herein to the contrary, Landlord and Tenant, and all parties claiming under them, hereby mutually release and discharge the other from all claims arising from or caused by any hazard covered by property insurance on the leased premises. Owner and Tenant shall and hereby do agree to a mutually waiver of subrogation for fire and extended property insurance.

14. **Condemnation.**

a. If the whole or any part of the leased premises shall be taken for any public or any quasi-public use under any statute or by right of eminent domain, or by purchase under threat of condemnation, then this lease shall automatically terminate as of the date that title shall be taken.

b. If any part of the building of which the leased premises comprise a part or any parking area adjacent thereto, shall be so taken and this lease shall not be terminated under the provisions of sub-paragraph (a) above, then Landlord shall have the option to terminate this lease upon ninety (90) days notice to Tenant if continued operation of the remaining structure or improvements is uneconomical in Landlord's sole discretion.

c. In any event, all compensation awarded or paid upon such a total or partial taking shall belong to and be the property of the Landlord without any participation by the Tenant; provided, however, that nothing contained herein shall be construed to preclude the Tenant from prosecuting any claim directly against the condemning authority in such condemnation proceeding for loss of business, depreciation to, damage to, or cost of removal of, or for the value of trade fixtures, furniture, and other personal property belonging to the Tenant; provided, however, that no such claim shall diminish or otherwise adversely affect the Landlord's award.

15. **Right of Entry.** Landlord, and its duly authorized agent, employees and contractors shall have access to the leased premises at all reasonable times for the purpose of inspecting the same and making necessary repairs or replacements as called for hereunder or as the Landlord shall elect to undertake for the safety, preservation, benefit or welfare of the building of which the leased premises constitute a part or other tenants thereof, or for exhibiting the building for sale, lease or financing, provided 24 hour notice be given to Tenant.

16. **Restrictions on Use.** The Tenant shall not allow, permit or suffer any noise, smoke or odor to escape from the leased property in a manner, which will disturb other occupants of the building, or occupy the leased property in such manner as to disturb the peaceful and quiet occupancy of the other tenants of the building or constitute a public or private nuisance. No sign, fixture, advertisement or notice shall be displayed, inscribed, painted or affixed by Tenant on any part of the inside or outside of the building without the prior written consent of the Landlord. Tenant shall not install any draperies, shades or venetian blinds visible from the exterior of the building, unless the color, materials, shape, style and size have been approved by the Landlord. Tenant shall not install or permit the installation of vending machines in the leased property, without the prior written consent of the Landlord. Movement in and out of the building of furniture or office equipment, or dispatch or receipt by the Tenant of any merchandise or materials, shall be done only during the hours designated by the Landlord and by means of elevator and exit designated by the Landlord.

17. **Rules**. The Landlord shall have the right, from time to time, to make, establish and promulgate reasonable rules and regulations for the building of which the leased premises comprise a part and the occupants and tenants thereof, and Tenant hereby covenants that it will observe, keep and comply with such rules and regulations.

18. **Assignment and Subletting.** Tenant shall not assign or encumber this lease, nor sublet nor permit the leased premises or any part thereof to be used by others, without first obtaining the prior written consent of the Landlord in each instance. Such consent shall not be unreasonably withheld by the Landlord. No such consent by the Landlord, nor the acceptance of an assignee, subtenant or occupant as a Tenant shall release the Tenant from the further performance by the Tenant of the covenants in this lease or be construed to relieve the Tenant from obtaining the consent in writing of the Landlord to any further assignment or subletting. In any event, Tenant shall remain primarily liable on this lease for the entire term hereof and shall in no way be released from the full and complete performance of all of the terms, conditions, covenants and agreements herein contained. This lease may be assigned by Landlord, in which event upon assumption of Landlord's duties and obligations hereunder by the assignee. Landlord shall be relieved of any further obligations and duties under this lease.

19. **Surrender upon Termination**. At the expiration of the lease term, Tenant shall surrender the leased premises in as good condition as they were at the beginning of the term, reasonable wear and tear excepted. Notwithstanding any provision of law or any judicial decision to the contrary, no notice shall be required to terminate the term of this lease as herein provided, and the term of this lease shall expire on the termination date herein mentioned without notice being required from either party. In the event that Tenant or any party holding under Tenant shall holdover the leased premise beyond the expiration of the term of this lease, whether by limitation or forfeiture, such party shall pay one and one-half (1 '/2) times rent hereunder during such holdover period. Provided, however, that if Tenant shall remain in possession of the leased premises beyond the expiration of the term with the express consent of the Landlord, then such possession shall be as a month-to-month Tenant at the same rent as the last month of the lease term, and the provisions of this lease shall be applicable. Prior to termination of this lease, or any extension thereof, if Tenant is not in default on any obligation or covenant under this lease. Tenant may remove its office supplies and movable office furniture and equipment from the leased premises, and shall promptly repair any damage caused by such removal.

20. **Default.** The following events shall be deemed to be events of default by Tenant under this lease. (i) There shall be no cure period for any monetary default, (ii) if Tenant shall fail to comply with any term, or provision, or covenant of this lease, other than the payment of rent, and shall not cure such default within ten (10) days after written notice thereof to Tenant, (iii) if Tenant shall become insolvent or shall make a transfer in fraud of its creditors or shall make an assignment for the benefit of its creditors, (iv) if Tenant shall file a petition under any section or chapter of the National Bankruptcy Act, as amended, or under any similar law or statute of the United States or any state thereof, or Tenant shall be adjudicated bankrupt or insolvent in proceedings filed against Tenant thereunder, (v) if a receiver or trustee shall be appointed for all or substantially all of the assets of Tenant or (vi) if Tenant shall desert or vacate any substantial portion of the leased premises.

Upon the occurrence of any such event of default, Landlord shall have the option to pursue any one or more of the following remedies (as well as any other remedies provided by law) without any notice or demand whatsoever.

a. Declare immediately due and payable the entire amount of the rent then remaining to be paid under this lease for the balance of the lease term.

b. Enter upon and take possession of the leased premises by summary proceedings, force or in any other manner, and disposes, expel, and remove the Tenant and any other person who may be occupying the leased premises or any part thereof (including changing or altering the locks and other security devices) and remove and expel any personal property or trade fixtures located therein, all without being liable to any prosecution therefore or for any damages resulting therefrom. Such re-entry and/or repossession by Landlord shall not terminate this lease nor relieve Tenant of its obligations under this lease, including its obligation to pay rent (whether or not the time for payment of rent has been accelerated). In the event of such re-entry or repossession by Landlord, Landlord shall also have the option to relet the leased premises as agent for Tenant, (in the name of Landlord or in the name of Tenant) at any rent and for any term readily obtainable and receive the rent thereof, in which event Tenant shall be given credit for any rents that may arise by reason of such re-letting (after first deducting all repossession costs, brokerage commissions, legal expenses, attorney fees and all other expenses in cleaning, repairing and altering the premises for re-letting).

c. Forfeit and terminate this lease forthwith. In the event of such termination, Tenant shall immediately surrender the leased premises to Landlord and if Tenant fails to do so, Landlord may enter upon and take possession of the leased premises and expel or remove Tenant and any other person who may be occupying said premises or any part thereof, and any personal property or trade fixtures located therein. In the event of the forfeiture of this lease as herein provided. Tenant agrees that the security deposit being held by Landlord hereunder shall be forfeited to Landlord as liquidated damages for Tenant's default, which liquidated damages shall be in addition to and not in lieu of any unpaid rent or any other damages accruing to Landlord by reason of the violation by Tenant of any of the terms, provisions and covenants of this lease.

Tenant hereby waives demand for rent, demand for possession, notice of forfeiture, notice of termination and any and all other demands or notices required by law.

Pursuit by Landlord of any of the foregoing remedies or any other remedy provided by law shall not constitute a forfeiture or waiver of any rent due to Landlord hereunder or of any damages accruing to Landlord by reason of the violation by Tenant of any of the terms, provisions and covenants of this lease. In no event shall Tenant be relieved from its obligation to pay the rentals specified in this lease by reason of a surrender of possession, termination of this lease or in any other manner whatsoever, unless specifically agreed to in writing by Landlord.

No waiver by landlord of any violation or breach of any of the terms, provisions and covenants of this lease shall be deemed or construed to constitute a waiver of any other violation or breach of any of the terms, provisions and covenants herein contained. Forbearance by Landlord to enforce one or more of the remedies herein provided upon an event of default, shall not be deemed or construed to constitute a waiver is such default.

If Landlord incurs any expenses, including court costs and attorneys fees, as a result of a default by Tenant under this lease then such expenses shall be reimbursed by Tenant as additional rent, whether or not such default is subsequently cured.

Tenant's delinquent payments shall bear interest at the rate of 18 % per annum from the date of delinquency until paid.

21. **Subordination and Attornment.** Tenant hereby agrees to the provisions set out in Exhibit "B" attached hereto and incorporated by reference as is fully set out herein.

22. **Insurance**. For claims caused by Tenant's negligence, Tenant shall, at Tenant's expense, maintain during the term, and all extensions thereof, comprehensive public liability insurance and property damage insurance under policies issued by insurers licensed to do business in the State of Missouri with limits of not less than One Million ($1,000,000.00) for bodily injury, death or for damage or injury to or destruction of property (including the loss of use thereof) for any occurrence typically insured under a standard comprehensive general liability policy. Tenant's policies shall name Landlord, its agents, servants and employees as designated additional insureds. Tenant shall supply Landlord with copies of said policies or with certificates or insurance evidencing such coverage.

23. **Estoppel Certificates**. The Landlord and Tenant shall certify in writing the status of this lease and the rent payable hereunder, at any time, upon ten (10) days' written notice. Such certificate shall be in a form reasonable satisfactory to a prospective purchaser or mortgagee of the fee title, or assignee of or subtenant under the lease.

24. **Notices**. Any notice under this lease shall be in writing and shall be deemed to be duly given if delivered personally or mailed by registered or certified mail, addressed to the Landlord at the address at which it receives rent and addressed to the Tenant at the leased property.

25. **Headings and Definitions.**

a. It is agreed that the headings and phrases as to the contents of particular paragraphs of this lease are inserted only as a matter of convenience and for reference, and in no way are or are intended to be a part of this lease, or in any way to define, limit or describe the scope or intent of the particular paragraph to which they refer.

b. Where, in this instrument, pronouns, or words indicating the singular number, appear, such words shall be considered as masculine, feminine or neuter pronouns or words indicating the plural number, and vice versa, where the context indicates the propriety of such use.

26. **Modifications**. Landlord and Tenant agree that this lease contains the entire agreement between them and shall not be modified in any manner, except by an instrument in writing signed by each of them.

27. **Benefit**. The lease shall inure to the benefit of and be binding upon the Landlord and Tenant and their respective heirs, executors, administrators, successors and such assigns and sub-leases as may be permitted hereunder.

28. **Authorization**. Each individual executing this lease on behalf of a Limited Liability Corporation, represents and warrants that he has been authorized to do so by the Managers of such corporation.

29. **Tenant Charges**. Tenant agrees to bear 0% of the cost of constructing the leased premises as set forth in Exhibit A attached hereto and by reference make a part hereof

30. **Default by Landlord**. In the event of any default hereunder by Landlord, Tenant agrees that no action will be taken as a result thereof unless or until written notice of the default has been given to Landlord and to the holder of any Deed of Trust encumbering the building whose name and address have been previously supplied to Tenant, in writing, and Landlord or such Deed of Trust holder shall have been given a reasonable time to cure the default.

31. **Sale of Building by Landlord.** In the event of any sale of the building in which the leased premises are located by Landlord, Landlord shall be relieved of any liability under any and all of its covenants and obligations contained in or derived from this lease arising out of any act, occurrence or omission occurring after the consummation of such sale, and the purchaser shall be deemed, without any further agreement between the parties, and any such purchaser, to have assumed and agreed to cam/ out any and all of the covenants and obligations of Landlord under this lease.

32. **Construction of Premises.** Landlord will, at its cost and expense, finish the space in accordance with Exhibit "A", attached hereto, on a "turnkey" basis, utilizing materials from Landlord's standard material selections, unless otherwise agreed upon in writing. New paint and carpet shall be mutually selected by Landlord and Tenant. Tenant approves the space plan attached to this Lease.

33. **Rent Payment.** All rents shall be payable to:

Nine East, L.L.C.
c/o Wellington Management Corp.
707 Spirit 40 Park Drive, Suite 140
Chesterfield, MO 63005

34. **Right of First Refusal**. Provided Tenant is not in default under the terms and conditions of this Lease, Tenant shall have a Right of First Refusal on the vacant spaces in the building which arc Suite 100 (3,051 rsf), Suite 105 (844 rsf) and Suite 120 (8,822 rst). Landlord shall inform Tenant in writing of the basic lease terms it is willing to enter into a lease with a third party in the vacant space listed above, and Tenant shall have 5 business days from such notice to accept such terms and lease the space. In the event Tenant does not notify Landlord in writing of Tenant's acceptance of the lease terms as provided herein within ten business days of Landlord's notification to Tenant, Tenant shall he deemed to have waived its Right of First Refusal on that space.

35. **Tenant Signage**. Landlord, at Landlord's expense, agrees to provide Tenant with interior marquee directory signage in the building nearest Tenant's main entrance.

36. **Brokers**. Prior disclosure has been made to the parties, and Landlord and Tenant agree, that no other Broker has been involved with this Lease, other than Scott C. Jenkins of Scott Jenkins Company and John H. Rothert, Spirit Realty Co, (Owner/Broker), both of which represent the Seller, and Steven Rees of Rees Realty, representing the Tenant. Seller is responsible for payment of brokers commission.

This lease consists of 36 paragraphs, numbered consecutively.

THIS LEASE CONTAINS A BINDING ARBITRATION PROVISION WHICH MAY BE ENFORCED BY THE PARTIES.

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands the day and year first above mentioned.

LANDLORD:	**TENANT:**
ONE WEST, L.L.C.	**Eclat Pharmaceutical LLC**
By: /s/ John Rothert	By: /s/ Michael Anderson
John Rothert	Michael Anderson
Date: July 23, 2013	Date: July 23, 2013

Exhibit A - Space Plan

EXHIBIT B

Subordination and Attornment

Tenant agrees that upon delivery to it by any mortgagee of the leased premises of a 'non-disturbance letter', as same is defined below, that this lease and Tenant's interest in this lease shall be subordinated to any mortgage, deed of trust or other method of financing or refinancing now or hereafter encumbering the leased premises, the land underlying the leased premises and/or the building of which the leased premises comprise a part; and to all renewals, modifications, replacements, consolidations and extensions thereof. Tenant further agrees that in such event it will execute and deliver any and all documents necessary to evidence the subordination of its rights under this lease as aforesaid. The `non-disturbance letter' referred to above shall be a letter from the holder of any such mortgage, deed of trust or other security instrument to the effect that in the event of a foreclosure or other action taken under any such security instrument that this lease and the rights of Tenant hereunder shall not be disturbed, diminished or interfered with, but shall continue in full force and effect so long as Tenant shall not be in default hereunder.

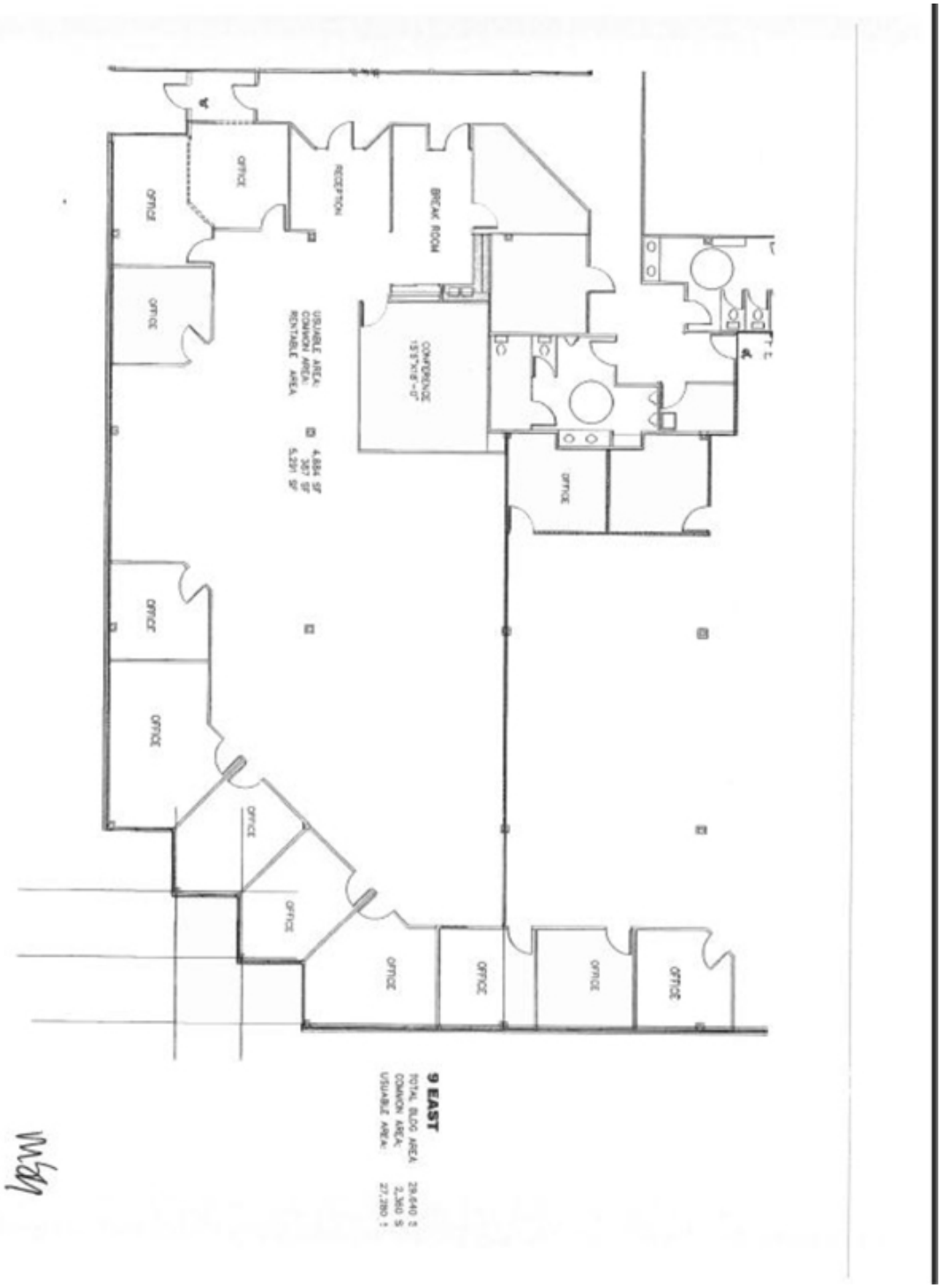
OFFICE
OFFICE
OFFICE
RECEPTION
BREAK ROOM
CONFERENCE
15'5"x13'-0"
USABLE AREA: 4,884 SF
COMMON AREA: 387 SF
RENTABLE AREA: 5,291 SF
OFFICE
OFFICE
OFFICE
OFFICE
OFFICE
OFFICE
OFFICE
OFFICE
OFFICE
9 EAST
TOTAL BLDG AREA: 23,640 S
COMMON AREA: 2,360 S
USABLE AREA: 21,280 S

Exhibit 10.16

OFFICE LEASE

THIS OFFICE LEASE is made and entered into as of October 5, 2015, by and between GROVE II LLC, a Missouri limited liability company ("Landlord"), and ECLAT PHARMACEUTICALS LLC, a Delaware limited liability company ("Tenant").

ARTICLE 1 - LEASE OF PREMISES

Section 1.01. Basic Lease Provisions and Definitions.

(a) Leased Premises (shown outlined on **Exhibit A** attached hereto): Suite 200 of the building located at 16640 Chesterfield Grove Road, Chesterfield, Missouri 63005 (the "Building").

(b) Rentable Area: approximately 12,000 rentable square feet. The Rentable Area includes the square footage within the Leased Premises plus a pro rata portion of the square footage of the common areas within the Building, as reasonably determined by Landlord.

(c) Tenant's Proportionate Share: 35.39%.

(d) Lease Term: Five (5) years.

(e) Target Commencement Date: November 2, 2015

(f) Minimum Annual Rent & Monthly Rental Installment:

Period	Minimum Annual Rent/RSF	Monthly Rental Installment
Year 1	$ 23.50/RSF	$ 23,500.00
Year 2	$ 24.00/RSF	$ 24,000.00
Year 3	$ 24.50/RSF	$ 24,500.00
Year 4	$ 25.00/RSF	$ 25,000.00
Year 5	$ 25.50/RSF	$ 25,500.00

(g) Base Year (for Operating Expenses): Calendar Year 2016.

(h) Security Deposit: $47,000.00.

(i) Permitted Use: General office purposes.

(j) Broker(s): Steve Rees, Jamestown Development, Inc., representing Tenant and none representing Landlord.

(k) Address for notices and payments are as follows:

Landlord:	Grove II LLC 540 Maryville Centre Drive, Suite 340 St. Louis, MO 63141
Tenant: (prior to occupancy)	Eclat Pharmaceuticals LLC 702 Spirit 40 Park Dr #108 Chesterfield, Missouri 63005

	Tenant: (following occupancy)	Eclat Pharmaceuticals LLC 16640 Chesterfield Grove Road, Suite 200 Chesterfield, Missouri 63005
(1)	Guarantor:	Flamel Technologies SA 16640 Chesterfield Grove Road, Suite 200 Chesterfield, Missouri 63005

EXHIBITS
Exhibit A - Leased Premises
Exhibit B - Tenant Improvements
Exhibit C - Letter of Understanding
Exhibit D - Rules and Regulations

Section 1.02. Lease of Premises. Landlord hereby leases to Tenant and Tenant hereby leases from Landlord the Leased Premises, under the terms and conditions herein, together with a non-exclusive right, in common with others, to use the following (collectively, the "Common Areas"): the areas of the Building and the underlying land and improvements thereto that are designed for use in common by all tenants of the Building and their respective employees, agents, customers, invitees and others.

ARTICLE 2 - TERM AND POSSESSION

Section 2.01. Term. The Lease Term shall commence as of the date (the "Commencement Date") that Substantial Completion (as defined in **Exhibit B** hereto) of the Tenant Improvements (as defined in Section 2.02 below) occurs.

Section 2.02. Construction of Tenant Improvements. Landlord, at Landlord’s cost, shall construct and install all leasehold improvements to the Leased Premises (collectively, the "Tenant Improvements") in accordance with **Exhibit B** attached hereto and made a part hereof.

Section 2.03. Surrender of the Premises. Upon the expiration or earlier termination of this Lease, Tenant shall, at its sole cost and expense, immediately (a) surrender the Leased Premises to Landlord in broom-clean condition and in good order, condition and repair, (b) remove from the Leased Premises (i) Tenant's Property (as defined in Section 8.01 below), and (ii) any alterations required to be removed pursuant to Section 7.03 below, and (c) repair any damage caused by any such removal and restore the Leased Premises to the condition existing upon the Commencement Date, reasonable wear and tear excepted. All of Tenant's Property that is not removed within ten (10) days following Landlord's written demand therefor shall be conclusively deemed to have been abandoned and Landlord shall be entitled to dispose of such property at Tenant's cost without incurring any liability to Tenant. This Section 2.03 shall survive the expiration or any earlier termination of this Lease.

Section 2.04. Holding Over. If Tenant retains possession of the Leased Premises after the expiration or earlier termination of this Lease, Tenant shall be a tenant at sufferance at two hundred percent (200%) of the Monthly Rental Installment and Annual Rental Adjustment (as hereinafter defined) for the Leased Premises in effect upon the date of such expiration or earlier termination, and otherwise upon the terms, covenants and conditions herein specified, so far as applicable. Acceptance by Landlord of rent after such expiration or earlier termination shall not result in a renewal of this Lease, nor shall such acceptance create a month-to-month tenancy. In the event a month-to-month tenancy is created by operation of law, either party shall have the right to terminate such month-to-month tenancy upon thirty (30) days' prior written notice to the other, whether or not said notice is given on the rent paying date. This Section 2.04 shall in no way constitute a consent by Landlord to any holding over by Tenant upon the expiration or earlier termination of this Lease, nor limit Landlord's remedies in such event.

ARTICLE 3 - RENT

Section 3.01. Base Rent. Tenant shall pay to Landlord the Minimum Annual Rent in the Monthly Rental Installments in advance, without demand, deduction or offset, on the Commencement Date and on or before the first day of each and every calendar month thereafter during the Lease Term. The Monthly Rental Installments for partial calendar months shall be prorated.

Section 3.02. Annual Rental Adjustment Definitions.

(a) "Annual Rental Adjustment" shall mean the amount of Tenant's Proportionate Share of Operating Expenses for a particular calendar year.

(b) "Operating Expenses" shall mean the amount of all of Landlord's costs and expenses paid or incurred in operating, repairing, replacing and maintaining the Building and the Common Areas in good condition and repair for a particular calendar year (including all additional costs and expenses that Landlord reasonably determines that it would have paid or incurred during such year if the Building had been fully occupied), including by way of illustration and not limitation, the following: all property taxes (real and personal), ad valorem taxes, and non-ad valorem taxes; all assessment (including levy district assessments) related to the Building and underlying property; insurance premiums and deductibles; water, sewer, electrical, gas and other utility charges other than the separately billed electrical and other charges paid by Tenant or other tenants in the Building; capital improvements to the extent necessary to comply with applicable law or which reduce any component cost of the Operating Expenses; service and other charges incurred in the repair, replacement, operation and maintenance of the elevators and the heating, ventilation and air-conditioning system; costs associated with providing fitness and/or conference facilities, if any; cleaning and other janitorial services; tools and supplies; repair costs; landscape maintenance costs; access patrols; license, permit and inspection fees; management fees; administrative fees (not to exceed 10% of the Operating Expense excluding such fee); supplies, costs, wages and related employee benefits payable for the management, maintenance and operation of the Building; maintenance, repair and replacement of the driveways, parking and sidewalk areas (including snow and ice removal), landscaped areas, and lighting; maintenance and repair costs, dues, fees and assessments incurred under any covenants, trust indentures or charged by any owners association; and expenses incurred by Landlord related to disputes of any of the foregoing. The cost of any Operating Expenses that are capital in nature shall be amortized over the useful life of the improvement (as reasonably determined by Landlord), and only the amortized portion shall be included in Operating Expenses.

(c) "Tenant's Proportionate Share of Operating Expenses" shall mean an amount equal to the product of Tenant's Proportionate Share multiplied by the difference of the Operating Expenses for the applicable calendar year minus the Operating Expenses for the Base Year; provided that such amount shall not be less than zero. All Operating Expenses shall be calculated by Landlord in accordance with generally accepted accounting principles, consistently applied.

Section 3.03. Payment of Additional Rent.

(a) Any amount required to be paid by Tenant hereunder (in addition to Minimum Annual Rent) and any charges or expenses incurred by Landlord on behalf of Tenant under the terms of this Lease, except for the Tenant Improvements set forth in Section 2.02, shall be considered "Additional Rent" payable in the same manner and upon the same terms and conditions as the Minimum Annual Rent reserved hereunder, except as set forth herein to the contrary. Any failure on the part of Tenant to pay such Additional Rent when and as the same shall become due shall entitle Landlord to the remedies available to it for non-payment of Minimum Annual Rent.

(b) In addition to the Minimum Annual Rent specified in this Lease, commencing on January 1, 2017, Tenant shall pay to Landlord as Additional Rent for the Leased Premises, in each calendar year or partial calendar year thereafter during the Lease Term, an amount equal to the Annual Rental Adjustment for such calendar year. Landlord shall estimate the Annual Rental Adjustment annually, and written notice thereof shall be given to Tenant prior to the beginning of each calendar year. Tenant shall pay to Landlord each month, at the same time the Monthly Rental Installment is due, an amount equal to one-twelfth (1/12) of the estimated Annual Rental Adjustment. If Operating Expenses increase during a calendar year, Landlord may increase the estimated Annual Rental Adjustment during such year by giving Tenant written notice to that effect, and thereafter Tenant shall pay to Landlord, in each of the remaining months of such year, an amount equal to the amount of such increase in the estimated Annual Rental Adjustment divided by the number of months remaining in such year. Within a reasonable time after the end of each calendar year, Landlord shall prepare and deliver to Tenant a statement showing the actual Annual Rental Adjustment. Within thirty (30) days after receipt of the aforementioned statement, Tenant shall pay to Landlord, or Landlord shall credit against the next rent payment or payments due from Tenant, as the case may be, the difference between the actual Annual Rental Adjustment for the preceding calendar year and the estimated amount paid by Tenant during such year. This Section 3.03 shall survive the expiration or any earlier termination of this Lease.

Section 3.04. Late Charges. Tenant acknowledges that Landlord will incur certain additional unanticipated administrative and legal costs and expenses if Tenant fails to pay timely any payment required hereunder. Therefore, in addition to the other remedies available to Landlord hereunder, if any payment required to be paid by Tenant to Landlord hereunder shall become overdue, such unpaid amount shall bear interest from the due date thereof to the date of payment at the prime rate of interest, as reported in the Wall Street Journal (the "Prime Rate") plus six percent (6%) per annum.

ARTICLE 4 - SECURITY DEPOSIT

Upon execution and delivery of this Lease by Tenant, Tenant shall deposit the Security Deposit with Landlord as security for the performance by Tenant of all of Tenant's obligations contained in this Lease. In the event of a Default by Tenant, Landlord may apply all or any part of the Security Deposit to cure all or any part of such Default; provided, however, that any such application by Landlord shall not be or be deemed to be an election of remedies by Landlord or considered or deemed to be liquidated damages. Tenant agrees promptly, upon demand, to deposit such additional sum with Landlord as may be required to maintain the full amount of the Security Deposit. All sums held by Landlord pursuant to this Article 4 shall be without interest and may be commingled by Landlord. At the end of the Lease Term, provided that there is then no uncured default or any repairs required to be made by Tenant pursuant to Section 2.03 above or Section 7.03 below, Landlord shall return the Security Deposit to Tenant within thirty (30) days following the end of the Lease Term. If any amounts are deducted from the Security Deposit due to repairs performed by Landlord, an accounting of such repairs and copies of any related invoices shall be provided to Tenant within thirty (30) days of the termination of this Lease.

ARTICLE 5 - OCCUPANCY AND USE

Section 5.01. Use. Tenant shall use the Leased Premises for the Permitted Use and for no other purpose without the prior written consent of Landlord.

Section 5.02. Covenants of Tenant Regarding Use.

(a) Tenant shall (i) use and maintain the Leased Premises and conduct its business thereon in a safe, careful, reputable and lawful manner, (ii) comply with all covenants that encumber the Building and all laws, rules, regulations, orders, ordinances, directions and requirements of any governmental authority or agency, now in force or which may hereafter be in force, including, without limitation, those which shall impose upon Landlord or Tenant any duty with respect to or triggered by a change in the use or occupation of, or any improvement or alteration to, the Leased Premises, and (iii) comply with and obey all reasonable directions, rules and regulations of Landlord, including the Building Rules and Regulations attached hereto as **Exhibit D** and made a part hereof, as may be modified from time to time by Landlord on reasonable notice to Tenant.

(b) Tenant shall not do or permit anything to be done in or about the Leased Premises that will in any way cause a nuisance, obstruct or interfere with the rights of other tenants or occupants of the Building or injure or annoy them. Landlord shall not be responsible to Tenant for the non-performance by any other tenant or occupant of the Building of any of Landlord's directions, rules and regulations, but agrees that any enforcement thereof shall be done uniformly. Tenant shall not use the Leased Premises, nor allow the Leased Premises to be used, for any purpose or in any manner that would (i) invalidate any policy of insurance now or hereafter carried by Landlord on the Building, or (ii) increase the rate of premiums payable on any such insurance policy unless Tenant reimburses Landlord for any increase in premium charged.

Section 5.03. Parking. Tenant may utilize up to a maximum of 36 parking spaces in the parking lot adjacent to the Building at no additional cost to Tenant. Only one (1) vehicle shall be parked in each space at any one time.

Section 5.04. Landlord's Rights Regarding Use. Without limiting any of Landlord's rights specified elsewhere in this Lease (a) Landlord shall have the right at any time, without notice to Tenant, to control, change or otherwise alter the Common Areas in such manner as it deems necessary or proper, so long as Tenant at all times has reasonable rights of access to the Demised Premises, and (b) Landlord, its agents, employees and contractors and any mortgagee of the Building shall have the right to enter any part of the Leased Premises at reasonable times upon reasonable notice (except in the event of an emergency where no notice shall be required) for the purposes of examining or inspecting the same (including, without limitation, testing to confirm Tenant's compliance with this Lease), showing the same to prospective purchasers, mortgagees or tenants (but, with respect to prospective tenants, only during the last year of the Lease Term), and making such repairs, alterations or improvements to the Leased Premises or the Building as Landlord may deem necessary or desirable, provided, however, that any such repairs, alterations or improvements shall be performed in a manner calculated to minimize, to the extent practical, the impact on Tenant’s business operations. Landlord shall incur no liability to Tenant for such entry, nor shall such entry constitute an eviction of Tenant or a termination of this Lease, or entitle Tenant to any abatement of rent therefor.

ARTICLE 6 - UTILITIES AND OTHER BUILDING SERVICES

Section 6.01. Services to be Provided. Provided Tenant is not in default, Landlord shall furnish to Tenant, except as noted below, the following utilities and other services to the extent reasonably necessary for Tenant's use of the Leased Premises for the Permitted Use, or as may be required by law or directed by governmental authority:

(a) Electricity, heating, ventilation and air-conditioning between the hours of 7:00 a.m. and 6:00 p.m. Monday through Friday and 7:00 a.m. to 1:00 p.m. on Saturday of each week except on legal holidays;

(b) Elevator service;

(c) Water in the Common Areas for lavatory and drinking purposes;

(d) Cleaning and janitorial service in the Leased Premises and Common Areas on Monday through Friday of each week except legal holidays; provided, however, Tenant shall be responsible for carpet cleaning other than routine vacuuming; and

(e) Maintenance of the Common Areas.

Section 6.02. Additional Services.

(a) If Tenant requests utilities or building services in addition to those identified above, or if (i) Tenant uses any of the above utilities or services in frequency, scope, quality or quantity substantially greater than that which Landlord determines is used by other commercial office tenants in the Building (measured proportionately based on space), and (ii) Landlord provides written notice thereof to Tenant, then Landlord shall use reasonable efforts to attempt to furnish Tenant with such additional utilities or services. In the event Landlord is able to and does furnish such additional utilities or services, the costs thereof (which shall be deemed to mean the cost that Tenant would have incurred had Tenant contracted directly with the utility company or service provider) shall be borne by Tenant, who shall reimburse Landlord monthly for the same as Additional Rent. Landlord shall also have the right to submeter or separately meter the Leased Premises at Tenant’s sole cost, and Tenant shall pay such utilities based on the submeter or separate meter; provided, however, no such additional submeter or separate meter shall be installed if the costs of installation thereof exceeds $1,000.00 unless the Tenant has provided its prior written consent to such installation.

(b) If any lights, density of staff, machines or equipment used by Tenant in the Leased Premises materially affect the temperature otherwise maintained by the Building's air-conditioning system or generate substantially more heat in the Leased Premises than that which would normally be generated by commercial office tenants in the Building using comparable sized space, then Landlord shall have the right to install any machinery or equipment that Landlord considers reasonably necessary in order to restore the temperature balance between the Leased Premises and the rest of the Building, including, without limitation, equipment that modifies the Building's air-conditioning system. All costs expended by Landlord to install any such machinery and equipment and any additional costs of operation and maintenance in connection therewith shall be borne by Tenant, who shall reimburse Landlord for the same as provided in this Section 6.02. Prior to installing any such machinery or equipment, Landlord must provide Tenant with written notice of its intent to install such equipment, and a period not less than thirty (30) days in which Tenant may attempt to cure the deficient temperature balance.

(c) If Tenant uses the HVAC outside of those hours listed in Section 6.01, Landlord shall bill Tenant monthly for "After Hours" use of HVAC at the rate of $100.00 per hour of usage.

Section 6.03. Interruption of Services. No interruption or malfunction of any of the services to be furnished by Landlord hereunder shall constitute an eviction or disturbance of Tenant's use and possession of Leased Premises, or a breech by Landlord of any of its obligations hereunder, or render Landlord liable for damages or entitle Tenant to be relieved of any of its obligations hereunder (including obligation to pay Rent) or grant Tenant any right of set-off or recoupment. In the event of any such interruption or malfunction of such services, however, Landlord agrees to use reasonable diligence to restore such service.

ARTICLE 7 - REPAIRS, MAINTENANCE AND ALTERATIONS

Section 7.01. Repair and Maintenance of Building. Landlord shall make all necessary repairs and replacements to the roof, exterior walls, exterior doors, windows, corridors and other Common Areas, and Landlord shall keep the Building in a clean and neat condition and use reasonable efforts to keep all equipment used in common with other tenants in good condition and repair. The cost of such repairs, replacements and maintenance shall be included in Operating Expenses to the extent provided in Section 3.02; provided however, to the extent any such repairs, replacements or maintenance are required because of the negligence, misuse or default of Tenant, its employees, agents, contractors, customers or invitees, Landlord shall make such repairs at Tenant's sole expense.

Section 7.02. Repair and Maintenance of Leased Premises. Landlord shall keep and maintain the Leased Premises in good condition and repair. The cost of such repairs and maintenance to the Leased Premises shall be included in Operating Expenses; provided however, to the extent any repairs or maintenance are required in the Leased Premises because of the negligence, misuse or default of Tenant, its employees, agents, contractors, customers or invitees or are made at the specific request of Tenant, Landlord shall make such repairs or perform such maintenance at Tenant's sole expense. Notwithstanding the above, Tenant shall be solely responsible for any repair or replacement with respect to Tenant's Property (as defined in Section 8.01 below) located in the Leased Premises. Nothing in this Article 7 shall obligate Landlord or Tenant to repair normal wear and tear to any paint, wall covering or carpet in the Leased Premises.

Section 7.03. Alterations. Tenant shall not permit alterations in or to the Leased Premises unless and until Landlord has approved the plans therefor in writing. As a condition of such approval, Landlord may require Tenant to remove the alterations and restore the Leased Premises upon termination of this Lease; otherwise, all such alterations shall at Landlord's option become a part of the realty and the property of Landlord, and shall not be removed by Tenant. Tenant shall ensure that all alterations shall be made in accordance with all applicable laws, regulations and building codes, in a good and workmanlike manner and of quality equal to or better than the original construction of the Building. No person shall be entitled to any lien derived through or under Tenant for any labor or material furnished to the Leased Premises, and nothing in this Lease shall be construed to constitute Landlord's consent to the creation of any lien. If any lien is filed against the Leased Premises for work claimed to have been done for or material claimed to have been furnished to Tenant, Tenant shall cause such lien to be discharged of record within thirty (30) days after filing; provided, however, that Tenant may in good faith contest the same by appropriate legal proceedings so long as a bond or other security covering the amount of the lien is furnished to Landlord. Tenant shall indemnify Landlord from all costs, losses, expenses and reasonable attorneys' fees in connection with any construction or alteration and any related lien; provided, however, that the foregoing indemnity shall not apply to with respect to the construction of the Tenant Improvements.

ARTICLE 8 - INDEMNITY AND INSURANCE

Section 8.01. Release. All of Tenant's trade fixtures, equipment, inventory and all other personal property in or about the Leased Premises, the Building or the Common Areas, which is deemed to include the trade fixtures, equipment, inventory and personal property of others located in or about the Leased Premises or Common Areas at the invitation or direction of Tenant (all of which property shall be referred to herein, collectively, as "Tenant's Property"), shall be and remain at Tenant's sole risk. Landlord shall not be liable to Tenant or to any other person for, and Tenant hereby releases Landlord from (a) any and all liability for theft or damage to Tenant's Property (except to the extent of the contributory negligence or willful misconduct of Landlord, its agents, employees or contractors), and (b) any and all liability for any injury to Tenant or its employees, agents, contractors, guests and invitees in or about the Leased Premises, the Building or the Common Areas, except to the extent caused directly by the negligence or willful misconduct of Landlord, its agents, employees or contractors. Nothing contained in this Section 8.01 shall limit (or be deemed to limit) the waivers contained in Section 8.06 below. In the event of any conflict between the provisions of Section 8.06 below and this Section 8.01, the provisions of Section 8.06 shall prevail. This Section 8.01 shall survive the expiration or earlier termination of this Lease.

Section 8.02. Indemnification by Tenant. Tenant shall protect, defend, indemnify and hold Landlord, its agents, employees and contractors harmless from and against any and all claims, damages, demands, penalties, costs, liabilities, losses, and expenses (including reasonable attorneys' fees and expenses at the trial and appellate levels) to the extent (a) arising out of or relating to any act, omission, negligence, or willful misconduct of Tenant or Tenant's agents, employees, contractors, customers or invitees in or about the Leased Premises, the Building or the Common Areas, (b) arising out of or relating to any of Tenant's Property, or (c) arising out of any other act or occurrence within the Leased Premises, in all such cases except to the extent caused directly by the negligence or willful misconduct of Landlord, its agents, employees or contractors. This Section 8.02 shall survive the expiration or earlier termination of this Lease.

Section 8.03. Indemnification by Landlord. Landlord shall protect, defend, indemnify and hold Tenant, its agents, employees and contractors harmless from and against any and all claims, damages, demands, penalties, costs, liabilities, losses and expenses (including reasonable attorneys' fees and expenses at the trial and appellate levels) to the extent arising out of or relating to any act, omission, negligence or willful misconduct of Landlord or Landlord's agents, employees or contractors, customers or invitees in or about the Leased Premises, the Building or the Common Areas. This Section 8.03 shall survive the expiration or earlier termination of this Lease.

Section 8.04. Tenant's Insurance. During the Lease Term (and any period of early entry or occupancy or holding over by Tenant, if applicable), Tenant shall maintain the following types of insurance, in the amounts specified below:

(a) Liability Insurance. Commercial General Liability Insurance (which insurance shall not exclude blanket contractual liability, broad form property damage, personal injury, or fire damage coverage) covering the Leased Premises and Tenant's use thereof against claims for bodily injury or death and property damage, which insurance shall provide coverage on an occurrence basis with a per occurrence limit of not less than $1,000,000, for each policy year, which limits may be satisfied by any combination of primary and excess or umbrella per occurrence policies.

(b) Property Insurance. Special Form Insurance (which insurance shall not exclude flood or earthquake) in the amount of the full replacement cost of Tenant's Property and betterments (including alterations or additions performed by Tenant pursuant hereto, but excluding those improvements, if any, made pursuant to Section 2.02 above), which insurance shall include an agreed amount endorsement waiving coinsurance limitations.

(c) Worker's Compensation Insurance. Worker's Compensation insurance in amounts required by applicable law.

All insurance required by Tenant hereunder shall (i) be issued by one or more insurance companies reasonably acceptable to Landlord, licensed to do business in the State in which the Leased Premises is located and having an AM Best's rating of A IX or better, and (ii) provide that said insurance shall not be materially changed, canceled or permitted to lapse on less than thirty (30) days' prior written notice to Landlord. In addition, Tenant's insurance shall protect Tenant and Landlord as their interests may appear, naming Landlord, Landlord's managing agent, and any mortgagee requested by Landlord, as additional insureds under its commercial general liability policies. On or before the Commencement Date (or the date of any earlier entry or occupancy by Tenant), and thereafter, within thirty (30) days prior to the expiration of each such policy, Tenant shall furnish Landlord with certificates of insurance in the form of ACORD 25 or ACORD 25-S (or other evidence of insurance reasonably acceptable to Landlord), evidencing all required coverages, together with a copy of the endorsement(s) to Tenant's commercial general liability policy evidencing primary and non-contributory coverage afforded to the appropriate additional insureds. Upon Tenant's receipt of a request from Landlord, Tenant shall provide Landlord with copies of all insurance policies, including all endorsements, evidencing the coverages required hereunder. If Tenant fails to carry such insurance and furnish Landlord with such certificates of insurance or copies of insurance policies (if applicable), after not less than ten (10) days prior written notice to Tenant, Landlord may obtain such insurance on Tenant's behalf and Tenant shall reimburse Landlord upon demand for the cost thereof as Additional Rent. Landlord reserves the right from time to time to require Tenant to obtain higher minimum amounts or different types of insurance if it becomes customary for other landlords of similar buildings in the area to require similar sized tenants in similar industries to carry insurance of such higher minimum amounts or of such different types.

ARTICLE 9 - CASUALTY

In the event of total or partial destruction of the Building or the Leased Premises by fire or other casualty, Landlord agrees promptly to restore and repair same; provided, however, Landlord's obligation hereunder with respect to the Leased Premises shall be limited to the reconstruction of such of the leasehold improvements as were originally required to be made by Landlord pursuant to Section 2.02 above, if any. Rent shall proportionately abate during the time that the Leased Premises or part thereof are unusable because of any such damage. Notwithstanding the foregoing, if the Leased Premises are (a) so destroyed that they cannot be repaired or rebuilt within six (6) months from the casualty date; or (b) destroyed by a casualty that is not covered by insurance or, if covered, such insurance proceeds are not released by any mortgagee entitled thereto or are insufficient to rebuild the Building and the Leased Premises; then, Landlord or Tenant may, upon thirty (30) days' written notice to Tenant, terminate this Lease with respect to matters thereafter accruing. Tenant waives any right under applicable laws inconsistent with the terms of this paragraph.

ARTICLE 10 - EMINENT DOMAIN

If all or any substantial part of the Building or Common Areas shall be acquired by the exercise of eminent domain, Landlord may terminate this Lease by giving written notice to Tenant on or before the date possession thereof is so taken. If all or any part of the Leased Premises shall be acquired by the exercise of eminent domain so that the Leased Premises shall become impractical for Tenant to use for the Permitted Use, Tenant may terminate this Lease by giving written notice to Landlord as of the date possession thereof is so taken. All damages awarded shall belong to Landlord; provided, however, that Tenant may claim dislocation damages if such amount is not subtracted from Landlord's award.

ARTICLE 11 - ASSIGNMENT AND SUBLEASE

Tenant shall not assign this Lease or sublet the Leased Premises in whole or in part without Landlord's prior written consent, which consent shall not be unreasonably withheld. In the event of any permitted assignment or subletting, Tenant shall remain primarily liable hereunder, and any extension, expansion, rights of first offer, rights of first refusal or other options granted to Tenant under this Lease shall be rendered void and of no further force or effect. The acceptance of rent from any other person shall not be deemed to be a waiver of any of the provisions of this Lease or to be consent to the assignment of this Lease or the subletting of the Leased Premises. Any assignment or sublease consented to by Landlord shall not relieve Tenant (or its assignee) from obtaining Landlord's consent to any subsequent assignment or sublease.

ARTICLE 12 - TRANSFERS BY LANDLORD

Section 12.01. Sale of the Building. Landlord shall have the right to sell the Building at any time during the Lease Term, subject only to the rights of Tenant hereunder; and such sale shall operate to release Landlord from liability hereunder after the date of such conveyance; provided that the purchaser shall have assumed and agreed to carry out any and all of the covenants and obligations of the Landlord under this Lease.

Section 12.02. Estoppel Certificate. Within ten (10) days following receipt of a written request from Landlord, Tenant shall execute and deliver to Landlord, without cost to Landlord, an estoppel certificate in such form as Landlord may reasonably request certifying (a) that this Lease is in full force and effect and unmodified or stating the nature of any modification, (b) the date to which rent has been paid, (c) that there are not, to Tenant's knowledge, any uncured defaults or specifying such defaults if any are claimed, and (d) any other matters or state of facts reasonably required respecting this Lease. Such estoppel may be relied upon by Landlord and by any purchaser or mortgagee of the Building.

Section 12.03. Subordination. Landlord shall have the right to subordinate this Lease to any mortgage, deed to secure debt, deed of trust or other instrument in the nature thereof, and any amendments or modifications thereto (collectively, a "Mortgage") presently existing or hereafter encumbering the Building by so declaring in such Mortgage. Within ten (10) days following receipt of a written request from Landlord or mortgagee, Tenant shall execute and deliver to Landlord or mortgagee, without cost, any instrument that Landlord deems reasonably necessary or desirable to confirm the subordination of this Lease. Notwithstanding the foregoing, if the holder of the Mortgage shall take title to the Leased Premises through foreclosure or deed in lieu of foreclosure, Tenant shall be allowed to continue in possession of the Leased Premises as provided for in this Lease so long as Tenant is not in Default.

ARTICLE 13 - DEFAULT AND REMEDY

Section 13.01. Default. The occurrence of any of the following shall be a "Default":

(a) Tenant fails to pay any Monthly Rental Installments or Additional Rent within ten (10) days after the same is due;

(b) Tenant fails to perform or observe any other term, condition, covenant or obligation required under this Lease for a period of thirty (30) days after written notice thereof from Landlord; provided, however, that if the nature of Tenant's default is such that more than thirty (30) days are reasonably required to cure, then such default shall be deemed to have been cured if Tenant commences such performance within said thirty (30) day period and thereafter diligently completes the required action within a reasonable time;

(c) Tenant shall vacate or abandon the Leased Premises, or fail to occupy the Leased Premises or any substantial portion thereof for a period of not less than thirty consecutive (30) days;

(d) Tenant shall assign or sublet all or a portion of the Leased Premises in contravention of the provisions of Article 11 of this Lease; or

(e) All or substantially all of Tenant's assets in the Leased Premises or Tenant's interest in this Lease are attached or levied under execution (and Tenant does not discharge the same within sixty (60) days thereafter); a petition in bankruptcy, insolvency or for reorganization or arrangement is filed by or against Tenant (and Tenant fails to secure a stay or discharge thereof within sixty (60) days thereafter); Tenant is insolvent and unable to pay its debts as they become due; Tenant makes a general assignment for the benefit of creditors; Tenant files a petition to declare bankruptcy or seeking a plan of reorganization; the appointment of a receiver or trustee in bankruptcy for Tenant or its assets if such receivership has not been vacated or set aside within sixty (60) days thereafter; or, dissolution or other termination of Tenant's corporate charter if Tenant is a corporation.

Section 13.02. Remedies. Upon the occurrence of any Default, Landlord shall have the following rights and remedies, in addition to those stated elsewhere in this Lease and those allowed by law or in equity, any one or more of which may be exercised without further notice to Tenant:

(a) Landlord may re-enter the Leased Premises and cure any Default of Tenant, and Tenant shall reimburse Landlord as Additional Rent for any costs and expenses which Landlord thereby incurs; and Landlord shall not be liable to Tenant for any loss or damage which Tenant may sustain by reason of Landlord's action.

(b) Without terminating this Lease, Landlord may terminate Tenant's right to possession of the Leased Premises, and thereafter, neither Tenant nor any person claiming under or through Tenant shall be entitled to possession of the Leased Premises, and Tenant shall immediately surrender the Leased Premises to Landlord, and Landlord may re-enter the Leased Premises and dispossess Tenant and any other occupants of the Leased Premises by any lawful means and may remove their effects, without prejudice to any other remedy that Landlord may have. Upon termination of possession, Landlord may (i) re-let all or any part thereof for a term different from that which would otherwise have constituted the balance of the Lease Term and for rent and on terms and conditions different from those contained herein, whereupon Tenant shall be immediately obligated to pay to Landlord an amount equal to the present value (discounted at the Prime Rate) of the difference between the rent provided for herein and that provided for in any lease covering a subsequent re-letting of the Leased Premises, for the period which would otherwise have constituted the balance of the Lease Term (the "Accelerated Rent Difference"), or (ii) without re-letting, declare the present value (discounted at the Prime Rate) of all rent which would have been due under this Lease for the balance of the Lease Term to be immediately due and payable as liquidated damages (the "Accelerated Rent"). Upon termination of possession, Tenant shall be obligated to pay to Landlord (A) the Accelerated Rent Difference or the Accelerated Rent, whichever is applicable, (B) all loss or damage that Landlord may sustain by reason of Tenant's Default ("Default Damages"), which shall include, without limitation, expenses of preparing the Leased Premises for re-letting, demolition, repairs, tenant finish improvements, brokers' commissions and attorneys' fees, and (C) all unpaid Minimum Annual Rent and Additional Rent that accrued prior to the date of termination of possession, plus any interest and late fees due hereunder (the "Prior Obligations").

(c) Landlord may terminate this Lease and declare the Accelerated Rent to be immediately due and payable, whereupon Tenant shall be obligated to pay to Landlord (i) the Accelerated Rent, (ii) all of Landlord's Default Damages, and (iii) all Prior Obligations. It is expressly agreed and understood that all of Tenant's liabilities and obligations set forth in this subsection (c) shall survive termination.

(d) Landlord and Tenant acknowledge and agree that the payment of the Accelerated Rent Difference or the Accelerated Rent as set above shall not be deemed a penalty, but merely shall constitute payment of liquidated damages, it being understood that actual damages to Landlord are extremely difficult, if not impossible, to ascertain. Neither the filing of a dispossessory proceeding nor an eviction of personalty in the Leased Premises shall be deemed to terminate this Lease.

(e) Landlord may sue for injunctive relief or to recover damages for any loss resulting from the Default.

Section 13.03. Landlord's Default and Tenant's Remedies. Landlord shall be in default if it fails to perform any term, condition, covenant or obligation required under this Lease for a period of thirty (30) days after written notice thereof from Tenant to Landlord; provided, however, that if the term, condition, covenant or obligation to be performed by Landlord is such that it cannot reasonably be performed within thirty (30) days, such default shall be deemed to have been cured if Landlord commences such performance within said thirty-day period and thereafter diligently undertakes to complete the same. Upon the occurrence of any such default, Tenant may sue for injunctive relief or to recover damages for any loss directly resulting from the breach, but Tenant shall not be entitled to terminate this Lease or withhold, offset or abate any sums due hereunder.

Section 13.04. Nonwaiver of Defaults. Neither party's failure or delay in exercising any of its rights or remedies or other provisions of this Lease shall constitute a waiver thereof or affect its right thereafter to exercise or enforce such right or remedy or other provision. No waiver of any default shall be deemed to be a waiver of any other default. Landlord's receipt of less than the full rent due shall not be construed to be other than a payment on account of rent then due, nor shall any statement on Tenant's check or any letter accompanying Tenant's check be deemed an accord and satisfaction. No act or omission by Landlord or its employees or agents during the Lease Term shall be deemed an acceptance of a surrender of the Leased Premises, and no agreement to accept such a surrender shall be valid unless in writing and signed by Landlord.

Section 13.06. Attorneys' Fees. If either party defaults in the performance or observance of any of the terms, conditions, covenants or obligations contained in this Lease and the non-defaulting party obtains a judgment against the defaulting party, then the defaulting party agrees to reimburse the non-defaulting party for reasonable attorneys' fees incurred in connection therewith. In addition, if a monetary Default shall occur and Landlord engages outside counsel to exercise its remedies hereunder, and then Tenant cures such monetary Default, Tenant shall pay to Landlord, on demand, all expenses incurred by Landlord as a result thereof, including reasonable attorneys' fees, court costs and expenses actually incurred.

ARTICLE 14 - RESERVED

Reserved.

ARTICLE 15 - TENANT'S RESPONSIBILITY REGARDING ENVIRONMENTAL LAWS AND HAZARDOUS SUBSTANCES

Section 15.01. Environmental Definitions.

(a) "Environmental Laws" shall mean all present or future federal, state and municipal laws, ordinances, rules and regulations applicable to the environmental and ecological condition of the Leased Premises, and the rules and regulations of the Federal Environmental Protection Agency and any other federal, state or municipal agency or governmental board or entity having jurisdiction over the Leased Premises.

(b) "Hazardous Substances" shall mean those substances included within the definitions of "hazardous substances," "hazardous materials," "toxic substances" "solid waste" or "infectious waste" under Environmental Laws and petroleum products.

Section 15.02. Restrictions on Tenant. Tenant shall not cause or permit the use, generation, release, manufacture, refining, production, processing, storage or disposal of any Hazardous Substances on, under or about the Leased Premises, or the transportation to or from the Leased Premises of any Hazardous Substances, except as necessary and appropriate for its Permitted Use in which case the use, storage or disposal of such Hazardous Substances shall be performed in compliance with the Environmental Laws and the highest standards prevailing in the industry.

Section 15.03. Notices, Affidavits, Etc. Tenant shall immediately (a) notify Landlord of (i) any violation by Tenant, its employees, agents, representatives, customers, invitees or contractors of any Environmental Laws on, under or about the Leased Premises, or (ii) the presence or suspected presence of any Hazardous Substances on, under or about the Leased Premises, and (b) deliver to Landlord any notice received by Tenant relating to (a)(i) and (a)(ii) above from any source. Tenant shall execute affidavits, representations and the like within five (5) days of Landlord's request therefor concerning Tenant's best knowledge and belief regarding the presence of any Hazardous Substances on, under or about the Leased Premises.

Section 15.04. Tenant's Indemnification. Tenant shall indemnify Landlord from any and all claims, losses, liabilities, costs, expenses and damages, including attorneys' fees, costs of testing and remediation costs, incurred by Landlord in connection with any breach by Tenant of its obligations under this Article 15. The covenants and obligations under this Article 15 shall survive the expiration or earlier termination of this Lease.

Section 15.05. Existing Conditions. Notwithstanding anything contained in this Article 15 to the contrary, Tenant shall not have any liability to Landlord under this Article 15 resulting from any conditions existing, or events occurring, or any Hazardous Substances existing, generated or released, at, in, on, under or in connection with the Leased Premises prior to the Commencement Date of this Lease (or any earlier occupancy of the Leased Premises by Tenant) except to the extent Tenant materially exacerbates the same. Landlord shall indemnify Tenant, its agents, employees and contractors from any and all claims, losses, liabilities, costs, expenses and damages, including attorneys' fees, costs of testing and remediation costs, incurred by Tenant in connection with any Hazardous Substances existing, generated or released, at, in, on, under or in connection with the Leased Premises prior to the Commencement Date of this Lease.

ARTICLE 16 - MISCELLANEOUS

Section 16.01. Benefit of Landlord and Tenant. This Lease shall inure to the benefit of and be binding upon Landlord and Tenant and their respective successors and assigns.

Section 16.02. Governing Law. This Lease shall be governed in accordance with the laws of the State of Missouri.

Section 16.03. Force Majeure. Landlord and Tenant (except with respect to the payment of any monetary obligation) shall be excused for the period of any delay in the performance of any obligation hereunder when such delay is occasioned by causes beyond its control, including but not limited to work stoppages, boycotts, slowdowns or strikes; shortages of materials, equipment, labor or energy; unusual weather conditions; or acts or omissions of governmental or political bodies.

Section 16.04. Examination of Lease. Submission of this instrument by Landlord to Tenant for examination or signature does not constitute an offer by Landlord to lease the Leased Premises. This Lease shall become effective, if at all, only upon the execution by and delivery to both Landlord and Tenant. Execution and delivery of this Lease by Tenant to Landlord constitutes an offer to lease the Leased Premises on the terms contained herein. The offer by Tenant will be irrevocable until 6:00 p.m. EST, fifteen (15) days after the date Landlord receives the Lease executed by Tenant.

Section 16.05. Indemnification for Leasing Commissions. The parties hereby represent and warrant that the only real estate brokers involved in the negotiation and execution of this Lease are the Brokers and that no other party is entitled, as a result of the actions of the respective party, to a commission or other fee resulting from the execution of this Lease. Each party shall indemnify the other from any and all liability for the breach of this representation and warranty on its part and shall pay any compensation to any other broker or person who may be entitled thereto. Landlord, at its own cost, shall pay any commissions due Brokers based on this Lease pursuant to separate agreements between Landlord and Brokers.

Section 16.06. Notices. Any notice required or permitted to be given under this Lease or by law shall be deemed to have been given if it is written and delivered in person or by overnight courier or mailed by certified mail, postage prepaid, to the party who is to receive such notice at the address specified in Section 1.01(l). If sent by overnight courier, the notice shall be deemed to have been given one (1) day after sending. If mailed, the notice shall be deemed to have been given on the date that is three (3) business days following mailing. Either party may change its address by giving written notice thereof to the other party.

Section 16.07. Partial Invalidity; Complete Agreement. If any provision of this Lease shall be held to be invalid, void or unenforceable, the remaining provisions shall remain in full force and effect. This Lease represents the entire agreement between Landlord and Tenant covering everything agreed upon or understood in this transaction. There are no oral promises, conditions, representations, understandings, interpretations or terms of any kind as conditions or inducements to the execution hereof or in effect between the parties. No change or addition shall be made to this Lease except by a written agreement executed by Landlord and Tenant.

Section 16.08. Financial Statements. During the Lease Term and any extensions thereof, Tenant shall provide to Landlord on an annual basis, within ninety (90) days following the end of Tenant's fiscal year, a copy of Tenant's most recent financial statements prepared as of the end of Tenant's fiscal year. Such financial statements shall be signed by Tenant or an officer of Tenant, if applicable, who shall attest to the truth and accuracy of the information set forth in such statements. All financial statements provided by Tenant to Landlord hereunder shall be prepared in conformity with generally accepted accounting principles, consistently applied.

Section 16.09. Representations and Warranties.

(a) Tenant hereby represents and warrants that (i) Tenant is duly organized, validly existing and in good standing (if applicable) in accordance with the laws of the State under which it was organized; (ii) Tenant is authorized to do business in the State where the Building is located; and (iii) the individual(s) executing and delivering this Lease on behalf of Tenant has been properly authorized to do so, and such execution and delivery shall bind Tenant to its terms.

(b) Landlord hereby represents and warrants that (i) Landlord is duly organized, validly existing and in good standing (if applicable) in accordance with the laws of the State under which it was organized; (ii) Landlord is authorized to do business in the State where the Building is located; and (iii) the individual(s) executing and delivering this Lease on behalf of Landlord has been properly authorized to do so, and such execution and delivery shall bind Landlord to its terms.

Section 16.10. Signage. Landlord, at its cost and expense, shall provide Tenant with Building standard signage on the main Building directory. Landlord may install such other signs, advertisements, notices or tenant identification information on the Building directory, tenant access doors or other areas of the Building, as it shall deem necessary or proper. Tenant shall not place any exterior signs on the Leased Premises or interior signs visible from the exterior of the Leased Premises without the prior written consent of Landlord. Notwithstanding any other provision of this Lease to the contrary, Landlord may immediately remove any sign(s) placed by Tenant in violation of this Section.

Section 16.11. Consent. Where the consent of a party is required, such consent will not be unreasonably withheld.

Section 16.12. Time. Time is of the essence of each term and provision of this Lease.

Section 16.13. Patriot Act. Each of Landlord and Tenant, each as to itself, hereby represents its compliance with all applicable anti-money laundering laws, including, without limitation, the USA Patriot Act, and the laws administered by the United States Treasury Department's Office of Foreign Assets Control, including, without limitation, Executive Order 13224 ("Executive Order"). Each of Landlord and Tenant further represents (i) that it is not, and it is not owned or controlled directly or indirectly by any person or entity, on the SDN List published by the United States Treasury Department's Office of Foreign Assets Control and (ii) that it is not a person otherwise identified by government or legal authority as a person with whom a U.S. Person is prohibited from transacting business. As of the date hereof, a list of such designations and the text of the Executive Order are published under the internet website address www.ustreas.gov/offices/enforcement/ofac.

Section 16.14. Option to Extend.

(a) Grant and Exercise of Option. Provided that (i) no Default by Tenant has occurred and is then continuing, (ii) the creditworthiness of Tenant is then reasonably acceptable to Landlord and (iii) Tenant originally named herein or its Permitted Transferee remains in possession of and has been continuously operating in the entire Leased Premises throughout the Lease Term, Tenant shall have one (1) option to extend the Lease Term for one (1) additional period of five (5) years (the "Extension Term"). The Extension Term shall be upon the same terms and conditions contained in the Lease except (x) Tenant shall not have any further option to extend, (y) any improvement allowances or other concessions applicable to the Leased Premises under the Lease shall not apply to the Extension Term, and (z) the Minimum Annual Rent shall be adjusted as set forth herein ("Rent Adjustment"). Tenant shall exercise such option by delivering to Landlord, no later than nine (9) months prior to the expiration of the current Lease Term, written notice of Tenant's desire to extend the Lease Term. Tenant's failure to properly exercise such option shall be deemed a waiver of such option. If Tenant properly exercises its option to extend, Landlord shall notify Tenant of the Rent Adjustment no later than ninety (90) days prior to the commencement of the Extension Term. Tenant shall be deemed to have accepted the Rent Adjustment if it fails to deliver to Landlord a written objection thereto within ten (10) business days after receipt thereof. If Tenant properly exercises its option to extend, Landlord and Tenant shall execute an amendment to the Lease (or, at Landlord's option, a new lease in the same form as this Lease) reflecting the terms and conditions of the Extension Term within thirty (30) days after Tenant's acceptance (or deemed acceptance) of the Rent Adjustment.

(b) Rent Adjustment. The Minimum Annual Rent for the Extension Term shall be an amount equal to the prevailing market rate for space of comparable size and quality in the Chesterfield, Missouri submarket; provided, however, that in no event shall the Minimum Annual Rent during the Extension Term be less than an amount equal to $24.00 per rentable square foot. The Monthly Rental Installments shall be an amount equal to one-twelfth (1/12) of the Minimum Annual Rent for the Extension Term and shall be paid at the same time and in the same manner as provided in this Lease.

Section 16.15. Furniture. Tenant shall be permitted to use certain furniture currently in the Leased Premises. The specific furniture shall be agreed upon by Landlord and Tenant prior to the Commencement Date and an inventory thereof shall be prepared and signed by Landlord and Tenant. The furniture shall remain the property of Landlord and upon termination of this Lease all such furniture shall remain in the Leased Premises. Reasonable care shall be taken with all furniture and Landlord shall not be responsible for repairs and maintenance of furniture.

[SIGNATURES CONTAINED ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Lease as of the day and year first above written.

LANDLORD:

GROVE II LLC,
a Missouri limited liability company

By: /s/ Christopher Pelligreen
Name: Christopher Pelligreen
Title: Authorized Signatory

STATE OF MISSOURI)
) SS:
COUNTY OF ST. LOUIS)

Before me, a Notary Public in and for said County and State, personally appeared _____, by me known and by me known to be the _____ of Grove II LLC, who acknowledged the execution of the foregoing instrument on behalf of said limited liability company as its free act and deed.

WITNESS my hand and Notarial Seal this _____ day of _____, 2015.

_____
Notary Public

_____
(Printed Signature)

[SIGNATURES CONTINUED ON THE FOLLOWING PAGE]

TENANT:

ECLAT PHARMACEUTICALS LLC,
a Delaware limited liability company

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Authorized Signatory

STATE OF MISSOURI)
) SS:
COUNTY OF ST. LOUIS)

Before me, a Notary Public in and for said County and State, personally appeared _____, by me known to be the _____ of Eclat Pharmaceuticals LLC, who acknowledged the execution of the foregoing instrument on behalf of said limited liability company as its free act and deed.

WITNESS my hand and Notarial Seal this _____ day of _____, 2015.

Notary Public

(Printed Signature)

EXHIBIT A

ILLUSTRATION OF LEASED PREMISES

[DRAWING ATTACHED]

EXHIBIT B

TENANT IMPROVEMENTS

1. Landlord's Obligations. Tenant has personally inspected the Leased Premises and accepts the same **"AS IS"** without representation or warranty by Landlord of any kind and with the understanding that Landlord shall have no responsibility with respect thereto except to construct and install within the Leased Premises, in a good and workmanlike manner, the Tenant Improvements, in accordance with this **Exhibit B**, and to deliver the Leased Premises to Tenant "broom clean" and in good condition and repair on the date of Substantial Completion. "Substantial Completion" (or any grammatical variation thereof) shall mean completion of construction of the Tenant Improvements, subject only to punch-list items to be identified by Landlord and Tenant in a joint inspection of the Leased Premises prior to Tenant's occupancy

2. Scope of Work. Landlord shall complete the following work prior to the date of Substantial Completion:

- Construct new demising walls where indicated in the attached drawing.
- Install four (4) new offices where indicated in the attached drawing.
- Install/remove doorways where indicated in the attached drawing.
- Replace carpet in Leased Premises, excluding reception area, conference room and kitchen.
- Replace carpet in kitchen with tile.
- Paint existing and new drywall surfaces.

3. Schedule and Early Occupancy. Landlord shall provide Tenant with a proposed schedule for the construction and installation of the Tenant Improvements and shall notify Tenant of any material changes to said schedule. Tenant agrees to coordinate with Landlord regarding the installation of Tenant's phone/data wiring and any other trade related fixtures that will need to be installed in the Leased Premises prior to Substantial Completion. In addition, if and to the extent permitted by applicable laws, rules and ordinances, Landlord will give Tenant access to the Leased Premises prior to the scheduled date for Substantial Completion (as may be modified from time to time) in order to install fixtures, equipment and phone/data wiring and otherwise prepare the Leased Premises for occupancy, which right shall expressly exclude making any structural modifications. During any entry prior to the Commencement Date, Tenant shall: (a) comply with all terms and conditions of this Lease other than the obligation to pay rent, (b) not interfere with Landlord's completion of the Tenant Improvements, (c) cause its personnel and contractors to comply with the terms and conditions of Landlord's rules of conduct (which Landlord agrees to furnish to Tenant upon request), and (d) not begin operation of its business therein. Tenant acknowledges that Tenant shall be responsible for obtaining all applicable permits and inspections relating to any such entry by Tenant.

4. Tenant Delay. Notwithstanding anything to the contrary contained in the Lease, if Substantial Completion of the Tenant Improvements is delayed beyond the Target Commencement Date as a result of Tenant Delay (as hereinafter defined), then, for purposes of determining the Commencement Date, Substantial Completion of the Tenant Improvements shall be deemed to have occurred on the date that Substantial Completion of the Tenant Improvements would have occurred but for such Tenant Delay. Without limiting the foregoing, Landlord shall use commercially reasonable speed and diligence to Substantially Complete the Tenant Improvements on or before the Target Commencement Date. "Tenant Delay" shall mean any delay in the completion of the Tenant Improvements attributable to Tenant, including, without limitation (i) Tenant's failure to meet any time deadlines specified herein, (ii) changes to the Tenant Improvements requested by Tenant after the date hereof, (iii) the performance of any other work in the Leased Premises by any person, firm or corporation employed by or on behalf of Tenant, or any failure to complete or delay in completion of such work, (iv) Landlord's inability to obtain an occupancy permit for the Leased Premises because of the need for completion of all or a portion of improvements being installed in the Leased Premises directly by Tenant, and (v) any other act or omission of Tenant.

5. Letter of Understanding. Promptly following the Commencement Date, Tenant shall execute Landlord's Letter of Understanding in substantially the form attached hereto as **Exhibit C** and made a part hereof, acknowledging (a) the Commencement Date of this Lease, and (b) except for any punchlist items, that Tenant has accepted the Leased Premises. If Tenant takes possession of and occupies the Leased Premises, Tenant shall be deemed to have accepted the Leased Premises and that the condition of the Leased Premises and the Building was at the time satisfactory and in conformity with the provisions of this Lease in all respects, subject to any punch-list items.

[DRAWING ATTACHED]

EXHIBIT C

LETTER OF UNDERSTANDING

Grove II LLC
540 Maryville Centre Drive, Suite 340
St. Louis, MO 63141

RE: Office Lease dated as of _____ ____, 2015 between Grove II LLC ("Landlord") and Eclat Pharmaceuticals LLC ("Tenant"), for 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005 (the "Leased Premises").

Dear _____:

The undersigned, on behalf of Tenant, certifies to Landlord as follows:

1. The Commencement Date under the Lease is _____.

2. The rent commencement date is _____.

3. The expiration date of the Lease (subject to extension as provided therein) is _____.

4. The Lease (including amendments or guaranty, if any) is the entire agreement between Landlord and Tenant as to the leasing of the Leased Premises and is in full force and effect.

5. The Landlord has completed the Tenant Improvements and Tenant has accepted the Leased Premises as of the Commencement Date.

6. To the best of the undersigned's knowledge, there are no uncured events of default by either Tenant or Landlord under the Lease.

IN WITNESS WHEREOF, the undersigned has caused this Letter of Understanding to be executed this ____ day of _____, 20___.

ECLAT PHARMACEUTICALS LLC,
a Delaware limited liability company

By: _____
Name: _____
Title: _____

EXHIBIT D

RULES AND REGULATIONS

OFFICE RULES AND REGULATIONS

1. Tenant shall not display, inscribe, paint or affix any sign, picture, showcase, advertisement or notice on any part of the outside or inside of the Building, or on or about the Leased Premises, without the prior written consent of Landlord, and then only of such color, size, style and material as approved by Landlord. Landlord reserves the right to remove such items placed in the lobbies or corridors or in front of the Building, other than those above provided for, without notice, and at Tenant's expense.

2. All informational signs to be placed on Tenant's access door must be specified by Landlord or someone designated by it, and the actual cost (including installation) thereof shall be paid by the Tenant. Tenant shall not install or cause to be installed, without Landlord's consent, any shades, blinds, awnings and screens. Tenant shall remove all such signs, shades, blinds, awnings and screens from the Building and the Leased Premises at the end of its tenancy or Landlord may cause the removal to be done at Tenant's expense.

3. Tenant shall not make any additions to, or alterations in, any part of the Building or Leased Premise by putting up or changing any partition, doors, windows, nor shall there be any nailing, boring, or screwing into the woodwork or walls, nor painting done without the prior written consent of Landlord in each instance. Any and all additions and alterations to the Leased Premises shall be at Tenant's expense.

4. All glass, locks and trimmings in or about the doors or windows, and all electric globes and shades belonging to the Building or Leased Premises shall be kept whole and, whenever broken by any Tenant, shall be immediately replaced or repaired and put in order by such Tenant to the satisfaction of Landlord.

5. Tenant shall not place additional locks upon any door of the Leased Premises, nor permit any duplicate keys to be made, but if more than two keys for any door are desired, the additional number must be procured from Landlord and paid for by Tenant. Tenant shall surrender all keys to the Leased Premises and Building at the end of its tenancy.

6. If Tenant desires telegraph, telephone or data connections, Landlord will direct the electricians (whether hired by Landlord or Tenant) as to where the wires are to be introduced at Tenant's expense, and without such direction no boring or cutting for wires shall be permitted.

7. Landlord reserves the right to prescribe the weight and proper position of safes and mechanical equipment. All safes, furniture, boxes and bulky articles and packages and any items similar to the foregoing (all of the foregoing being referred to as the "Items") shall be moved into or out of the Building or from one part of the Building to another under the supervision of Landlord and at such times and according to such regulations as may be designated from time to time by Landlord. The Items shall be carried up or down only in the elevator and at the entrance designated by Landlord. Tenant shall be responsible for all damage to the walls, floors or other parts of the Building caused by or connected with any moving, or caused by and Item while in the Building. Tenant shall not place any engine, boiler or other machinery upon the Leased Premises.

8. Tenant shall not do or permit anything to be done in the Leased Premises, or bring or keep anything therein which will in any way increase the rate of insurance on the Building, or on property kept therein; or anything which will be dangerous to life, or limb, or which will lend to create a nuisance or injure the reputation of the Building; or use flammable liquid, camphene, alcohol, kerosene or anything except steam, gas or electricity in lighting or heating the Leased Premises; or bring into the Leased Premises or keep therein any heating or lighting apparatus, except floor and desk lamps, other than that provided by Landlord; or install any air conditioning or air-cooling apparatus without the written consent of Landlord; or obstruct or interfere with the rights of other tenants or Landlord; or in any way injure or annoy them, or conflict with the laws relating to fires, or with the regulations of the Fire Department, or with any insurance policy upon the Building or any part thereof; or conflict with any of the laws, rules or regulations of any governmental agency or municipality having jurisdiction.

9. Tenant shall not use the Leased Premises for an illegal or immoral purpose. Tenant shall not sell or distribute beer, wine or intoxicating liquor in the Building without the written consent of Landlord in each instance.

10. Tenant shall not occupy or use any room or rooms as sleeping or lodging apartments.

11. The sidewalk, passages, lobbies, corridors, elevator and stairways shall not be obstructed by Tenant, or used except for ingress and egress to the Leased Premises.

12. The doors, skylights, windows and transoms that reflect or admit light into passageways or any areas in the Building, shall not be covered or obstructed by Tenant. Nothing shall be thrown by the Tenant, its agents, employees, invitees and guests, out of the windows or door, or down the passages or skylights of the Building.

13. Tenant, its agents, employees, invitees and guests shall not make noise, cause disturbances or vibrations or use or operate any electrical or electronic devices or any other devices that emit sounds or disturbances, or create odors that interfere or annoy in any way the other tenants, their agents, employees, invitees and guests. Tenant shall not conduct auctions in the Leased Premises nor make any room-to-room canvass to solicit business from other tenants in the Building.

14. Tenant shall not cause or allow to be caused any waste or misuse of water or other utilities. Building equipment and utilities shall not be used for any purpose other than those for which they were constructed, and any damage resulting to them from misuse shall be borne by the tenant causing same.

15. Tenant shall, when leaving the Leased Premises at close of business, or when the Leased Premises are unoccupied at any time, lock doors, and in the event of any default or carelessness in this respect, shall be liable for all injury sustained by other tenants, by Landlord, or by either of them, for damages resulting from such default or carelessness.

16. Tenant shall not allow any animals or birds in any part of the Building without the consent of Landlord.

17. Any person or persons, other than the janitorial staff of Landlord, who shall be employed for the purpose of cleaning the Leased Premises, shall be employed at Tenant's expense, and Landlord shall be in no way responsible for any loss of property on or from the Leased Premises, however occurring, or any damage done to the furniture or other effects of any tenant, by any cleaning contractor furnished by Tenant or anyone under him. Tenant will report any lack of attention in service of the Building to Landlord.

18. Landlord shall have the right, with pass key or otherwise, to enter any Leased Premises at any time with 24 hours’ notice or in case of emergency, or times to examine the same or to make such repairs or alterations as it shall deem necessary for the safety, preservation or improvement of the Building or the Leased Premises, or for the purpose of cleaning, watching or inspecting same and, during the last six (6) months of the term of the Lease, may show the premises to prospective tenants and put up customary "For Rent" signs.

19. Tenant shall not accumulate or store in the Leased Premises any waste paper, discarded records, books, paper, files, rubbish or other combustible matter.

20. The Landlord reserves the right to exclude from the Building all drunken and disorderly persons, solicitors, persons creating a disturbance and persons entering in crowds or in such unusual numbers as to cause inconvenience to the tenants of the Building.

21. Landlord reserves the rights to vending services in the Building.

22. Building hours are as follows:

Monday through Friday	7:00 A.:M. - 6:00 P.M.
Saturday	7:00 A.M. - 1:00 P.M.
Sunday and Legal Holidays	None

23. All smoking of cigarettes, cigars, pipes, etc., is prohibited within the Building or within fifty (50’) feet of any entrance thereto.

It is Landlord's desire to maintain in the Building and Common Areas the highest standard of dignity and good taste consistent with comfort and convenience for tenants. Any action or condition not meeting this high standard should be reported directly to Landlord. The Landlord reserves the right to make such other and further rules and regulations as in its judgment may from time to time be necessary for the safety, care and cleanliness of the Building and Common Areas, and for the preservation of good order therein.

Exhibit 10.17

Dated the 3rd day of July 2015

Channor Limited **First Part**

Blanchardstown Corporate Park Management Limited **Second Part**

Flamel Ireland Limited **Third Part**

Flamel Technologies, S.A. **Fourth Part**

Lease of Second Floor, Block 10, Unit 1, Blanchardstown Corporate Park 1, Blanchardstown, Dublin 15

AMOSS Solicitors
26 Burlington Road
Ballsbridge
Dublin 4

COUNTY DUBLIN

FOLIO 113065F

(Part of)

THIS INDENTURE made the day of 2015

1. BETWEEN

1.1 **CHANNOR LIMITED** having its registered office at Block 10, Unit 3, Blanchardstown Corporate Park, Dublin 15 (hereinafter called **"the Landlord"** which expression shall where the context so admits or requires include its successors and assigns) of the First Part;

1.2 **BLANCHARDSTOWN CORPORATE PARK MANAGEMENT LIMITED** having its registered office at Block 10, Unit 3, Blanchardstown Corporate Park, Dublin 15 (hereinafter called **"the Management Company"** which expression shall where the context so admits or requires include its successors and assigns) of the Second Part;

1.3 **FLAMEL IRELAND LIMITED** having its registered office at Arthur Cox Building, Earlsfort Terrace, Dublin 2 (hereinafter called "**the Tenant"** which expression shall where the context so admits or requires include its successors and assigns) of the Third Part;

1.4 **FLAMEL TECHNOLOGIES, S.A.** having its registered office at 33 avenue du Dr. Georges Levy, 69200 Vénissieux, France (hereinafter called "**the Guarantor"** which expression shall where the context so admits or requires include its successors and assigns)

WITNESSETH

2. DEFINITIONS

In this Lease unless the context otherwise requires the following expressions shall have the following meanings:-

2.1 **"the Base Rate"** means the annual rate of interest for the time being chargeable under Section 22 of the Courts Act 1981;

2.2 **"Block"** means Block 10, Blanchardstown Corporate Park 1, Blanchardstown, Dublin 15, together with the building erected thereon of which the Demised Premises forms part;

2.3 **"Blocks"** means all blocks currently constructed at the Park together with the buildings erected thereon and such other blocks as may be constructed by the Landlord in the Park;

2.4 **"Business Days"** means a day(s) (other than a Saturday or a Sunday) on which banks are normally open for trade in Dublin;

2.5 **"the Commencement Date"** means ;

2.6 **"Common Areas"** means all roads, bridges, pedestrian ways, water courses, lakes, reservoirs, fountains, landscaped areas and recreational areas together with all buildings and other structures erected thereon as well as all buildings and other structures which are from time to time during the Term designated and allocated by the Landlord and/or the Management Company for the common use and benefit of occupiers and tenants of the Park and for the purpose of the passage of such goods and vehicles as the Landlord and/or the Management Company may designate for the time being and from time to time but does not include the Demised Premises, all other Units (or any parts thereof) in the Park and all Blocks (or any parts thereof) in the Park (including for the avoidance of doubt the Retained Parts) **PROVIDED ALWAYS** that if the Park shall in any way be altered by extension or addition or otherwise then the definition of "the Common Areas" shall, as and where necessary, be modified accordingly;

2.7 **"Common Areas Service Charge**" means the aggregate of the costs, expenses and outgoings paid and incurred or borne or to be paid, incurred or borne as set forth in Part II of the Third Schedule by the Landlord until the transfer of the Common Areas to the Management Company and thereafter by the Management Company in discharging the obligations, executing the works and providing the services, amenities and facilities specified in Part I of the Third Schedule, or all or any of them pursuant to the Landlord's and/or Management Company's covenant in that behalf contained at Clause 7 of this Lease;

2.8 **"Conduits"** mean gutters, gullies, pipes, drains, sewers, watercourses, channels, trunks, ducts, flues, wires, cables and other conducting media and installations of whatsoever nature or kind passing through the Park, the Block or the Demised Premises or part thereof from time to time;

2.9 **"Demised Premises"** means the premises hereby demised and more particularly described in the First Schedule;

2.10 **"Gross Internal Floor Area"** means the gross internal floor area (as defined from time to time in the Measuring Practice Guidance Notes issued jointly by the Society of Chartered Surveyors and others) of the Demised Premises;

2.11 **"Group Company"** has the same meaning as a related company pursuant to section 140(5)(a)-(d) of the Companies Act, 1990.

2.12 **"Initial Rent"** means eighty one thousand euros (€81,000.00) per annum (exclusive of VAT, which is payable);

2.13 **"Instalment Days"** means 1st January, 1st April, 1st July and 1st October in each year of the Term;

2.14 **"Insured Risks"** means, subject always to such exclusions, excesses and limitations as are normally available and as may be imposed by the Landlord's insurers, all or any loss or damage or prospective loss or damage by fire, flooding, water, storm, tempest, lightning, explosion, earthquake, weather conditions, impact of aircraft and articles dropped therefrom, impact by road vehicle, civil commotion, malicious damage, bursting or overflowing of water tanks, apparatus and pipes, riot, affray, civil disturbance, war, revolution, subsidence and such further risks, perils to or in connection with the Demised Premises forms part and the fixtures and fittings thereof and any such fees, expenses, charges and monies of and incidental to the rebuilding, re-instatement or loss (whether total or otherwise) of the Demised Premises or any part thereof as the Landlord may from time to time reasonably deem it desirable to insure against;

2.15 **"Internal Decoration Years"** mean the year ending on the third anniversary hereof and the year ending on the sixth anniversary hereof ;

2.16 **"Landlord's Fixtures and Fittings"** means the fixtures and fittings set out in the Fifth Schedule hereto;

2.17 **"Lettable Areas"** means any area (excluding Common Areas or areas which may be included within Units but which are not for the exclusive benefit of the occupiers of said Unit) leased, disposed of or intended to be leased or disposed of to occupiers or occupational tenants;

2.17 **"Local Authority"** means Fingal County Council or such other body entrusted with the duties of same;

2.18 **"Management Company Agreement"** means the Agreement dated 20th November 1998 made between the Landlord and the Management Company;

2.19 **"Park"** means the lands, hereditaments and premises known as Blanchardstown Corporate Park 1, Blanchardstown, Dublin 15, the present boundaries of which are shown edged blue on Plan A annexed hereto and which expression shall include all additions and extensions to the said lands which are from time to time declared by the Landlord at its discretion to form part of the Park for the purpose of this Lease and which shall exclude those parts thereof which are from time to time declared by the Landlord at its discretion not to form part of the Park for the purposes of this Lease;

2.20 **"Permitted User"** means use as offices;

2.21 **"Planning Acts"** shall be deemed to include the Local Government (Planning and Development) Acts 1963 to 1999, the Planning and Development Acts 2000 to 2014, the Local Government (Sanitary Services) Act 1878 to 1964, the Building Control Acts 1990 - 2007, the Fire Services Act 1981, the Safety Health and Welfare at Work Act 1989 and any Act or Acts for the time being in force amending, extending or replacing the same and any Orders, Regulations or Directions issued under or by virtue of the said Acts of the Oireachtas for the time being in force amending or replacing same. Reference to any other Acts of the Oireachtas shall where necessary or appropriate be deemed to include any Act amending, extending or replacing the same and any Orders or regulations made thereunder or under any such amending extending or replacing Acts;

2.22 **"Rent"** means the Initial Rent and such revised rent as may from time to time become payable under the provisions of the Fourth Schedule hereto;

2.23 **"Rent Commencement Date"** means the Commencement Date;

2.24 **"Retained Parts"** means the parts of the Block which do not comprise Lettable Areas including without prejudice to the generality of the foregoing (1) any parts of the main structure, roof, external walls and internal load bearing walls, foundations, fire escape and structural parts of the roof along with the lift, stairs, lobbies, hallways, corridors, ceilings, floors, beams, joists, all party structures, boundary walls, railings, and fences and all exterior parts of the Block and car parking areas, if any, within the curtilage of the Block, (2) any parts of the Block reserved by the Landlord for the housing of plant, machinery and equipment or otherwise in connection with or required for the provision of services and (3) all conduits in, upon, under or within and exclusively serving the Block except any that form part of a Lettable Area;

2.25 **"Retained Parts Service Charge"** means the aggregate of the costs, expenses and outgoings paid and incurred or borne to be paid, incurred or borne as set forth in Part IV of the Third Schedule by the Landlord in discharging the obligations, executing the works and providing the services, amenities and facilities specified in Part III of the Third Schedule, or all or any of them pursuant to the Landlord's and/or the Management Company's covenant in that behalf contained at Clause 7 of this Lease;

2.26 **"Reserved Property"** means the Park save the Demised Premises;

2.27 **"Service Charge"** means together the Common Areas Service Charge and the Retained Parts Service Charge, which sum is payable by the Tenant as set out herein;

2.28 **"Services"** means water, soil, air, electricity, telephone transmissions, radio transmissions, television transmissions, oil, heating fuels and other services servicing the Park;

2.29 **"Term"** means ten (10) years from the Commencement Date.

2.30 **"Tenant's Proportion of the Common Area Service Charge"** means a due proportion of the Common Areas Service Charge equal to the ratio which the Gross Internal Floor Area of the Demised Premises bears from time to time to the aggregate of the Gross Internal Floor Areas of all of the Lettable Areas within the Park;

2.31 **"Tenant's Proportion of the Retained Parts Service Charge"** means a due proportion of the Retained Parts Service Charge equal to the ratio which the Gross Internal Floor Area of the Demised Premises bears from time to time to the aggregate of the Gross Internal Floor Areas of all of the Lettable Areas within the Block;

2.32 "**Tenant's Proportion of the Utilities Service Charge**" means one third of the Utilities Service Charge;

2.33 **"Unit" or "Units**" mean any part of the Park (including the Demised Premises) which is let or intended to be let or disposed of to another tenant, which is comprised of (either wholly or partly) Lettable Areas;

2.34 **"Utilities"** means all channels, conduits, ducts, pipes, drains, watercourses, ditches, gutters, wires, mains, cables, lighting installations and such like for the Services;

2.35 "**Utilities Service Charge**" means the aggregate of the sums due in respect of gas and water provided to and used by all occupants of Block 10 and the associated administrative and management fees.

2.36 **"VAT"** means Value Added Tax.

2.37 **"VAT Act"** means Value Added Tax Consolidation Act, 2010;

3. INTERPRETATION

3.1 Where two or more persons are included in the expression "the Landlord", "the Guarantor" and/or "the Tenant", such expressions include all or any of such persons and the covenants which are expressed to be made by the Landlord, the Guarantor and/or the Tenant shall be deemed to be made by or with such persons jointly and severally.

3.2 Words importing the masculine gender only include the feminine gender and words importing the singular number only include the plural number and vice versa.

3.3 Any covenant by the Tenant not to do any act or thing shall include an obligation not to permit or suffer such act or thing to be done;

3.4 References to any right of the Landlord to have access to or entry upon the Demised Premises shall be construed as extending to all persons authorised by the Landlord and its agents, professional advisors, prospective purchasers of any interest of the Landlord in the Demised Premises or in the Retained Parts, contractors, workmen or others;

3.5 the titles or headings appearing in this Lease are for reference only and shall not affect its construction or interpretation;

3.6 any reference to a clause or schedule shall mean a clause or schedule of this Lease;

3.7 if any term or provision in this Lease shall be held to be illegal or unenforceable in whole or in part, such term shall be deemed not to form part of this Lease but the enforceability of the remainder of this Lease shall not be affected.

4. DEMISE

In consideration of the Rent (and all variations thereof as hereinafter provided), and the covenants and conditions hereinafter reserved and contained the Landlord hereby **DEMISES** unto the Tenant **ALL THAT** the Demised Premises **TOGETHER WITH** the rights specified in Part I of the Second Schedule and the Management Company hereby confirms the rights specified in Part I of the Second Schedule **EXCEPTING AND RESERVING** unto the Landlord, the Management Company as the case may be, the rights specified in Part II of the Second Schedule **TO HOLD** the same for the Term **YIELDING AND PAYING** during the Term the Rent as defined herein, payable quarterly in advance by equal payments on the Instalment Days and all payments to be made (at the option of the Landlord, which said option may be exercised on any number of occasions) either by standing order, direct debit, credit transfer or cheque without any deductions, set-off or counterclaim whatsoever, **AND ALSO PAYING** to the Landlord and/or the Management Company as the case may be;

4.1 a percentage or due proportion (equivalent to the ratio which the Gross Internal Floor Area of the Demised Premises bears to the aggregate of the Gross Internal Floor Areas of all of the Lettable Areas within the Block) of all sums which the Landlord shall from time to time pay for insuring the Block against the Insured Risks pursuant to Clause 6.2 (including the whole of the sums which the Landlord shall from time to time pay for insuring against three years loss of the Rent or such longer period as the Landlord may, from time to time, reasonably deem to be necessary to insure against and the Service Charge), all such sums to be paid on demand the first payment to be made on the execution hereof and to be such amount as has been advised to the Tenant prior to the delivery of this Lease;

4.2 the Service Charge to be paid in accordance with Parts II and IV (as the case may be) of the Third Schedule quarterly in advance by equal payments on the Instalment Days by direct debit;

4.3 the Tenant’s Proportion of the Utilities Service Charge payable upon demand being made by the Landlord and in such manner as the Landlord shall direct;

4.4 any other sum recoverable by the Landlord as costs or expenses under this Lease, the same to be paid at the times and in the manner herein prescribed for the payment of same

such sums to be recoverable by action or distress as rent in arrears.

5. TENANT'S COVENANTS

AND THE TENANT HEREBY COVENANTS with the Landlord in the following manner:-

5.1 **Rents**

To pay the Rent referred to at Clause 4 and any additional sums payable herein at the times and in the manner herein prescribed for the payment of same.

5.2 **Interest on Arrears**

If the Tenant shall fail to pay the Rent herein reserved or any other sum reserved or made payable hereunder within twenty one (21) days of the date and in the manner herein prescribed for the payment of same, whether demanded or not, such unpaid rent or sum shall bear interest from and including the day or days on which the same became due to the date of actual payment at a rate which shall be the Base Rate per annum which interest shall be recoverable by and be subject to all the rights and remedies of the Landlord for the recovery of rent subject always and without prejudice to all rights of the Landlord hereunder.

5.3 **Outgoings**

5.3.1 To pay and indemnify the Landlord against all existing (from the date of this Lease) and future rates, taxes, duties, charges, assessments, impositions and outgoings whatsoever (whether parliamentary, parochial, local or of any other description and whether or not of a capital or non-recurring nature) which now are or may at any time during the Term be charged, levied, assessed or imposed upon or payable in respect of the Demised Premises or upon the owner or occupier of them (excluding any tax payable by the Landlord upon any of the rents herein received or occasioned by any disposition of or dealing with the reversion of this Lease);

5.3.2 To pay all charges for electricity, gas (if any), water and other services consumed in the Demised Premises, including any connection and hiring charges and meter rents and to perform and observe all present and future regulations and requirements of the electricity, gas and water supply authorities or boards in respect of the supply and consumption of electricity, gas and water on the Demised Premises and to keep the Landlord indemnified against any breach thereof.

5.4 **Repairs**

To repair and keep in good and substantial repair and condition the Demised Premises and, as often as may be necessary, to rebuild, reinstate or renew any part or parts of the Demised Premises (damage by the Insured Risks excepted) (other than in respect of any amount which may be deducted or disallowed by the insurers pursuant to any excess provision in the insurance policy upon settlement of any claim by the Landlord) save to the extent that payment of the insurance moneys shall be withheld by reason of any act, neglect or default of the Tenant or the servants or agents of the Tenant or any undertenant or any person under its or their control) and, as and when necessary, to replace any of the Landlord's Fixtures and Fittings which may be or become beyond repair with new ones which are similar in type and quality AND in case the Demised Premises or any part thereof shall be destroyed or become ruinous and uninhabitable or incapable of beneficial occupation or enjoyment by for or from any of the Insured Risks the Tenant hereby absolutely waives and abandons its rights (if any) to surrender this Lease under the provisions of Section 40 of the 1860 Act or otherwise PROVIDED ALWAYS THAT the Tenant shall not be obliged to maintain the Demised Premises in any better state or condition than exists at the date hereof as shown in the schedule of condition annexed hereto at the Fifth Schedule.

5.5 **Decorations**

In every Internal Decoration Year and also in the last three months of the Term (whether determined by effluxion of time or otherwise) in a good and workmanlike manner to prepare and decorate (with two coats at least of good quality paint) or otherwise treat, as appropriate, all parts of the Demised Premises required to be so treated and, as often as may be reasonably necessary, to wash down all tiles, glazed bricks and similar washable surfaces such decorations and treatment in the last three months of the Term to be executed in such colours and materials as the Landlord may reasonably require.

5.6 **Cleaning**

To keep the Demised Premises in a clean and tidy condition AND as often as reasonably necessary to clean properly all windows and window frames and all other glass in the Demised Premises.

5.7 **Yield Up**

5.7.1 At the expiration or sooner determination of the Term quietly to yield up the Demised Premises in such good and substantial repair and condition as shall be in accordance with the covenants on the part of the Tenant herein contained and in any licence or consent granted by the Landlord pursuant to the provisions of this Lease and in case any of the Landlord's Fixtures and Fittings shall be missing, broken damaged or destroyed to forthwith replace them with others of a similar kind and of equal value and to remove from the Demised Premises any moulding, sign, writing or painting of the name or business of the Tenant or occupiers and if so required by the Landlord, but not otherwise, to remove and make good to the original prevailing condition, all alterations or additions made by the Tenant to and/or within those parts of the Demised Premises shown edged in blue on the plan annexed at the Sixth Schedule hereto including the making good of any damage caused to the Demised Premises by the removal of the Tenant’s fixtures, fittings, furniture and effects therein.

5.7.2 For the avoidance of doubt the Landlord and the Tenant agree to jointly inspect the Demised Premises prior to the Determination Date or prior to the expiration or sooner determination of the Term to ensure that the Demised Premises are returned to the original prevailing condition as per the photographic schedule of condition, agreed between the parties, attached to this lease at the Fifth Schedule BUT PROVIDED ALWAYS that notwithstanding the foregoing provisions, the Tenant shall not be obliged to remove its fit-out, fixtures and fittings to and/or within the area shown edged in green on the plan annexed at the Sixth Schedule hereto.

5.8 **Rights of entry by Landlord and Management Company**

To permit the Landlord and/or the Management Company with all necessary materials and appliances at all reasonable times upon reasonable prior notice (except in cases of emergency) to enter and remain upon the Demised Premises for any of the following purposes:-

5.8.1 to view and examine the state and condition of the Demised Premises and to take schedules or inventories of the Landlord's Fixtures;

5.8.2 to exercise any of the rights excepted and reserved by this Lease or of the covenants contained in this Lease;

5.8.3 for any other purpose connected with the interest of the Landlord or the Management Company in the Demised Premises or the Block, including but not limited to, valuing or disposing of any interest of the Landlord or the Management Company.

5.9 **To Comply with Notices**

Whenever the Landlord shall give written notice to the Tenant of any defects, wants of repair or breaches of covenant (other than covenants for payment of rents and other sums payable to the Landlord under this Lease), the Tenant shall within sixty (60) days of such notice, or sooner if requisite, make good and remedy the breach of covenant to the reasonable satisfaction of the Landlord and if the Tenant shall fail within twenty-one (21) days of such notice, or as soon as reasonably possible in the case of emergency, to commence and then diligently and expeditiously to continue to comply with such notice, the Landlord may enter the Demised Premises and carry out or cause to be carried out all or any of the works referred to in such notice and all reasonable and properly vouched costs and expenses thereby incurred shall be paid by the Tenant to the Landlord on demand, and in default of payment, shall be recoverable as rent in arrears.

5.10 **Dangerous materials and use of machinery**

5.10.1 Not to bring into the Block or keep in or on the Demised Premises any article or thing which is or might become dangerous, offensive, unduly combustible or inflammable, radio-active or explosive or which might unduly increase the risk of fire or explosion;

5.10.2 Not to keep or operate in the Demised Premises any machinery which shall be unduly noisy or cause vibration or which is likely to annoy or disturb the other tenants and occupiers of the Block or of the Park.

5.11 **Overloading floors and services**

5.11.1 Not to overload the floors of the Demised Premises or suspend any excessive weight from the roofs, ceilings, walls, stanchions or structure of the Block and not to overload the utilities and Conduits in or serving the Block and the Park;

5.11.2 Not to do anything which may subject the Demised Premises or the Block or any parts thereof to any strain beyond that which they are designed to bear with due margin for safety;

5.11.3 to observe the weight limits and capacity prescribed for all lifts in the Block.

5.12 **Conduits**

Not to discharge into any Conduits any oil or grease or any noxious or deleterious effluent or substance whatsoever which may cause an obstruction or might be or become a source of danger, or which might injure the Conduits or the drainage system of the Block or the Park.

5.13 **Disposal of Refuse**

Not to deposit in or on the Retained Parts or Common Areas any trade empties, rubbish or refuse of any kind, other than in proper receptacles, provided for the purpose or as may be designated by the Landlord and/or the Management Company and not to burn any rubbish or refuse on the Demised Premises.

5.14 **Obstruction of Common Areas and Retained Parts**

Not to do anything whereby the Common Areas or the Retained Parts or other areas over which the Tenant may have rights of access or use may be damaged, or the fair use thereof by others may be obstructed in any manner whatsoever

5.15 **Prohibited users**

5.15.1 Not to use the Demised Premises or any part thereof for any public or political meeting, public exhibition or public entertainment show or spectacle of any kind, nor for any dangerous, noisy, noxious or offensive trade, business or occupation whatsoever, nor for any illegal or immoral purpose, nor for residential or sleeping purposes but not so as to prevent the Lessee from time to time as the need arises to invite selected retailers and other parties to the Demised Premises for the purpose of performing training seminars and demonstrations of its products and such like activities at the Demised Premises and not so as to prevent the Lessee holding open days at the Demised Premises as may be required from time to time for such purposes;

5.15.2 Not to use the Demised Premises or any part thereof for gambling, betting, gaming or wagering, or as a betting office, or as a club, or for the sale of beer, wines and spirits, and not to play or use any musical instrument, record player, loud speaker or similar apparatus in such a manner as to be audible outside the Demised Premises, and not to hold any auction on the Demised Premises;

5.15.3 Not to place outside the Demised Premises, nor to expose from the windows of the Demised Premises, any articles, goods or things of any kind.

5.16 **User**

5.16.1 Not without the prior written consent of the Landlord (which consent shall not be unreasonably withheld) to use the Demised Premises or any part thereof except for the Permitted User **PROVIDED NEVERTHELESS FIRSTLY THAT** the Landlord shall be entitled to withhold such consent if the Landlord considers that:

(a) The change of the user would substantially increase the rate of insurance in respect of the Demised Premises, the Park or nearby or adjoining Units unless the Tenant agrees to pay for any such increase in premium; or

(b) The alternative user would not be in the interests of good estate management of the Park; or

(c) If at the time of such application the Landlord is under any legal or contractual obligation which prohibits the Landlord and/or the Management Company from allowing the alternative user to be carried on in or on the Demised Premises.

(d) The proposed new user being similar to a user or users already carried on in the Park and in the reasonable opinion of the Landlord it would be undesirable for the benefit of the Park to have another Unit or building in the Park being used for business already carried on therein or similar to a business already carried on in the Park; or

AND SECONDLY that the approval of the Local Authority to the change of user is first obtained (should same be necessary).

5.16.2 Not to leave the Demised Premises continuously unoccupied (other than for normal holiday periods) without notifying the Landlord and providing such caretaking or security arrangements as the Landlord shall reasonably require in order to protect the Demised Premises from vandalism, theft or unlawful occupation;

5.16.3 At all times to comply with all requirements of the relevant Local Authority in connection with the user of the Demised Premises for the purpose of the Tenant's business;

5.16.4 To provide the Landlord with the name, address and home telephone number of at least two authorised key holders for the time being of the Demised Premises and to notify the Landlord of any changes in the person(s) so authorised as keyholders of the Demised Premises;

5.17 **Nuisance**

Not to do anything in or about the Demised Premises or the Block which may be or become a nuisance, or which may cause damage, annoyance, inconvenience or disturbance to the Landlord or the other tenants in the Block or the owners, tenants or occupiers of the Park, or which may be injurious to the value, tone, amenity or character of the Block and/or the Park.

5.18 **Alterations**

5.18.1 Not to make any alterations or additions of any sort to any structural parts of the Demised Premises and not to make any alterations or additions to the Landlord's Fixtures and Fittings or to any of the Conduits;

5.18.2 Not to make any internal alterations or additions of a non-structural nature to the Demised Premises without obtaining the prior written consent of the Landlord, (such consent not to be unreasonably withheld or delayed);

5.18.3 The Landlord may, as a condition of giving any such consent, require the Tenant to enter into such covenants as the Landlord shall reasonably require, regarding the execution of any such works and the reinstatement of the Demised Premises at the end or sooner determination of the Term.

5.18.4 If any alterations or additions to or within the Demised Premises result in a variation of the reinstatement cost of the Demised Premises from the said cost prior to such alterations or additions;

5.18.4.1 Forthwith to give notice in writing to the Landlord of the variation in value so caused to enable the Landlord to alter the insurance cover in respect of the Demised Premises;

5.18.4.2 To pay or reimburse to the Landlord any shortfall of insurance cover caused by a failure to comply with the requirements in Sub-Clause 5.18.4.1;

5.18.4.3 Notice under Sub-Clause 5.18.4.1 notifying the variation of the reinstatement cost shall only be sufficient notice if it refers to the Sub-Clause in question and the Landlord shall not otherwise be deemed to have received such notice or to be responsible for varying the said insurance cover.

5.18.4.4 When executing any works pursuant to the provisions of this Clause 5.18, the Tenant shall comply with the Safety, Health and Welfare at Work (Construction) Regulations 1995 and shall supply the Landlord with a copy of any Health and Safety file required to be maintained by the Tenant under those regulations.

5.19 **Signs and advertisements**

Not without the prior written consent of the Landlord (such consent not to be unreasonably withheld or delayed) to erect or display on the exterior of the Demised Premises or in the windows thereof so as to be visible from the exterior, any pole, flag, aerial, advertisement poster, notice or other sign or thing whatsoever, save that the Tenant may display on the entrance door to the Demised Premises a sign, in keeping with the existing signage, stating the Tenant's name and business or profession on obtaining the prior written consent of the Landlord to the size, style and the position thereof and the materials to be used (such consent not to be unreasonably withheld).

5.20 **Alienation**

Not to assign, transfer, mortgage, charge, underlet, or part with the possession or occupation of the Demised Premises or any part thereof or suffer any person to occupy the Demised Premises or any part thereof as a licensee **BUT SO THAT NOTWITHSTANDING** the foregoing the Landlord shall not unreasonably withhold its consent to an assignment of the entire or to an underletting of the entire of the Demised Premises to an assignee or underlessee of good and sufficient financial standing and otherwise reasonably acceptable to the Landlord subject always to the following provisions or such of them as may be appropriate, that is to say:-

5.20.1 The Tenant shall prior to any such alienation as aforesaid apply to the Landlord and give all reasonable information concerning the proposed transaction and concerning the proposed assignee, under-lessee or disponee as the Landlord may require, including without prejudice to the generality of the foregoing, in a case where the proposed assignee, under lessee or disponsee is a limited liability company audited accounts showing net profits of at least three times the rent payable for the three years immediately prior to the year in which the application for consent is made;

5.20.2 The Landlord's consent to any such alienation shall be in writing and shall be given in such manner as the Landlord shall decide and the Tenant shall pay the reasonable costs of the Landlord in connection with the furnishing of such consent;

5.20.3 In the case of an assignment to a limited liability company, it shall be deemed reasonable for the Landlord to require that two sureties of standing satisfactory to the Landlord shall join in such consent as aforesaid as sureties for such company in order jointly and severally to covenant with the Landlord in the manner described in and in accordance with such provisions as the Landlord may deem fit;

5.20.4 In the case of an under-lease the same shall be of the entire of the Demised Premises and shall be made without taking a fine or premium at the then full open market rent and the under-lessee shall, if required by the Landlord, enter into a direct covenant with the Landlord to perform and observe all the covenants (other than that for payment of the rents hereby reserved) and conditions herein contained and every such under-lease shall also be subject to the following conditions, that is to say that it shall contain:-

5.20.4.1 provisions for the review of the rent thereby reserved (which the Tenant hereby covenants to operate and enforce) at the open market rent corresponding both as to terms and dates and in all other respects (mutatis mutandis) with the rent review provisions contained in this Lease;

5.20.4.2 a covenant by the undertenant (which the Tenant hereby covenants to enforce) prohibiting the undertenant from doing or suffering any act or thing upon or in relation to the Demised Premises inconsistent with, or in breach of, the provisions of this Lease;

5.20.4.3 a condition for re-entry on breach of any covenant by the undertenant;

5.20.4.4 the same restrictions as to alienation, assignment, underletting, parting with or sharing the possession or occupation of the premises underlet;

5.20.4.5 Any sub-lease must be granted in such a manner as will not give rise to rights to a renewal of a tenancy or other rights or interests in the Demised Premises or any part thereof as provided for under Part II of the Landlord and Tenant (Amendment) Act 1980 and any under-lessee shall be required to provide a deed of renunciation of such rights on entering into the under lease.

5.20.5 To enforce at the Tenant's own expense the performance and observance by every such undertenant of the covenants, provisions and conditions of the under-lease and not, at any time, either expressly or by implication, to waive any breach of the same;

5.20.6 Not to agree any reviewed rent with the undertennant or any rent payable on any renewal thereof which is less than the open market rent without the prior written consent of the Landlord (such consent not to be unreasonably withheld) and to notify the Landlord of the reviewed rent agreed within 14 days of every rent review referred to in this Clause 5.20.6;

5.20.7 Not to vary the terms of any permitted under-lease without the prior written consent of the Landlord, such consent not to be unreasonably withheld or delayed.

5.20.8 Notwithstanding anything contained in this Lease the Tenant shall be entitled (without requiring the consent of the Landlord) to share or sub-let the entire or part of the Demised Premises with any Group Company subject to the following:

5.20.8.1. prior written notification being provided to the Landlord by the Tenant at least 14 days prior to occupation by any Group Company;

5.20.8.2 The Tenant procuring a Deed of Renunciation from the Group Company renouncing any entitlement the Group Company may have pursuant to the provisions of Section 17(1)(a) of the Landlord and Tenant (Amendment) Act 1980 (as amended by Section 4 of the Landlord and Tenant (Amendment) Act 1994 and further amended by Section 47 of the Civil Law (Miscellaneous Provisions) Act 2008.

5.20.8.3 The Tenant procures that any such Group Company also vacates the Demised Premises on the expiry or sooner determination of the Term unless the Landlord permits otherwise.

5.20.8.4 For the avoidance of doubt, an assignment of the Demised Premises or part thereof to a Group Company is expressly prohibited without the Landlords prior written consent such consent not to be unreasonably withheld or delayed.

5.21 **Registration of dispositions**

Within twenty-one (21) days of every alienation, assignment, transfer, assent, under-lease, assignment of under-lease, mortgage, charge (including lodgement of the relevant document or instrument as security) or any other disposition, whether mediate or immediate, of or relating to the Demised Premises or any part thereof, to produce to and leave with the Landlord or its solicitors a certified copy of the deed, instrument or other document evidencing or effecting such disposition and to pay to the Landlord's solicitors their reasonable legal costs and other expenses in connection with such alienation.

5.22 **Disclosure of information**

Upon making any application or request in connection with the Demised Premises or this Lease, to disclose to the Landlord such information as the Landlord may reasonably require and, whenever the Landlord shall reasonably request, to supply full particulars;

5.23.1 of all persons in actual occupation or possession of the Demised Premises and of the right in which they are in such occupation or possession, and

5.23.2 of all persons having an interest in the Demised Premises (other than in the reversion to the Term).

5.23 **Landlord's costs**

To pay and indemnify the Landlord against all reasonable and properly vouched costs, fees, charges, disbursements and expenses properly incurred by the Landlord, including, but not limited to, those payable to solicitors, counsel, architects, surveyors and sheriffs:

5.23.1 in relation to the preparation and service of a notice under Section 14 of the 1881 Act and of any proceedings under the 1881 Act and/or the 1860 Act (whether or not any right of re-entry or forfeiture has been waived by the Landlord or a notice served under Section 14 of the 1881 Act has been complied with by the Tenant and notwithstanding that forfeiture has been avoided otherwise than by relief granted by the Court);

5.23.2 in relation to the preparation and service of all notices and schedules relating to wants of repair, whether served during or after the expiration of the Term (but relating in all cases only to such wants of repair that accrued not later than the expiration or sooner determination of the Term);

5.23.3 in connection with the recovery or attempted recovery of arrears of the Rent or other sums due from the Tenant, or in procuring the remedying of the breach of any covenant by the Tenant;

5.23.4 in relation to any application for consent required or made necessary by this Lease whether or not the same is granted (except in cases where the Landlord is obliged not to unreasonably withhold its consent and the withholding of its consent is held to be unreasonable), or whether or not the application has been withdrawn;

5.23.5 In relation to any application made by the Landlord at the request of the Tenant and whether or not such application is accepted, refused or withdrawn.

5.24 **Statutory requirements**

5.24.1 At the Tenant's own expense, to comply in all respects with the provisions of all Acts, Statutory Instruments, Bye Laws and other regulations now in force or which may hereafter be in force and any other obligations imposed by law relating to the Demised Premises or the user thereof since the date of the Lease;

5.24.2 To execute all works and provide and maintain all arrangements upon or in respect of the Demised Premises or the user thereof since the date of the Lease, which are directed or required (whether of the Landlord, Tenant or occupier) by any statute now in force or which may hereafter be in force or by any government department, local or other competent authority or duly authorised officer or court of competent jurisdiction acting under or in pursuance of any statute and to indemnify and keep the Landlord indemnified against all costs, charges, fees and expenses of or incidental to the execution of any works or the provision or maintenance of any arrangements so directed or required;

5.24.3 Not to do in or near the Demised Premises, any act or thing by reason of which the Landlord may, under any statute, incur or have imposed upon it or become liable to pay any penalty, damages, compensation, costs, charges or expenses.

5.25 **Planning Acts, Building Control Act and Public Health Acts**

5.25.1 Not to do or omit to do anything on or in connection with the Demised Premises the doing or omission of which shall be a contravention of the Planning Acts or of any notices, orders, licences, consents, permissions and conditions (if any) served, made, granted or imposed thereunder and to indemnify (as well after the expiration of the Term by effluxion of time or otherwise as during its continuance) and keep indemnified the Landlord against all actions, proceedings, damages, penalties, costs, charges, claims and demands in respect of such acts and omissions or any of them and against the costs of any application for planning permission, commencement notices, fire safety certificates and the works and things done in pursuance thereof;

5.25.2 In the event of the Landlord giving written consent to any of the matters in respect of which the Landlord's consent shall be required under the provisions of this Lease or otherwise and in the event of permission or approval from any local authority under the Planning Acts or the Building Control Act or the Public Health Acts being necessary for any addition, alteration or change in or to the Demised Premises or for the change of user thereof, to apply, at the cost of the Tenant, to the relevant local authority for all approvals, certificates, consents and permissions which may be required in connection therewith and to give notice to the Landlord of the granting or refusal (as the case may be) together with copies of all such approvals, certificates, consents and permissions forthwith on the receipt thereof and to comply with all conditions, regulations, bye laws and other matters prescribed by any competent authority either generally or specifically in respect thereof and to carry out such works at the Tenant's own expense in a good and workmanlike manner to the satisfaction of the Landlord, acting reasonably;

5.25.3 To give notice forthwith to the Landlord of any notice, order or proposal for a notice or order served on the Tenant under the Planning Acts or the Building Control Act or the Public Health Acts and if so required by the Landlord to produce the same and at the request of the Landlord but at the cost of the Tenant, to make or join in making such objections or representations in respect of any proposal as the Landlord may require;

5.25.4 To comply at its own cost with any notice or order served on the Tenant under the provisions of the Planning Acts or the Building Control Act or the Public Health Acts;

5.25.5 Not to implement any planning permission before it and any necessary fire safety certificates have been produced to and approved in writing by the Landlord (such approval not to be unreasonably withheld) **PROVIDED THAT** the Landlord may refuse to approve such planning permission or fire safety certificate on the grounds that any condition contained in it or anything omitted from it or the period referred to in it would, in the reasonable opinion of the Landlord, be or be likely to be, prejudicial to the Landlord's interest in the Demised Premises.

5.25.6 To produce to the Landlord within five days of demand all plans, documents and other evidence as the Landlord may reasonably require in order to satisfy itself that all of the provisions in this covenant have been complied with.

5.26 **Statutory notices**

Within fourteen (14) days of receipt of the same (or sooner if requisite having regard to the requirements of the notice or order in question or the time limits stated therein) to produce to the Landlord a true copy and any further particulars required by the Landlord of any notice or order or proposal for the same given to the Tenant and relevant to the Demised Premises or the occupier thereof by any government department or local or public or statutory authority, and, without delay, to take all necessary steps to comply with the notice or order in so far as the same is the responsibility of the Tenant, and, at the request of the Landlord but at the cost of the Tenant, to make or join with the Landlord in making such objection or representation against or in respect of any such notice, order or proposal as the Landlord shall deem expedient.

5.27 **Fire and safety precautions and equipment**

5.27.1 To comply with the requirements and recommendations (whether notified or directed to the Landlord and/or the Management Company and then to the Tenant or directly to the Tenant) of the appropriate local authority, the insurers of the Block, the Retained Parts or the Common Areas and the Landlord and/or the Management Company in relation to fire and safety precautions affecting the Demised Premises, the Block and/or the Park;

5.27.2 Not to obstruct the access to or means of working any fire fighting, extinguishing and other safety appliances for the time being installed in the Demised Premises, the Block or in the Park or the means of escape from the Demised Premises, the Block or the Park in case of fire or other emergency.

5.28 **Electro-Magnetic Compatibility**

To ensure that all electrical and electronic equipment located placed or installed in the Demised Premises is, insofar as it is reasonably practicable and foreseeable to do so, located, placed or installed and kept and maintained in such place and in such manner as to avoid or minimize electromagnetic interference, including malfunction in its own or in other electrical and electronic equipment in the Block or the Park, including in particular (but without prejudice to the generality of the foregoing), data transmission systems;

5.29 **Encroachments and easements**

Not to stop up, darken or obstruct any of the windows or lights belonging to the Demised Premises and not to permit any new window, light, opening, doorway, passage, Conduit or other encroachment or easement to be made or acquired into, upon or over the Demised Premises or any part thereof, and in case any person shall attempt to make or acquire any encroachment or easement whatsoever, to give written notice thereof to the Landlord immediately the same shall come to the notice of the Tenant, and, at the request of the Landlord but at the cost of the Tenant, to adopt such means as may be reasonably required by the Landlord for preventing any such encroachment or the acquisition of any such easement.

5.30 **Reletting notices**

To permit the Landlord at all reasonable times during the last six (6) months of the Term to enter upon the Demised Premises and affix and retain without interference upon any suitable parts of the Demised Premises or the exterior thereof (but not so as to materially affect the access of light and air to the Demised Premises) notices for reletting the same and not to remove or obscure the said notices and to permit all persons with the written authority of the Landlord to view the Demised Premises at all reasonable hours in the daytime, upon prior notice having been given.

5.31 **Tenant's Effects**

5.31.1 The Tenant irrevocably appoints the Landlord to be the Tenant's agent to store or dispose of any effects left by the Tenant on the Demised Premises for more than seven days after the expiry or sooner determination of the Term subject to any condition which the Landlord thinks fit and without the Landlord being liable to the Tenant save to account for the net proceeds of sale less the costs of storage (if any) and any other expenses reasonably incurred by the Landlord.

5.31.2 Any goods or other effects left at the Demised Premises on or after the expiry or sooner determination of the Term shall be subject to a lien in favour of the Landlord in respect of any liability of the Tenant to the Landlord pursuant to or arising out of this Lease and the Landlord shall have power to sell or otherwise dispose of all such goods and effects on whatever terms the Landlord shall think fit and to apply the net proceeds of such sale or disposal towards satisfaction of such liability.

5.32 **Indemnity**

5.32.1 To keep the Landlord and the Management Company fully indemnified from and against all actions, proceedings, claims, demands, losses, costs, expenses, damages and liability arising in any way directly or indirectly out of any act, omission or negligence of the Tenant or any persons in on or about the Demised Premises expressly or impliedly with the Tenant's authority or the user of the Demised Premises or any breach of the Tenant's covenants or the conditions or other provisions contained in this Lease;

5.32.2 To effect and keep in force during the Term such public liability, employer's liability, equipment insurance and other policies of insurance (to the extent that such insurance cover is available) as may be necessary to cover the Tenant against any claim arising under this covenant **AND** whenever required to do so by the Landlord and/or the Management Company to produce to the relevant party the said policy or policies together with satisfactory evidence that the same is/are valid and subsisting and that all premiums due thereon have been paid.

5.33 **Landlord's Regulations**

To comply with all reasonable regulations made by the Landlord and the Management Company from time to time and notified to the Tenant in writing for the general management and security of the Block and any other areas used or to be used in common with others.

5.34 **Stamp Duty and Value Added Tax**

5.34.1 To pay to the Landlord the stamp duty payable on this Lease and the counterpart thereof and to pay and indemnify the Landlord against any Value Added Tax payable on the delivery hereof or on the rents reserved herein.

5.34.2 The Landlord notifies and confirms to the Tenant that the Landlord is hereby exercising the Landlord’s option to apply VAT to the Rent and other consideration payable in respect of this lease pursuant to section 97(1) of the VAT Act and that VAT is chargeable on the Rent and such other sums payable by the Tenant reserved by this lease subject to the production of a valid VAT invoice in advance.

6. **LANDLORD’S COVENANTS**

THE LANDLORD COVENANTS with the Tenant as follows:-

6.1 **Quiet Enjoyment**

That the Tenant paying the Rent for the Demised Premises, the contribution to the insurance premium, Service Charge and all payments required to be made hereunder and observing and performing the several covenants and stipulations herein on its part contained shall and may peaceably hold and enjoy the Demised Premises without any interruption by the Landlord or any person rightly claiming under or in trust for the Landlord.

6.2 **Insurance**

(a) Subject to the necessary insurance cover being obtainable a reputable insurance company, to effect insurance in a sum not less than the full reinstatement cost (to be determined from time to time by the Landlord acting reasonably) of the Block against loss or damage by the Insured Risks and the following;

i. Architects, Surveyors, Consultants and other professional fees (including Value Added Tax thereon).

ii. the costs of shoring up, demolishing, site clearing and similar expenses;

iii. all stamp duty and other taxes or duties exigible on any building or like contract as may be entered into and all other incidental expenses relative to the reconstruction, reinstatement or repair of the Demised Premises;

iv. such provision for inflation as the Landlord in its reasonable discretion shall deem appropriate;

v. the loss of rent and the Service Charge, from time to time payable, or reasonably estimated to be payable under this Lease (taking account of any review of the rent which may become due under this Lease) following loss or damage to the Demised Premises by the Insured Risks, for three (3) years or such longer period as the Landlord may, from time to time, reasonably deem to be necessary to insure against;

vi. property owners, public, employer's and other liability of the Landlord arising out of or in relation to the Demised Premises; and

vii. such other insurances as the Landlord may, in its reasonable discretion from time to time, deem necessary to effect.

(b) To produce to the Tenant on demand the policy or policies of such insurance and the receipt for the current premiums.

(c)

In case the Block or any part thereof shall be destroyed or damaged by any of the Insured Risks and insurance cover against such perils has been obtained as aforesaid and unless payment of the insurance monies shall be refused in whole or in part by reason of any act, neglect or default of the Tenant or any under-tenant or any person under its control (and subject to the previous compliance by the Tenant with the provisions of Clause 5 hereof) the Landlord shall take such steps as may be requisite and proper to obtain any necessary planning permission, building licences and permits under any regulations or enactment for the time being in force to enable the Landlord to rebuild and reinstate same and will, as soon as such planning permission, building licences and permits have been obtained and as soon as is reasonably practicable to, and subject to the necessary labour and materials being and remaining available (in respect of which the Landlord shall use reasonable endeavours to obtain), lay out the proceeds of such insurance to rebuild, reinstate, replace and make good the same substantially as the same were prior to any such destruction or damage (but not so as to provide accommodation identical in layout and manner or method of construction if it would not be reasonably practical to do so) provided that the Landlord shall not be liable to rebuild or reinstate any part of the Block of which the Demised Premises forms part in respect of which the Landlord is unable (having used all reasonable endeavours) to obtain planning permission, permits and consents necessary to execute such rebuilding and reinstating and in any such case the Landlord shall then be entitled to retain all insurance monies received by the Landlord for its own use and benefit absolutely and the Tenant agrees to surrender this Lease.

(d) If after the commencement of the Term, the Block of which the Demised Premises forms part or any part thereof or any Part of the Park giving access thereto (thus making the Demised Premises inaccessible) shall be destroyed or damaged by any of the Insured Risks or it shall be impossible as a consequence of this to access the Demised Premises so as to render the Demised Premises unfit for occupation or use and the policy or policies of insurance effected by the Landlord shall not have been vitiated or payment of the policy monies refused in whole or in part in consequence of any act or default of the Tenant under the terms hereof the Initial Rent and Service Charge hereby reserved or a fair proportion thereof according to the nature and extent of the damage sustained shall be suspended until the Demised Premises shall have again been rendered fit for occupation or use by the Tenant or until the expiration of three (3) years from the date of damage or destruction whichever is the earlier.

PROVIDED THAT if any question shall arise as to whether the Block or any part thereof (including the Demised Premises) or any necessary means of access thereto shall have been destroyed or damaged by or by any of the Insured Risks so as to interfere with the beneficial occupation thereof or what proportion of the Rent or Service Charge ought to be suspended on account thereof such question shall be referred to an independent surveyor to be nominated by agreement of the Landlord and Tenant and the surveyor’s decision shall be final and binding on the parties hereto. The fees and expenses of the surveyor shall be borne equally by the Tenant and the Landlord.

AND FURTHER PROVIDED THAT if the Block and/or the Demised Premises is not reinstated after three years following its destruction then either the Landlord or the Tenant shall then be entitled to terminate this Lease by written notice given to the other but without prejudice to any claims by either party against the other in respect of any antecedent breach of covenant.

(e) To use all reasonable endeavours to:

i. procure (and keep in full force and effect during the Term) a waiver by the Landlord's insurers of all rights and subrogation as against the Tenant, its servants, agents or invitees or a note of the Tenant's interest on the Landlord's insurance policy, whichever is available;

and

ii. to ensure that the Landlord's insurance policy contains a non-invalidation clause and to notify the Tenant of all material changes in such insurance from time to time during the term of the Lease.

6.3 **Services**

To use all reasonable endeavours to provide the services as set out in Part I and III of the Third Schedule in an efficient and cost effective manner and in accordance with the principles of good estate management.

7. **LANDLORD, AND/OR MANAGEMENT COMPANY COVENANTS**

THE LANDLORD (until the transfer of the Common Areas) **AND THE MANAGEMENT COMPANY** (pursuant to the Management Company Agreement and from the time when the Common Areas and the Retained Parts have been transferred to the Management Company) **HEREBY COVENANTS** with the Tenant to use all reasonable endeavours to provide the services as set out in Part I and Part III of the Third Schedule in an efficient and cost effective manner and in accordance with the principles of good estate management.

8. GUARANTOR'S COVENANTS

The Guarantor **HEREBY COVENANTS** with the Landlord, as a primary obligation, as follows:-

8.1 **Covenant and Indemnity**

That the Tenant or the Guarantor shall at all times during the Term of the Guarantee duly perform and observe all the covenants on the part of the Tenant contained in the Lease, including payment of the Rent and all other sums payable under this Lease in the manner and at the times herein specified and all sums which may be due to the Landlord for the mesne rates or as payment for the use and occupation of the Demised Premises and the Guarantor hereby indemnifies the Landlord against all claims, demands, losses, damages, liability, costs, fees and expenses whatsoever sustained by the Landlord by reason of or arising in any way directly or indirectly out of any default by the Tenant in the performance and observance of any of its obligations or the payment of any rent and other sums arising before or after the expiration or termination of the Lease.

8.2 **Joint and several liability**

That the Guarantor is jointly and severally liable with the Tenant during the Term (whether before or after any disclaimer by a liquidator of the Tenant) for the fulfilment of all the obligations of the Tenant under this Lease and agrees that the Landlord, in the enforcement of its rights hereunder, may proceed during the Term of the Guarantee against the Guarantor as if the Guarantor was named as Tenant in this Lease.

8.3 **Waiver**

That the Guarantor hereby waives any right to require the Landlord to proceed against the Tenant during the Term or to pursue any other remedy whatsoever which may be available to the Landlord before proceeding against the Guarantor during the Term.

8.4 **Postponement of claims**

That during the Term of the Guarantee the Guarantor will not claim in any liquidation, bankruptcy, composition or arrangement of the Tenant in competition with the Landlord and will remit to the Landlord the proceeds of all judgments and all distributions it may receive from any liquidator of the Tenant and will hold for the benefit of the Landlord all security and rights the Guarantor may have over assets of the Tenant whilst any liabilities of the Tenant or the Guarantor to the Landlord remain outstanding.

8.5 **Postponement of participation**

That the Guarantor is not entitled, during the Term of the Guarantee, to participate in any security held by the Landlord in respect of the Tenant's obligations to the Landlord under this Lease or to stand in the place of the Landlord in respect of any such security until all obligations of the Tenant or the Guarantor to the Landlord during the Term under this Lease have been performed or discharged.

8.6 **Release**

That none of the following, or any combination thereof, releases, determines, discharges or in any way lessens or affects the liability of the Guarantor as principal debtor under this Lease or otherwise prejudices or affects the right of the Landlord to recover from the Guarantor to the full extent of this guarantee during the Term:-

8.6.1 any neglect, delay or forbearance of the Landlord in endeavouring to obtain payment of any part of the Rent or the other amounts required to be paid by the Tenant or in enforcing the performance or observance of any of the obligations of the Tenant under this Lease;

8.6.2 any refusal by the Landlord to accept rent tendered by or on behalf of the Tenant at a time when the Landlord was entitled (or would after the service of a notice under section 14 of the Conveyancing Act, 1881 have been entitled) to re-enter the Demised Premises;

8.6.3 any extension of time given by the Landlord to the Tenant;

8.6.4 any variation of the terms of this Lease (including any reviews of the rent payable under this Lease) or the transfer of the Landlord's reversion

8.6.5 any change of the constitution, structure or powers of either the Tenant, the Guarantor or the Landlord or the liquidation or bankruptcy (as the case may be) of either the Tenant of the Guarantor;

8.6.6 any legal limitation, or any immunity, disability or incapacity of the Tenant (whether or not known to the Landlord) or the fact that any dealings with the Landlord by the Tenant may be outside or in excess of the powers of the Tenant;

8.6.7 any other act, omission, matter or thing whatsoever whereby, but for this provision, the Guarantor would be exonerated either wholly or in part (other than a release under seal given by the Landlord**)** and other than as provided for at sub clause 8.10.

8.6.8 Disclaimer or Forfeiture

That if a liquidator or Official Assignee shall disclaim or surrender this Lease or this Lease shall be forfeited or the Tenant shall cease to exist during the Term **THEN** the Guarantor shall during the Term, if the Landlord by notice in writing given to the Guarantor within six months after such disclaimer, or other event so requires, accept from and execute and deliver to the Landlord a new lease of the Demised Premises subject to and with the benefit of this Lease (if same shall still be deemed to be extant at such time) for a term commencing on the date of this disclaimer or other event and continuing for the residue then remaining unexpired of the Term, such new lease to be at the reasonable cost of the Guarantor and to be at the same rents and subject to the same covenants, conditions and provisions as are contained in this Lease;

8.7 If the Landlord does not require the Guarantor to take a new lease, the Guarantor shall nevertheless upon demand pay to the Landlord a sum equal to the Rent and other sums that would have been payable under this Lease during the Term but for the disclaimer, forfeiture or other event in respect of the period from and including the date of such disclaimer, forfeiture or other event until the expiration of twelve months therefrom or until the Landlord has granted a lease of the Demised Premises to a third party (whichever shall first occur).

8.8 **Benefit of Guarantee**

This guarantee enures for the benefit of the successors and assigns of the Landlord under this Lease during the Term without the necessity for any assignment thereof.

8.9 **Jurisdiction**

That the Guarantor will submit to the jurisdiction of the Irish Courts in relation to any proceedings taken against the Guarantor or in relation to any new lease granted as aforesaid.

8.10 **Lapse of Guarantee**

That this guarantee shall automatically lapse and have no further force or effect upon the assignment of this Lease by the Tenant provided the prior consent of the Landlord has been obtained to such assignment and, if required by the Landlord, the Guarantor is replaced by a suitable alternative Guarantor

9. TENANTS BREAK OPTION

9.1 If the Tenant desires to determine the Term at the expiration of the last day of the fifth (5^{th}) year of the Term ("**the Determination Date**") and gives to the Landlord not less than twelve (12) month's prior notice in writing of its intention to so do, such notice to be accompanied by a bank draft payable to the Landlord for a sum equivalent to three (3) month's rent and subject to compliance with the following conditions, it shall be entitled to do so;

9.1.1 it discharging the Rent and all and any other sums due under this Lease duly apportioned up to the Determination Date.

9.1.2 upon the Tenant being in compliance with the material covenants on the Tenant's part and the conditions herein contained up to the Determination Date.

9.1.3 the Tenant discharges, on or prior to the Determination Date, all VAT (if any) arising as a result of the termination of this Lease which the Tenant is the responsible party for in accordance with the VAT Act;

9.1.4 the Tenant delivers up to the Landlord on or before the Determination Date the Demised Premises with vacant possession of the entire thereof;

9.1.5 the Tenant furnishes to the Landlord, on or prior to the Determination Date, evidence of payment of rates payable in respect of the Demised Premises up to the Determination Date;

9.1.6 the Tenant furnishes to the Landlord, on or prior to the Determination Date, the original of this Lease, a duly executed and stamped deed of surrender of this Lease in favour of the Landlord, a duly executed release of any mortgage, charge or encumbrance thereover, evidence of termination of any sub-leases of the Demised Premises, and the originals of any material documents relating to this Lease furnished by the Landlord to the Tenant on the execution of this Lease.

9.2 The Term shall cease on the Determination Date, but without prejudice to the remedies of either the Landlord or the Tenant against the other in respect of any antecedent breach of any of the covenants or conditions contained in this Lease.

9.3 Time shall be of the essence in the performance of the Tenant's obligations under this Clause.

9.4 For the avoidance of doubt, the break option provided for in this Clause 9 is for the sole benefit of Flamel Ireland Limited and shall not be for the benefit of its successors in title or assigns.

10. AND IT IS HEREBY AGREED BETWEEN THE LANDLORD, THE MANAGEMENT COMPANY AND THE TENANT as follows:

10.1 **Warranty**

Nothing herein contained shall be deemed to constitute any warranty by the Landlord that the Demised Premises or any part thereof are authorised under the Planning Acts or otherwise for use for any specific purpose.

10.2 **Notice**

Any notice under this Lease to be served on any party to the Lease shall, in the case of the Tenant, be in writing addressed to its registered office, and in the case of the Landlord be in writing to the Landlord's address listed above, and in the case of the Guarantor be in writing to its registered office of the Tenant any such notice sent by post must be sent under registered cover and shall be deemed to have been served at the expiration of forty eight hours after the time of posting. In proving personal service it shall be sufficient to prove that the envelope containing the notice was duly addressed to the party to be served in accordance with this clause and left at or posted to the place at which it was so addressed.

10.3 **Provisions For Dealing With Disputes**

Save as otherwise herein provided for any dispute or difference arising between the Tenant and other tenants or occupiers of the Block relating to any easement, quasi-easement, right, privilege or conduit in connection with the Demised Premises or the Block shall be fairly and reasonably determined by the Landlord or the Management Company, as the case may be provided always that any easements rights and privileges granted to the Tenant under this Lease shall not be interfered with.

10.4 **Forfeiture**

Without prejudice to any other remedy or power herein contained or available to the Landlord

(a) if the Rent hereby reserved or any part thereof or any other payment hereby reserved shall be unpaid for twenty one (21) days after they become payable (whether formally demanded or not); or

(b) if any covenant on the Tenant's part herein contained shall not in a material way be performed or observed; or

(c) if the Tenant or the Guarantor (being a company) shall enter into liquidation whether compulsory or voluntary (save for the purpose of reconstruction or amalgamation without insolvency) or (not being a company) shall become bankrupt or shall call a meeting of or enter into any composition with creditors or suffer any distress or execution to be levied on the goods of the Tenant

then and in any such case it shall be lawful to re-enter upon the Demised Premises or any part thereof in the name of the whole and thereupon this demise shall absolutely determine but without prejudice to any claim by either the Landlord or the Tenant in respect of any antecedent breach by the other of any covenant or provision herein contained.

10.5 **Governing Law**

This Lease, together with all schedules, covenants and conditions contained herein shall be construed and enforced in accordance with the laws of the Republic of Ireland and the parties hereto submit to the exclusive jurisdiction of the Irish Courts.

Name and address for service of proceedings on the Tenant, the Guarantor and the Landlord:

1. Tenant: Flamel Ireland Limited, Arthur Cox Building, Earlsfort Terrace, Dublin 2.

2. Landlord: Channor Limited, Block 10, Unit 3 Blanchardstown Corporate Park, Blanchardstown, Dublin 15.

3. Guarantor: Flamel Technologies, S.A., 33 avenue du Dr. Georges Levy, 69200 Vénissieux, France

10.6 **Failure By Landlord or Management Company To Provide Services**

The Landlord or the Management Company shall not be liable to the Tenant in respect of any failure by either of them to perform any of the Common Areas Services or the Retained Parts Services referred to in this Lease, whether express or implied, unless and until the Tenant has notified the relevant party of such failure and either the Landlord or the Management Company (as the case may be) has failed within a reasonable time to remedy the same and then in such case either the Landlord or the Management Company (as the case may be) shall (subject to the provisions of Clause 9.7 below) be liable to compensate the Tenant only for actual (but not consequential) loss or damage sustained by the Tenant after such reasonable time has elapsed.

10.7 **Exclusion Of Landlord's and the Management Company's Liability**

The Landlord or the Management Company shall not, in any circumstances, incur any liability for any failure or interruption in any of the services provided by either party or for any inconvenience or injury to person or property arising from such failure or interruption due to mechanical breakdown, failure or malfunction, overhauling, maintenance, repair or replacement, strikes, labour disputes shortages of labour or materials, inclement weather or any cause or circumstance beyond the reasonable control of the Landlord or the Management Company but the Landlord or the Management Company shall use their reasonable endeavours to cause the service in question to be reinstated without delay.

10.8 **Representations**

The Tenant acknowledges that this Lease has not been entered into in reliance wholly or partly on any statement or representation made by or on behalf of the Landlord, except any such statement or representation that is expressly set out in this Lease.

10.9 **No Implied Easements**

Nothing herein contained shall implicitly confer upon or grant to the Tenant any easements rights or privileges other than those expressly granted by this Lease.

10.10 **Covenants Relating To The Units**

Nothing contained in or implied by this Lease shall give to the Tenant the benefit of or the right to enforce or to prevent the release or modification of any covenant, agreement or condition entered into by any tenant of the Landlord in respect of the other Lettable Areas within the Block or the Units.

10.11 **Effect Of Waiver**

Each of the Tenant's covenants shall remain in full force both at law and in equity notwithstanding that the Landlord shall have waived or released temporarily any such covenant, or waived or released temporarily or permanently, revocably or irrevocably a similar covenant or similar covenants affecting other property belonging to the Landlord.

IT IS HEREBY FURTHER CERTIFIED for the purposes of Section 29 of the Companies Act 1990 that the Landlord and the Tenant are not bodies corporate connected with one another in a manner which would require this transaction to be ratified by Resolution of either of them.

AND THE LANDLORD HEREBY ASSENTS to the registration of the within Lease as a burden on Folio 113065F of the Register County Dublin.

IN WITNESS whereof the parties hereto have caused their Common Seal to be affixed and/or have set their hands and affixed their seals as appropriate the day and year first herein written.

FIRST SCHEDULE
The Demised Premises

ALL THAT AND THOSE the premises comprising the property known as the Second Floor, Block 10 Unit 1, Blanchardstown Corporate Park 1, Blanchardstown, Dublin 15 being part of the premises more particularly delineated and outlined in red on Plan "1" annexed hereto, being part of the property comprised in Folio 113065F of the Register of County Dublin.

The Demised Premises shall include:-

1. The floor and ceiling finishes but not any other part of the floor slabs and ceiling slabs that bound the Demised Premises;

2. The inner half served medially of the internal non-loadbearing walls that divide the Demised Premises from any other premises;

3. The interior plaster and decorative finishes of all walls bounding the Demised Premises;

4. The doors and windows and doors and window frames of the Demised Premises;

5. All additions and improvements to the Demised Premises carried out by the Tenant and the Landlord where so required by this Lease;

6. All the Landlord's Fixtures and Fittings and fixtures of any kind that are from time to time in or on the Demised Premises whether originally fixed or fastened to or on the Demised Premises or otherwise, except any fixtures installed by the Tenant that can be removed from the Demised Premises without defacing or causing damage to same;

7. The Conduits and plant in, upon, under or over and exclusively serving the Demised Premises;

together with the exclusive right to use twelve (12) car park spaces identified and coloured yellow on Plan "2" annexed hereto but with the right of the Landlord and/or Management Company to re-locate the said twelve (12) car parking spaces at any time in the Park provided always that the Landlord will give the Tenant at least two weeks advance notice of such re-location and the substituted spaces are no more than 300 metres from the Demised Premises.

SECOND SCHEDULE

Part I

The following rights are granted for the benefit of the Demised Premises;

i. Full right and liberty for the Tenant, its servants, agents and invitees at all times by day or by night, with or without vehicles to go, pass or repass over and along the Common Areas for the purpose of gaining access to and egress from the Demised Premises from and to the public roadway abutting the Park.

ii. Full right and liberty for Tenant its servants, agents and invitees at all times by day or by night to go pass and repass on through over such parts of the Retained Parts as is necessary to gain access to and from the Demised Premises and for the purpose of loading or unloading goods and for the purpose of access to and egress from and for the purpose of repair and maintenance of any plant or equipment exclusively serving the Demised Premises.

iii. The free and uninterrupted passage and running of the Utilities to and from the Demised Premises through the Conduits which are now, or may at any time during the Term be, in, on, under or passing through or over the Reserved Property.

iv. The rights of support and protection for the benefit of the Demised Premises as is now enjoyed from all other parts of the Block.

Part II

Easements Rights and Privileges
Excepted and Reserved out and over the Demised Premises

The following rights and easements are excepted and reserved out of the Demised Premises to the Landlord and tenants and occupiers of the Reserved Property, the Management Company and all other persons authorised by the Landlord or the Management Company or having the like rights and easements:-

1. The free and uninterrupted passage and running of the Utilities through the Conduits which are now, or may at any time during the Term be in, on, under, or passing through or over the Demised Premises.

2. The right at all reasonable times upon giving not less than 48 hours prior written notice, except in cases of emergency, to enter the Demised Premises in order to:-

   2.1 inspect, cleanse, maintain, repair, connect, remove, lay, renew, relay, replace with others, alter or execute any works whatsoever to or in connection with the Conduits and any other Services;

2.2 execute repairs, decorations, alterations and any other works and to make installations to the Demised Premises or, the Retained Parts or to do anything whatsoever which the Landlord may or must do under this Lease.

2.3 see that no unauthorised erections, additions or alteration have been made and that authorised erections, additions and alterations are being carried out in accordance with any consent given herein and any permission or approval granted by the Local Authority.

PROVIDED THAT the Landlord or the person exercising the foregoing rights shall cause as little inconvenience as possible to the Demised Premises and shall make good, without delay, any damage thereby caused to the Demised Premises and the Tenants fixtures and fittings situated therein.

3. The right to erect scaffolding for the purpose of repairing or cleaning the Retained Parts and any building now or hereafter erected on the Reserved Property or in connection with the exercise of any of the rights mentioned in this Schedule notwithstanding that such scaffolding may temporarily interfere with the proper access to or the enjoyment and use of the Demised Premises provided that any damage thereby occasioned shall be made good by the Landlord without delay;

4. The right to erect and maintain signs on the Demised Premises and on the Retained Parts and any premises abutting the same advertising the sale or letting of any part of the Demised Premises for the purpose of planning or other application in respect of the Demised Premises provided that the said signage indicates that the Tenant's occupation is not affected.

5. The rights of light, air, support, protection and shelter and all other easements and rights now or hereafter belonging to or enjoyed by other parts of the Block or the adjoining building.

6. Full right and liberty at any time hereafter to erect any new buildings of any height on the Reserved Property in such a manner as the Landlord or the person exercising the right shall think fit notwithstanding the fact that the same may interfere with the passage of light and air to the Demised Premises but not so that the Tenant’s use and occupation of the Demised Premises is otherwise affected;

7. The right to enter the Demised Premises (in times of emergency or during fire-drills) for the purpose of obtaining access to, or using, any of the fire escapes or routes of escape in the Block whether or not in existence at the date hereof.

8. Full right and liberty at any time to erect build alter extend or redevelop any part of the Park (save for the Block or any part thereof) or any adjoining or adjacent property of the Landlord or the Management Company in such manner as the Landlord or the Management Company may think fit provided there is no material interference with the access of light or air for the time being enjoyed by the Demised Premises or any part thereof and the right of the Landlord or the Management Company to vary or permit the variation of the present or any future scheme, layout or use of the Park including the right to alter the lay-out or extent of the Common Areas and notwithstanding that any such erection, building, alteration, addition or extension or redevelopment may temporarily interfere in a non material manner with the occupation, use, amenity or enjoyment of the Demised Premises subject to any damage thereby occasioned being made good by the Landlord with all convenient speed.

THIRD SCHEDULE
PART I

Maintenance and Services to be provided by the Landlord and/or Management Company in respect of the Common Areas.

1. Repair and Cleaning

As often as may be required to cleanse, repair, renew, maintain and decorate the whole of the Common Areas including the Conduits and the accommodation necessary to house equipment and personnel used for the maintenance, operating and functioning of the Park and all advertising panels and information panels but excluding plant, machinery, apparatus and equipment exclusively serving the Demised Premises or any other Unit in the Park.

2. Repair - Equipment

As often as shall be necessary to maintain, cleanse, repair and renew all electrical, mechanical and other plant equipment, chattels, features, fixtures and fittings or ornament or utility in use in the Common Areas for common benefit, cleaning equipment and the direction and other signs and any fencing or boundary walls in or surrounding the Common Areas.

3. Operate, maintain and renew

To operate, maintain and renew:-

3.1 Fire mains, hydrants and other requisite fire fighting equipment (if any) in relation to the Common Areas.

3.2 Electric services and power installations to the curtilage of the Demised Premises and lighting to all the Common Areas and a sprinkler system (if any) to serve the Common Areas.

3.3 Rainwater outlets and all drainage (save to the extent that the Tenant may be liable therefore under the provisions of the within Lease).

3.4 The insurance (including public liability and employers liability insurance) of the Common Areas (including demolition and site clearance) and of all necessary equipment, plant and machinery of every kind presently or in the future situate thereon against such risks as the Landlord at its sole discretion shall consider necessary.

3.5 Emergency lighting in the Common Areas

3.6 Alarm Systems (if any)

3.7 Television aerials, car park control equipment and neon signs.

4. Personnel

From time to time to provide such agent or agents and/or management personnel for the management of the Park as are necessary and shall pay such agents fees.

5. Rates

To provide for the cost of rates (if any) charged on the Common Areas and any special costs which may be charged by the Local Authority on the Park as a whole.

6. Office Accommodation - Personnel and Equipment

To provide the cost of appropriate accommodation for security staff and personnel (which accommodation will specifically exclude residential accommodation) and the cost of equipment and plant used in providing management and services for the Park and the cost of providing, repairing, renewing and maintaining office accommodation situate in or near the Park and car parking used solely for the purposes of the Park and occupied by the Management Company, its servants or agents.

7. Payment – Personnel

From time to time provide and discharge the costs of wages, pensions, uniforms and insurance for such manager, porter, attendant, security, maintenance, cleaning and other staff (excluding the staff of any tenants in the Park) serving the Park.

8. Benefits - Personnel

To discharge such periodic payments in respect of national health, social welfare, industrial training levies, redundancy and similar or ancillary payments required by statute to be made by the Management Company in respect of all persons from time to time employed by it for purposes connected with the Park.

9. Professional Fees

From time to time to provide for the auditor’s and any surveyor’s fees and on all services provided hereunder.

10. Reserve Fund

The Management Company shall if it is deemed reasonable and prudent to do so, provide for such sinking or reserve fund as the Management Company shall deem fit for the replacement and the renewal of the mechanical, electrical or other equipment in the Park and the Management Company shall have power:

10.1 annually or at such other intervals as the Management Company may determine review the cost or prospective cost of such replacements and renewals with a view to allowing for all such additional or further costs and expenditures as may be attributable to the differential in the value of money or inflationary or other like trends and changing technology as between one date and another, and

10.2 to allow for all such amounts as may be determined on review in computing the contribution from time to time to the sinking or reserve fund provided however that this clause shall not impose upon the Management Company any obligations to provide for or continue to provide for, if already established, such sinking or reserve fund.

PROVIDED ALWAYS that such sinking or reserve fund shall be placed in a separate account and shall be held as trustee by the Management Company for the benefit of the tenants of the Park.

11. Common Areas and the Park

To provide for the cost and expense of repairing, maintaining, renewing and rebuilding any part of the Common Areas of the Park to the extent that such is not wholly reimbursed by the Tenant or any other tenant of the Landlord or by any third party.

11.1 To provide for the cost of repairing, maintaining and renewing any sprinkler, intruder alarm, fire alarm, and any closed circuit T.V. system.

11.2 To provide for the cost of operating, repairing, maintaining and renewing the machinery and all electrical, mechanical and other plant, machinery, apparatus and equipment, chattels, features and fittings of ornament or utility in use in the Common Areas for the common benefit of the Tenant and the occupiers of the Park.

12. Finance

To make provision for the cost of financing the maintenance and services specified in this Schedule.

12.1 To make provision for such reasonable expenses of a periodic or recurring nature as the Landlord and/or Management Company shall think fit together with a reasonable provision for forecast expenditure.

12.2 To provide for the cost of providing such further services as are in the reasonable opinion of the Landlord and/or Management Company acting in accordance with the principles of good estate management, necessary for the comfort and convenience of the Tenant or the tenants as occupiers of the Park generally and their customers or for the amenity of the Park.

THIRD SCHEDULE
PART II

The Tenant's Liability to Contribute to the Common Areas Service Charge

1. Payment dates

The Tenant's Proportion of the Common Areas Service Charge for each Service Charge Period shall be discharged by means of equal quarterly payments in advance to be made on the Instalment Days in each year of the Term or on such date on which a demand therefore is made (whichever shall be the earlier date) and by such additional payments as maybe required under Clauses 3 and 7 of this Part II of this Schedule.

2. Service Charge Period

For the purposes of this Part II of this Schedule, "Service Charge Period" means the period of twelve months from 1st January to 31st December in each year (or such other period not exceeding twelve (12) months as the Landlord and/or the Management Company may from time to time determine).

3. Advance Payments

Subject to Clause 4 of this Part II of this Schedule and subject also as hereinafter set out, the amount of each advance payment of the Common Areas Service Charge shall be one quarter of such amount as the Management Company may reasonably estimate to be the Tenant's Proportion of the Common Areas Service Charge for the relevant Service Charge Period and which is notified to the Tenant at or before the time when the demand for an advance payment is made or such payment falls due, **PROVIDED HOWEVER** that in the event of the Gross Internal Floor Area of any of the Blocks or Lettable Areas of the Units being added to, extended or redeveloped from time to time during the Term, the Tenant's Proportion of the Common Areas Service Charge payable by the Tenant during the relevant Service Charge Period and, if necessary, the estimate of the amount of the Common Areas Service Charge for the current Service Charge Period, shall be amended on the Instalment Day (or on such date on which a demand therefore is made whichever shall be the later date) next ensuing and the Tenant shall pay on the remaining Instalment Days of such Service Charge Period such sums as the Management Company shall certify to be necessary to ensure that the Tenant pays the Tenant's Proportion of the revised Common Areas Service Charge for the relevant Service Charge Period.

4. Daily rate of calculation

The Common Areas Service Charge shall be deemed to accrue on a day-to-day basis in order to ascertain yearly rates and for the purposes of apportionment in relation to periods other than a Service Charge Period. In the event that this Lease shall commence on a day which is not one of the Instalment Days, then the Tenant's Proportion of the Common Areas Service Charge shall be the apportioned amount of the Tenant's Proportion of the Common Areas Service Charge due up to the next Instalment Day and thereafter the provisions of Clause 3 of this Part II of this Schedule shall apply.

5. Service cost Statement

5.1 The Management Company as soon as practicable after the end of each Service Charge Period shall submit to the Tenant the Management Company's service cost statement duly audited and certified by the Management Company's auditors (acting as an expert and not an arbitrator). Such service cost statement shall be prepared on an accruals basis and shall inter alia disclose:-

5.1.1 the total expenditure for the Service Charge Period ended itemised under the various heads of expense; and

5.1.2 the balancing payment or allowance due from or credited to the Tenant as the case may be.

6. Balancing Adjustment

If the Tenant's Proportion (expressed as a cash amount) of the Common Areas Service Charge as certified shall be more or less than the total of the advance payments referred to in Clause 3 of this Part II of this Schedule above, then any sum due to or allowable by the Management Company in respect of the Tenant's Proportion of the Common Areas Service Charge for the relevant Service Charge Period shall forthwith be paid or allowed as the case may be.

7. Exceptional Costs

In the event that the Management Company at any time during any Service Charge Period incurs heavy exceptional expenditure which forms part of the Common Areas Service Charge, the Management Company shall be entitled to recover from the Tenant the Tenant's Proportion of the Common Areas Service Charge representing the whole of that expenditure on the Instalment Day next following.

8. Claims by third parties in respect of loss or damage in or about the Common Areas:

8.1 The Management Company shall be entitled to include in the Common Areas Service Charge any payments properly made to third parties in settlement of any claims by such third parties in respect of any loss or damage sustained by the same in or about the Common Areas to the extent that such claims are not recovered under any policy of insurance effected by the Management Company on either of the following grounds:-

8.1.1 by reason of the fact that the amount claimed by any third party falls within the excess amount stipulated on the relevant insurance policy; or

8.1.2 by reason of the fact that the cost in terms of any consequential increase for the future in the premium payable on foot of the relevant policy that will cover any such payments from the relevant policy would in the sole opinion of the Management Company exceed the amount necessary to settle such claims.

8.2 Notwithstanding any provision to the contrary contained in this Lease, the Common Areas Service Charge shall include the cost of Common Areas Services in respect of any matter which is either wholly or partly covered by insurance effected by the Landlord and/or the Management Company in respect of the Park including the Common Areas PROVIDED ALWAYS that if and when the proceeds of any such insurance are received by the Landlord or the Management Company as the case may be the relevant proportion thereof shall be deducted from the Tenant's Proportion of the Common Areas Service Charge payable by the Tenant on the Instalment Day next following.

9. Restrictions on objections to Common Areas Service Charge:

The service cost statement described in Clause 5 of this Part II of this Schedule shall be conclusive evidence for the purpose hereof of the matters which it purports to certify save in the case of manifest error.

10. Sinking Fund and Reserve:

In the event that a sinking fund is established pursuant to Clause 10 of Part I of this Schedule, the Management Company shall be entitled to include in the Common Areas Service Charge for any Service Charge Period an amount which the Management Company reasonably determines is appropriate to build up and maintain such sinking fund.

11. Service Charge Exclusions

There shall be excluded from the items comprised in the Common Areas Service Charge any liability or expense for which the Landlord, the Tenant or other tenants or occupiers of Units shall individually be responsible, any liability in respect of vacant Units and any arrears of service charge due and owing from any other tenant or occupier of any part of the Park.

12. Management Charges:

The Management Company shall be entitled to include in the Common Areas Service Charge a reasonable fee for the provision of the Common Area Services and any cost of the Management Company's auditors for auditing the Common Areas Service Charge or providing other services in connection with the Common Areas Service Charge.

THIRD SCHEDULE
PART III

Maintenance and services to be provided by the Landlord and/or the Management Company in relation to the Retained Parts.

1. Whenever the Landlord regards it as necessary to cleanse, tidy renew, repair, maintain, replace or decorate the Retained Parts in good substantial repair and condition.

2. Supplying hot and cold water to any lavatory facilities in the Retained Parts.

3. Providing reasonable heating and lighting in the Retained Parts and providing air conditioning to the Retained Parts (if applicable).

4. Discharging all existing or future rates, taxes, duties, charges, assessments, outgoings and impositions levied in relation to the Retained Parts.

5. Inspecting, and maintaining in good working order and where necessary overhauling, decorating, redecorating, cleaning, treating, replacing, renewing and operating the plant and equipment and the Conduits is so far as they relate to the Retained Parts.

6. The Landlord shall if it is deemed reasonable and prudent to do so, provide for such sinking or reserve fund as the Landlord shall deem fit for the replacement and the renewal of the Retained Parts and the Landlord shall have power:

   6.1 annually or at such other intervals as the Landlord may determine review the cost or prospective cost of such replacements and renewals with a view to allowing for all such additional or further costs and expenditures as may be attributable to the differential in the value of money or inflationary or other like trends and changing technology as between one date and another, and

   6.2 to allow for all such amounts as may be determined on review in computing the contribution from time to time to the sinking or reserve fund provided however that this clause shall not impose upon the Landlord any obligations to provide for or continue to provide for, if already established, such sinking or reserve fund.

THIRD SCHEDULE
PART IV

The Tenant's Liability to Contribute to the Retained Parts Service Charge

1. Payment dates:

The Tenant's Proportion of the Retained Parts Service Charge for each Service Charge Period shall be discharged by means of equal quarterly payments in advance to be made on the Instalment Days in each year of the Term or on such date on which a demand therefore is made (whichever shall be the earlier date) and by such additional payments as maybe required under Clauses 3 and 7 of this Part IV of this Schedule.

2. Service Charge Period:

For the purposes of this Part IV of this Schedule, "Service Charge Period" means the period of twelve months from 1st January to 31st December in each year (or such other period not exceeding twelve (12) months as the Landlord may from time to time determine).

3. Advance Payments:

Subject to Clause 4 of this Part IV of this Schedule and subject also as hereinafter set out, the amount of each advance payment of the Retained Parts Service Charge shall be one quarter of such amount as the Landlord may reasonably estimate to be the Tenant's Proportion of the Retained Parts Service Charge for the relevant Service Charge Period and which is notified to the Tenant at or before the time when the demand for an advance payment is made or such payment falls due, **PROVIDED HOWEVER** that in the event of the Gross Internal Floor Area of any of the Lettable Areas within the Block being added to, extended or redeveloped from time to time during the Term, the Tenant's Proportion of the Retained Parts Service Charge payable by the Tenant during the relevant Service Charge Period and, if necessary, the estimate of the amount of the Retained Parts Service Charge for the current Service Charge Period, shall be amended on the Instalment Day (or on such date on which a demand therefore is made whichever shall be the later date) next ensuing and the Tenant shall pay on the remaining Instalment Days of such Service Charge Period such sums as the Landlord shall certify to be necessary to ensure that the Tenant pays the Tenant's Proportion of the revised Retained Parts Service Charge for the relevant Service Charge Period.

4. Daily rate of calculation:

The Retained Parts Service Charge shall be deemed to accrue on a day-to-day basis in order to ascertain yearly rates and for the purposes of apportionment in relation to periods other than a Service Charge Period. In the event that this Lease shall commence on a day which is not one of the Instalment Days, then the Tenant's Proportion of the Retained Parts Service Charge shall be the apportioned amount of the Tenant's Proportion of the Retained Parts Service Charge due up to the next Instalment Day and thereafter the provisions of Clause 3 of this Part IV of this Schedule shall apply.

5. Service cost Statement:

5.1 The Landlord as soon as practicable after the end of each Service Charge Period shall submit to the Tenant the Landlord's statement duly audited and certified by the Landlord's auditors (acting as an expert and not an arbitrator). Such service cost statement shall be prepared on an accruals basis and shall inter alia disclose:-

5.1.1 the total expenditure for the Service Charge Period ended itemised under the various heads of expense; and

5.1.2 the balancing payment or allowance due from or credited to the Tenant as the case may be.

6. Balancing Adjustment:

If the Tenant's Proportion (expressed as a cash amount) of the Retained Parts Service Charge as certified shall be more or less than the total of the advance payments referred to in Clause 3 of this Part IV of this Schedule above, then any sum due to or allowable by the Landlord in respect of the Tenant's Proportion of the Retained Parts Service Charge for the relevant Service Charge Period shall forthwith be paid or allowed as the case may be.

7. Exceptional Costs:

In the event that the Landlord at any time during any Service Charge Period incurs heavy exceptional expenditure which forms part of the Retained Parts Service Charge, the Landlord shall be entitled to recover from the Tenant the Tenant's Proportion of the Retained Parts Service Charge representing the whole of that expenditure on the Instalment Day next following.

8. Claims by third parties in respect of loss or damage in or about the Retained Parts:

8.1 The Landlord shall be entitled to include in the Retained Parts Service Charge any payments properly made to third parties in settlement of any claims by such third parties in respect of any loss or damage sustained by the same in or about the Retained Parts to the extent that such claims are not recovered under any policy of insurance effected by the Landlord on either of the following grounds:-

8.1.1 by reason of the fact that the amount claimed by any third party falls within the excess amount stipulated on the relevant insurance policy; or

8.1.2 by reason of the fact that the cost in terms of any consequential increase for the future in the premium payable on foot of the relevant policy that will cover any such payments from the relevant policy would in the sole opinion of the Landlord exceed the amount necessary to settle such claims.

8.2 Notwithstanding any provision to the contrary contained in this Lease, the Retained Parts Service Charge shall include the cost of Retained Parts Services in respect of any matter which is either wholly or partly covered by insurance effected by the Landlord in respect of the Block **PROVIDED ALWAYS** that if and when the proceeds of any such insurance are received by the Landlord as the case may be the relevant proportion thereof shall be deducted from the Tenant's Proportion of the Retained Parts Service Charge payable by the Tenant on the Instalment Day next following.

9. Restrictions on objections to Retained Parts Service Charge:

The service cost Statement described in Clause 5 of this Part IV of this Schedule shall be conclusive evidence for the purpose hereof of the matters which it purports to certify save in the case of manifest error.

10. Sinking Fund and Reserve:

In the event that a sinking fund is established pursuant to Clause 6 of Part III of the this Schedule, the Landlord shall be entitled to include in the Retained Parts Service Charge for any Service Charge Period an amount which the Landlord reasonably determines is appropriate to build up and maintain such sinking fund.

11. Service Charge Exclusions:

There shall be excluded from the items comprised in the Retained Parts Service Charge any liability or expense for which the Landlord, the Tenant or other tenants or occupiers of Units in the Block shall individually be responsible, any liability in respect of vacant Units and any arrears of service charge due and owing from any other tenant or occupier of any part of the Park.

12. Management Charges:

The Landlord shall be entitled to include in the Retained Parts Service Charge a reasonable fee for the provision of the Retained Parts Services and any cost of the Landlord's auditors for auditing the Retained Parts Service Charge or providing other services in connection with the Retained Parts Service Charge.

FOURTH SCHEDULE
Provisions for Rent Review

1. **Definitions**

In this Schedule, the following expressions shall have the following meanings:-

1.1 **Review Date** means the Review Date specified in Clause 2 herein;

1.2 **Open Market Rent** means the full open market rent without any deductions whatsoever at which the Demised Premises might reasonably be expected to be let in the open market with vacant possession at the Review Date by a willing landlord to a willing tenant and without any premium or any other consideration for the grant thereof for a term equal to the Term, subject to break options at the intervals provided for in this Lease and on the same terms and conditions and subject to the same covenants and provisions contained in this Lease (other than the amount of the Rent payable hereunder but including these provisions for the review of rent) and having regard to other open market rental values current at the Review Date in so far as the Surveyor (as defined in Clause 1.5 of this Schedule) may deem same to be pertinent to the matters under consideration by him and making the Assumptions but disregarding the Disregarded Matters;

1.3 the **Assumptions** mean the following assumptions (if not facts) at the Review Date:-

1.3.1 that the Demised Premises are ready and available for immediate occupation and use by the Tenant and may be lawfully used by any person for the Permitted User;

1.3.2 that no work has been carried out to the Demised Premises by the Tenant, any undertenant or their respective predecessors in title during the Term, which has diminished the rental value of the Demised Premises;

1.3.3 that if the Demised Premises or any part or parts thereof have been destroyed or damaged, they have been fully rebuilt and reinstated;

1.3.4 that the Demised Premises are in a good state of repair and decorative condition;

1.3.5 that all the covenants on the part of the Tenant contained in this Lease have been fully performed and observed;

1.3.6 that the Initial Rent paid pursuant to this Lease is eighty one thousand euros (€81,000.00) per annum (exclusive of VAT, which is payable).

1.4 the **Disregarded Matters** mean:-

1.4.1 any effect on rent of the fact that the Tenant, any permitted undertenant or their respective predecessors in title have been in occupation of the Demised Premises or any part thereof or of the terms of any sub lease permitted in accordance with the provisions of Clause 5.20.4;

1.4.2 any goodwill attaching to the Demised Premises by reason of the business then carried on at the Demised Premises by the Tenant or any permitted undertenant;

1.4.3 any increase in rental value of the Demised Premises attributable to the existence at the Review Date, of any works (otherwise than in pursuance of an obligation under this Lease or any agreement therefore) executed by and at the expense of the Tenant (or any party lawfully occupying the Demised Premises under the Tenant) with the consent of the Landlord (where required under this Lease) in on or to the Demised Premises or any part thereof;

1.4.4 any rent free concession, reduced rent or other inducement which would or might be given to an incoming tenant on the grant of a lease of the Demised Premises at the Review Date to the intent that no reduction shall be made in ascertaining the Open Market Rent to reflect such rent free concession, reduced rent or other inducement to compensate the Tenant for the absence thereof.

1.5 the **Surveyor** means an independent chartered surveyor who is experienced in the valuation and leasing of property similar to the Demised Premises and is acquainted with the market in the area in which the Demised Premises are located, appointed from time to time to determine the Open Market Rent pursuant to the provisions of this Schedule;

1.6 the **President** means the President for the time being of the Society of Chartered Surveyors and includes the Vice-President or any person authorised by the President to make appointments on his behalf;

1.7 **Rent Restrictions** means the restrictions imposed by any statute for the control of rent in force on a Review Date or on the date on which any reviewed rent is ascertained in accordance with this Schedule and which operate to impose any limitation, whether in time or amount, on the collection of an increase in the rent first reserved by this Lease or any part thereof.

2. **Rent review**

The Initial Rent shall be reviewed on the first day of the sixth (6^{th}) year of the Term (the "**Review Date**") in accordance with the provisions of this Schedule and, from and including the Review Date, the Rent shall be either the Rent contractually payable immediately before the Review Date or the Open Market Rent on the Review Date, as agreed or determined pursuant to the provisions of this Schedule.

3. **Agreement or determination of the reviewed rent**

The Open Market Rent at the Review Date may be agreed in writing at any time between the Landlord and the Tenant but if, for any reason, they have not so agreed by the Review Date, either party may (whether before or after the Review Date) by notice in writing to the other require the Open Market Rent to be determined by the Surveyor.

4. **Appointment of Surveyor**

In default of agreement between the Landlord and the Tenant on the appointment of the Surveyor, the Surveyor shall be appointed by the President on the written application of either party, such application to be made not earlier than twelve (12) months before and not later than twelve (12) months after the Review Date.

5. Functions of the Surveyor: The Surveyor shall:-

5.1 at the option of the Landlord act either as an arbitrator in accordance with the Arbitration Act, 2010 or as an expert, such option to be exercised by the Landlord giving written notice to the President at the time of the Landlord's written application to the President or, if application is made by the Tenant, then within seven (7) days of the Landlord being notified of the appointment of the Surveyor but if no written notice is given by the Landlord as aforesaid, the Surveyor shall act as an arbitrator;

5.2 (if acting as an expert) invite the Landlord and the Tenant to submit to him, within such time limits (not being less than fifteen (15) Business days) as he shall consider appropriate, a valuation accompanied, if desired, by a statement of reasons and such representations and cross - representations as to the amount of the Open Market Rent with such supporting evidence as they may respectively wish;

5.3 within sixty (60) days of his appointment, or within such extended period as the Landlord and the Tenant shall jointly agree in writing, give to each of them written notice of the amount of the Open Market Rent as determined by him.

6. **Fees of Surveyor**

The fees and expenses of the Surveyor (if acting as an expert), including the costs of his nomination, shall be in the award of the Surveyor (but this shall not preclude the Surveyor from notifying both parties of his total fees and expenses notwithstanding the non-publication at that time of his award) and, failing such award, the same shall be payable by the Landlord and the Tenant in equal shares who shall each bear their own costs, fees and expenses. Without prejudice to the foregoing, both the Landlord and the Tenant shall each be entitled to pay the entire fees and expenses, due to the Surveyor and thereafter recover as a simple contract debt the amount (if any) due from the party who failed or refused to pay same.

7. **Appointment of new Surveyor**

If the Surveyor fails to give notice of his determination within the time aforesaid, or if he dies, or is unwilling to act, or becomes incapable of acting, or if, for any other reason, he is unable to act, either party may request the President to discharge the Surveyor and appoint another surveyor in his place to act in the same capacity, which procedure may be repeated as many times as necessary.

8. **Interim payments pending determination**

In the event that by the Review Date the amount of the reviewed rent has not been agreed or determined as aforesaid (the date of agreement or determination being herein called "**the Determination Date**") then, in respect of the period (herein called "**the Interim Period**") beginning with the Review Date and ending on the day before the Quarterly Instalment Day following the Determination Date:

8.1 the Tenant shall pay to the Landlord Rent at the yearly rate payable immediately before the Review Date, and within twenty one days of the Determination Date, the Tenant shall pay to the Landlord, as arrears of rent, the amount (if any) by which the reviewed rent exceeds the Rent actually paid during the Interim Period (apportioned on a daily basis) together with interest thereon at the Base Rate from the Review Date to the date of actual payment; or

8.2 the Landlord shall pay to the Tenant within twenty one days of the Determination Date the amount by which the reviewed rent is less than the Rent actually paid by the Tenant during the Interim Period (apportioned on a daily basis) together with interest thereon at the Base Rate from the Review Date to the date of actual payment.

9. **Rent Restrictions**

On each and every occasion during the Term that Rent Restrictions shall be in force, then and in each and every case:

9.1 the operation of the provisions herein for review of the Rent shall be postponed to take effect on the first date or dates thereafter upon which such operation may occur, and

9.2 the collection of any increase or increases in the Rent shall be postponed to take effect on the first date or dates thereafter that such increase or increases may be collected and/or retained in whole or in part and on as many occasions as shall be required to ensure the collection of the whole increase

AND until the Rent Restrictions shall be relaxed either partially or wholly the rent reserved by this Lease (which if previously reviewed shall be the rent payable under this Lease immediately prior to the imposition of the Rent Restrictions) shall (subject always to any provision to the contrary appearing in the Rent Restrictions) be the maximum Rent from time to time payable hereunder.

10. **Memoranda of reviewed rent**

As soon as the amount of any reviewed rent has been agreed or determined, memoranda thereof shall be prepared by the Landlord or its solicitors and thereupon shall be signed by or on behalf of the Tenant and the Landlord, and the Tenant shall be responsible for and shall pay to the Landlord the stamp duty (if any) payable on such memoranda and any counterparts thereof but the parties shall each bear their own costs in respect thereof.

11. **Time not of the essence**

For the purpose of this Schedule, time shall not be of the essence.

FIFTH SCHEDULE

Photographic schedule of condition and Landlord's Fixtures and Fittings

- Raised access floors.
- Suspended ceilings
- Cat 2 recessed strip lighting
- 3 phase power in a stand-alone Power Distribution Board (PBC)
- Fully finished bathrooms
- Access control and intercom
- Front and rear access

SIXTH SCHEDULE

Plan (re: Yield Up Obligations)

PRESENT when the Common Seal of
CHANNOR LIMITED was affixed hereto:-

PRESENT when the Common Seal of
BLANCHARDSTOWN CORPORATE PARK MANAGEMENT LIMITED
was affixed hereto:-

GIVEN under the **COMMON SEAL**
of **FLAMEL IRELAND LIMITED**
and **DELIVERED** as a **DEED**:-

/s/ Ross Gorman
Director

/s/ Michael S. Anderson
Director

FLAMEL TECHNOLOGIES S.A.
Executed by Michael S. Anderson
In his capacity as General Manager (*Directeur Général*)

DATED THE DAY OF 2015

Channor Limited
First Part

Blanchardstown Corporate Park Management Limited
Second Part

Flamel Ireland Limited
Third Part

Flamel Technologies S.A.
Fourth Part

LEASE

AMOSS Solicitors
26 Burlington Road
Ballsbridge
Dublin 4

Exhibit 10.18

EXECUTION COPY

EMPLOYMENT
AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "*Agreement*") is entered into as of the 8th of July, 2015, with the employment to which it pertains beginning on 29th of June , 2015 (the "*Effective Date*"), by and among Sandra Hatten ("*Executive*"), a citizen of the United States currently residing at 546 Donne Avenue, University City, MO 63130; FLAMEL TECHNOLOGIES SA, a French Societe Anonyme with a principal office located at 33, avenue du Dr. Georges Levy, Parc Club du Moulin a Vent, 69200 Venissieux, France ("*Flamel*"); and ECLAT PHARMACEUTICALS, LLC, a Delaware limited liability company and affiliate of the Company with a principal office located at 702 Spirit 40 Park Drive, Suite 108, Chesterfield, MO 63005 ("*Eclat*") together with Flamel (the "*Company*").

WITNESSETH

WHEREAS, Executive is a citizen of the United States and a resident of the State of Missouri; and

WHEREAS, the Company desires to employ Executive as its Senior Vice President, Quality and Regulatory Affairs; and

WHEREAS, Executive desires to accept such employment with the Company on the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. Executive shall act as Senior Vice President, Quality and Regulatory Affairs for the Company and shall carry out such work reasonably required by the Company in the course of its business consistent with this position. Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, MO), but shall also travel to and work from the Company's offices in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of Executive's business hours to the Company, and during such time will make the best use of Executive's energy, knowledge, and training, to advancing the Company's interests. The Executive will accept no other employment during his employment with the Company.

(b) Reporting. In her capacity as Senior Vice President, Quality and Regulatory Affairs for the Company, Executive shall report directly to the Chief Executive Officer, currently Michael S. Anderson.

(c) Confidentiality.

(i) (A) To the fullest extent under applicable law, Executive agrees at all times during the term of this Agreement and for a period of five (5) years after termination of this Agreement, and any applicable extensions thereof, to hold in strictest confidence, and not to use, except for the benefit of the Company to the extent necessary to perform his obligations to the Company under this Agreement, and not to disclose to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer, General Counsel or Board of Directors of the Company, any confidential information of the Company that Executive obtains or creates. Any breach of this obligation will be considered a material breach of this Agreement.

(B) For the avoidance of doubt, confidential information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by Executive in violation of the provisions hereof; or (3) was already in the possession of Executive without an obligation of confidentiality prior to becoming a party to this Agreement.

(d) Non-Disparagement. Executive agrees not to disparage or otherwise refer to Company, its Executives, officers or directors in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (e.g., e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of Employment and any benefits paid hereunder. Company, together with its executives, officers and directors, agrees not to disparage or otherwise refer to Executive in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (e.g., e-mail, Twitter, Facebook, etc).

(e) Non-Solicitation. For a period of one (1) year after the termination of this Agreement or Executive's employment with the Company, Executive will not directly or indirectly solicit any Company employee to perform services for the Executive or for any other business or entity, whether as an Executive, consultant, partner or participant in any such business or entity. This Section 1.1(e) shall cease to be applicable to any activity of the Executive from and after such time as the Company has ceased all business activities or has made a decision to cease all business activities.

1.2 Status. For as long as she remains an Executive of the Company, Executive's employment shall be governed by the laws of the United States and the State of Missouri to the fullest extent permitted by law. It is the intent of the parties that at all times during Executive's employment with the Company, she will remain a citizen of the United States.

1.3 Duration. This term of this Agreement shall be one (1) year, beginning on the Effective Date, with the Agreement automatically renewing for successive one (1) year periods, unless Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, Executive's employment with the Company shall terminate simultaneously.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to Executive a gross annual base salary of Two Hundred Ninety-Two Thousand Dollars ($292,000) per year payable in accordance with the Company's normal payroll practices as are in effect from time to time. The Company will review the base salary on or about the first of every year, and in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for an annual bonus of up to forty percent (40%) of Executive's base salary. Payment of the annual bonus will be based upon Executive's achievement of certain business and individual performance objectives as well as the Company's performance against the Company's objectives.

2.3 Stock Option.

(a) Grant of Options. Upon approval of the Board of Directors, the Company shall grant to Executive the option ("Option") to purchase One Hundred Thousand (100,000) shares of the Company's common stock ("Option Shares ") in accordance with this Section 2.3 and the Company's stock option plan (or other applicable plan), to the extent that such plan is not contrary to this Agreement.

(b) Vesting. Executive shall vest in the Option Shares in accordance with the Company's approved vesting schedule in accordance with the stock option plan (or other applicable plan).

(c) Exercise of Option. The Option may be exercised as set forth in the Company's stock option plan (or other applicable plan). All shares of the Company's common stock issuable upon the exercise of the Option shall, when issued, be validly issued, fully paid and non-assessable.

2.4 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate Executive's and his family's participation in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established. Executive acknowledges that the current insurance plans are offered through Eclat and are subject to reasonable changes at the business discretion of the Company and/or Eclat. At Employee's discretion, in lieu of her and her family's participation in the Company's Plan, Company shall be reimburse Employee for Employee's and her family's participation in a similar or like Company Plan, including but not limited to COBRA participation in Employee's former insurance plan or program.

(b) Vacation and Paid Time Off. Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other Executives at similar levels of authority (currently fifteen (15) days). Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at Executive's discretion.

(c) Indemnification: General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by her under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of Executive 's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to Executive the costs of defending any claim, suit, or action against her if she undertakes to repay the funds advanced, with interest, should it later be determined that s he is not entitled to indemnification under this Section 2.4(c).

(ii) The Company shall provide coverage to Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of Executive or plea to a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by Executive of any asset or property of the Company, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach of any of the material obligations contained in this Agreement; (iv) conduct by Executive materially contrary to the material policies of the Company; (v) material failure by Executive to meet the goals and objectives established by the Company; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to her regarding such failure; or (vi) conduct by Executive that results in a material detriment to the Company, its program, or goals or is inimical to the Company's reputation and interests; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to her regarding such conduct. Any reoccurrence of such acts constituting Good Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) Executive may terminate Executive's employment with the Company with or without "Good Reason". "Good Reason" means: (i) the failure of the Company to timely pay to the Executive any compensation owed to her under this Agreement; (ii) the Company's diminution in the Executive's duties in any material respect or the Company's assignment to the Executive of duties that are materially inconsistent with the duties stated in this Agreement; (iii) the relocation of the Company's offices of the Executive's employment more than sixty (60) miles outside the greater St. Louis metropolitan area; (iv) a material breach by the Company of this Agreement; (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of the Company.

(c) In the event that Executive desires to resign from the Company, she shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. Any reoccurrence of such acts constituting Good Reason within one (1) year of the original occurrence will require no such pre-termination right of the Company to cure.

(d) In the event that the Company desires to terminate Executive's employment, with or without Cause, the Company shall promptly give Executive written notice of the date that such termination will be effective, provided that the notice period shall be no less than thirty (30) days.

3.2 **Severance**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, the Company shall pay to Executive a severance indemnity of: (i) severance pay equal to Executive's then-current annual base salary, paid in continuous payments in accordance with the Company's normal payroll practices for a period of twelve (12) months; and (ii) all accrued but unpaid vacation, expense reimbursement, wages and other benefits due to Executive under any Company provided plans, policies and arrangements; and (iii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company will pay for Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to Executive's termination) until the earlier of: (A) a period of twelve (12) months from the date of termination or (B) the date upon which Executive becomes covered under similar plans. Executive's receipt of the Severance Indemnity is conditioned upon his and the Company's execution of a reasonable settlement agreement governing the termination of the employment relationship between Executive and the Company. All payments set forth in this Section 3.2(i), (ii) and (iii) are defined as (the "Severance Indemnity").

3.3 **Change of Control**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period, the Company shall pay to Executive a change of control indemnity of: (i) the Severance Indemnity as defined in Section 3.2; and (ii) a lump-sum payment equal to one hundred percent (100%) of the higher of: (A) the greater of (x) Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (y) Executive's target bonus as in effect for the fiscal year in which Executive's termination of employment occurs; or (B) Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs. For avoidance of doubt, the amount paid to Executive pursuant to this Section 3.3 will not be prorated based on the actual amount of time Executive is employed by the Company during the fiscal year (or the relevant performance period if something different than a fiscal year) during which this termination occurs; and (iii) one hundred percent (100%) of Executive's outstanding and unvested Option Shares will become vested in full. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments set forth in this Section 3.3 (i), (ii) and (iii) defined as (the "Change of Control Indemnity").

3.4 **Change of Control Definitions**. For purposes of Section 3.3 above, the following definitions shall apply: (a) "Change of Control" means the occurrence of any of the following events: (i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change or Control; or (ii) A change in the effective control of the Company which occurs on the date that a majority of the members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change of Control; or (iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions.

(b) "*Change of Control Period*" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

4. MISCELLANEOUS

4.1 **Entire Agreement**. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements, either oral or in writing, among the parties with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof.

4.2 **Severability**. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

4.3 **Survival**. Notwithstanding expiration or termination of this Agreement, Sections l.1(c), 1.1(d), 2.3, 2.4(c), Section 3 and Section 4 shall survive such expiration or termination.

4.4 **Interpretation of Agreement**.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated fully in the negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

4.5 **Taxes**. The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A. Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law.

4.6 **Governing Law**. Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

4.7 **Binding Arbitration**.

(a) All disputes arising under this Agreement or arising out of or relating to Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association. Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct American Arbitration Association ("AAA") arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover his or its reasonable costs and attorneys' fees associated with the arbitration. The non-prevailing party shall be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

4.8 **Amendments**. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

4.9 **Binding Effect**. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

4.10 **No Assignment**.

(a) This Agreement and all of Executive's rights and obligations hereunder are personal to Executive and may not be transferred or assigned by her at any time, except that any assets accruing to Executive in connection with this Agreement shall accrue to the benefit of Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

4.11 **Waiver**. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

4.12 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date and year first above written.

THE COMPANY

FLAMEL TECHNOLOGIES SA

By: /s/ Phil Thompson
Name: Phil Thompson
Title: Sr. Vice President, General Counsel

ECLAT PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

EXECUTIVE

By: /s/ Sandy Hatten
Name: Sandy Hatten
Title: SR VP Quality and Reaffairs

Exhibit 10.19

EXECUTION COPY

EMPLOYMENT
AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "*Agreement*") is entered into as of the 7th of July, 2015, with the employment to which it pertains beginning on 25th of November, 2013 (the "*Effective Date*"), by and among Phillandas T. Thompson ("*Executive*"), a citizen of the United States currently residing at 16329 Justus Post Road, Chesterfield, MO 63017; FLAMEL TECHNOLOGIES SA, a French Societe Anonyme with a principal office located at 33, avenue du Dr. Georges Levy, Parc Club du Moulin a Vent, 69200 Venissieux, France ("*Flamel*"); and ECLAT PHARMACEUTICALS, LLC, a Delaware limited liability company and affiliate of the Company with a principal office located at 702 Spirit 40 Park Drive, Suite 108, Chesterfield, MO 63005 ("*Eclat*") together with Flamel (the "*Company*").

WITNESSETH

WHEREAS, Executive is a citizen of the United States and a resident of the State of Missouri; and

WHEREAS, the Company desires to employ Executive as its Senior Vice President, General Counsel and Corporate Secretary; and

WHEREAS, Executive desires to accept such employment with the Company on the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Position at the Company. Executive shall act as Senior Vice President, General Counsel and Corporate Secretary for the Company and shall carry out such work reasonably required by the Company in the course of its business consistent with this position. Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, MO), but shall also travel to and work from the Company's offices in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of Executive's business hours to the Company, and during such time will make the best use of Executive's energy, knowledge, and training, to advancing the Company's interests. The Executive will accept no other employment during his employment with the Company.

(b) Reporting. In his capacity as Senior Vice President, General Counsel and Corporate Secretary for the Company, Executive shall report directly to the Chief Executive Officer, currently Michael S. Anderson.

(c) Confidentiality.

(i) (A) To the fullest extent under applicable law, Executive agrees at all times during the term of this Agreement and for a period of five (5) years after termination of this Agreement, and any applicable extensions thereof, to hold in strictest confidence, and not to use, except for the benefit of the Company to the extent necessary to perform his obligations to the Company under this Agreement, and not to disclose to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of the Company, any confidential information of the Company that Executive obtains or creates. Any breach of this obligation will be considered a material breach of this Agreement.

(B) For the avoidance of doubt, confidential information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by Executive in violation of the provisions hereof; or (3) was already in the possession of Executive without an obligation of confidentiality prior to becoming a party to this Agreement.

(d) Non-Disparagement. Executive agrees not to disparage or otherwise refer to Company, its Executives, officers or directors in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (e.g., e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of Employment and any benefits paid hereunder. Company, together with its executives, officers and directors, agrees not to disparage or otherwise refer to Executive in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (e.g., e-mail, Twitter, Facebook, etc).

(e) Non-Solicitation. For a period of one (1) year after the termination of this Agreement or Executive's employment with the Company, Executive will not directly or indirectly solicit any Company employee to perform services for the Executive or for any other business or entity, whether as an Executive, consultant, partner or participant in any such business or entity. This Section 1.1(e) shall cease to be applicable to any activity of the Executive from and after such time as the Company has ceased all business activities or has made a decision to cease all business activities.

1.2 Status. For as long as he remains an Executive of the Company, Executive's employment shall be governed by the laws of the United States and the State of Missouri to the fullest extent permitted by law. It is the intent of the parties that at all times during Executive's employment with the Company, he will remain a citizen of the United States.

1.3 Duration. This term of this Agreement shall be one (1) year, beginning on the Effective Date, with the Agreement automatically renewing for successive one (1) year periods, unless Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the termination of this Agreement, Executive's employment with the Company shall terminate simultaneously.

2. COMPENSATION; BENEFITS

2.1 **Base Salary**. The Company shall pay to Executive a gross annual base salary of Two Hundred Eighty-Eight Thousand Four Hundred Dollars ($288,400) per year payable in accordance with the Company's normal payroll practices as are in effect from time to time. The Company will review the base salary on or about the first of every year, and in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 **Bonus**. The Executive shall be eligible for an annual bonus of up to forty percent (40%) of Executive's base salary. Payment of the annual bonus will be based upon Executive's achievement of certain business and individual performance objectives as well as the Company's performance against the Company's objectives.

2.3 **Stock Option**.

(a) Grant of Options. Upon approval of the Board of Directors, the Company shall grant to Executive the option ("*Option*") to purchase One Hundred Thousand (100,000) shares of the Company's common stock ("*Option Shares*") in accordance with this Section 2.3 and the Company's stock option plan (or other applicable plan), to the extent that such plan is not contrary to this Agreement.

(b) Vesting. Executive shall vest in the Option Shares in accordance with the Company's approved vesting schedule in accordance with the stock option plan (or other applicable plan).

(c) Exercise of Option. The Option may be exercised as set forth in the Company's stock option plan (or other applicable plan). All shares of the Company's common stock issuable upon the exercise of the Option shall, when issued, be validly issued, fully paid and non-assessable.

2.4 **Auto Allowance**. The Company shall provide Executive an automobile allowance of Seven Hundred Fifty dollars ($750.00) per month.

2.5 **Insurance and Benefits**.

(a) Plan Participation. The Company shall facilitate Executive's and his family's participation in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established. Executive acknowledges that the current insurance plans are offered through Eclat and are subject to reasonable changes at the business discretion of the Company and/or Eclat.

(b) Vacation and Paid Time Off. Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other Executives at similar levels of authority (currently fifteen (15) days). Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at Executive's discretion.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of Executive 's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

3. TERMINATION AND SEVERANCE

3.1 **Termination**.

(a) Nothing in this Agreement shall prevent the Company from terminating Executive's employment with the Company at any time, with or without "Cause." "*Cause*" means: (i) conviction of Executive or plea to a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by Executive of any asset or property of the Company, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach of any of the material obligations contained in this Agreement; (iv) conduct by Executive materially contrary to the material policies of the Company; (v) material failure by Executive to meet the goals and objectives established by the Company; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by Executive that results in a material detriment to the Company, its program, or goals or is inimical to the Company's reputation and interests; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Good Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) Executive may terminate Executive's employment with the Company with or without "Good Reason". "*Good Reason*" means: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's duties in any material respect or the Company's assignment to the Executive of duties that are materially inconsistent with the duties stated in this Agreement; (iii) the relocation of the Company's offices of the Executive's employment more than sixty (60) miles outside the greater St. Louis metropolitan area; (iv) a material breach by the Company of this Agreement; (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of the Company.

(c) In the event that Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. Any reoccurrence of such acts constituting Good Reason within one (1) year of the original occurrence will require no such pre-termination right of the Company to cure.

(d) In the event that the Company desires to terminate Executive's employment, with or without Cause, the Company shall promptly give Executive written notice of the date that such termination will be effective, provided that the notice period shall be no less than thirty (30) days.

3.2 **Severance**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, the Company shall pay to Executive a severance indemnity of: (i) severance pay equal to Executive's then-current annual base salary, paid in continuous payments in accordance with the Company's normal payroll practices for a period of twelve (12) months; and (ii) all accrued but unpaid vacation, expense reimbursement, wages and other benefits due to Executive under any Company provided plans, policies and arrangements; and (iii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("*COBRA*"), then the Company will pay for Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to Executive's termination) until the earlier of: (A) a period of twelve (12) months from the date of termination or (B) the date upon which Executive becomes covered under similar plans. Executive's receipt of the Severance Indemnity is conditioned upon his and the Company's execution of a reasonable settlement agreement governing the termination of the employment relationship between Executive and the Company. All payments set forth in this Section 3.2(i), (ii) and (iii) are defined as (the "*Severance Indemnity*").

3.3 **Change of Control**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period, the Company shall pay to Executive a change of control indemnity of: (i) the Severance Indemnity as defined in Section 3.2; and (ii) a lump-sum payment equal to one hundred percent (100%) of the higher of: (A) the greater of (x) Executive's target bonus as in effect for the fiscal year in which the Change of Control occurs or (y) Executive's target bonus as in effect for the fiscal year in which Executive's termination of employment occurs; or (B) Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs. For avoidance of doubt, the amount paid to Executive pursuant to this Section 3.3 will not be prorated based on the actual amount of time Executive is employed by the Company during the fiscal year (or the relevant performance period if something different than a fiscal year) during which this termination occurs; and (iii) one hundred percent (100%) of Executive's outstanding and unvested Option Shares will become vested in full. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments set forth in this Section 3.3 (i), (ii) and (iii) defined as (the "*Change of Control Indemnity*").

3.4 **Change of Control Definitions**. For purposes of Section 3.3 above, the following definitions shall apply: (a) "*Change of Control*" means the occurrence of any of the following events: (i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("*Person*"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change or Control; or (ii) A change in the effective control of the Company which occurs on the date that a majority of the members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change of Control; or (iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions.

(b) "*Change of Control Period*" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

4. MISCELLANEOUS

4.1 **Entire Agreement**. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements, either oral or in writing, among the parties with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof.

4.2 **Severability**. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

4.3 **Survival**. Notwithstanding expiration or termination of this Agreement, Sections1.1(c), 1.1(d), 2.3, 2.5(c), Section 3 and Section 4 shall survive such expiration or termination.

4.4 **Interpretation of Agreement**.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated fully in the negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

4.5 **Taxes**. The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A. Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law.

4.6 **Governing Law**. Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

4.7 **Binding Arbitration**.

(a) All disputes arising under this Agreement or arising out of or relating to Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association. Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct American Arbitration Association ("AAA") arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover his or its reasonable costs and attorneys' fees associated with the arbitration. The non-prevailing party shall be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

4.8 **Amendments**. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

4.9 **Binding Effect**. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

4.10 **No Assignment**.

(a) This Agreement and all of Executive's rights and obligations hereunder are personal to Executive and may not be transferred or assigned by him at any time, except that any assets accruing to Executive in connection with this Agreement shall accrue to the benefit of Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

4.11 **Waiver**. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

4.12 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[*Signature page follows]*.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date and year first above written.

THE COMPANY

FLAMEL TECHNOLOGIES SA

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

ECLAT PHARMACEUTICALS, LLC

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

EXECUTIVE

By: /s/ Phil Thompson
Name: Phil Thompson
Title: Sr. Vice President, General Counsel and Corporate Secretary

Exhibit 10.20

EXECUTION VERSION

MEMBERSHIP INTEREST PURCHASE AGREEMENT

by and among

FSC HOLDING COMPANY, LLC,
a Delaware limited liability company,

FSC THERAPEUTICS, LLC,
a Delaware limited liability company,

FSC LABORATORIES, INC.
a Delaware corporation,

PETER STEELMAN,

JAMES FLYNN,

and

DEERFIELD CSF, LLC,
a Delaware limited liability company, on the one hand

and

FLAMEL US HOLDINGS, INC.,
a Delaware corporation,

and

FLAMEL TECHNOLOGIES SA,
a société anonyme organized under the laws of the Republic of France,
solely for purposes of Section 1.7, on the other hand

Dated as of February 5, 2016

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MEMBERSHIP INTEREST PURCHASE AGREEMENT

THIS MEMBERSHIP INTEREST PURCHASE AGREEMENT (this "***Agreement***") is made and entered into as of February 5, 2016, by and among **JAMES FLYNN**, **PETER STEELMAN**, **DEERFIELD CSF, LLC**, a Delaware limited liability company (collectively, the "***Sellers***"), **FSC HOLDING COMPANY, LLC**, a Delaware limited liability company (the "***Company***"), **FSC THERAPEUTICS, LLC**, a Delaware limited liability company ("***FSC Therapeutics***"), **FSC LABORATORIES, INC.**, a Delaware corporation ("***FSC Labs***"), on the one hand and **FLAMEL TECHNOLOGIES SA**, a société anonyme organized under the laws of the Republic of France ("***Flamel SA***"), solely for purposes of Section 1.7, and **FLAMEL US HOLDINGS, INC.**, a Delaware corporation (the "***Buyer***"), on the other hand. Certain capitalized terms used in this Agreement are defined in **Exhibit A**.

RECITALS

The Sellers desires to sell, and the Buyer desires to purchase, all of the issued and outstanding membership interests of the Company, consisting of 1,000 Preferred Units and 1,000 Common Units (together the "***Units***"), for the consideration and on the terms and subject to the conditions set forth herein.

AGREEMENT

The Parties to this Agreement, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and 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, Sellers shall sell and deliver to the Buyer, and the Buyer shall purchase and accept from Sellers, all of the Units, free and clear of all Encumbrances, in exchange for the consideration set forth herein.1.2 **Consideration**. The Buyer shall make the following payments to the Sellers as consideration for the sale of the Units from Sellers to Buyer (all such payments together, following all adjustments contemplated in this Agreement, the "***Purchase Price***"):

(a) The Buyer shall pay to the Sellers $262,500 on the last business day of each April, July, October and January starting with the last business day of April 2016 and ending with the last business day of October 2020 and shall pay $15,262,500 to the Sellers on the last business day of January 2021 for a total of $20,250,000 (all such payments together, the "***Fixed Payments***"); and

(b) The Buyer shall pay the Deferred Consideration to the Sellers subject to and in accordance with **Section 1.6**.

All payments of the Purchase Price shall be made among the Sellers in the amounts designated in Exhibit B by wire transfer of immediately available funds to the account(s) designated in Exhibit B or otherwise designated by the Sellers in writing no later than five Business Days prior to the date such payment shall be due. Each Seller acknowledges and agrees to such allocation notwithstanding the terms, conditions and allocations set forth in the operating agreement or other governing documents of the Company.

1.3 **Indebtedness; Transaction Expenses; Post-Closing Adjustment**.

(a) Immediately prior to the Closing: (1) Deerfield PDI Financing II, L.P. shall transfer to Deerfield Private Design International II, L.P. all of its rights, title and interest in the Affiliated Company Indebtedness, (2) Deerfield Private Design International II, L.P. and Deerfield Private Design Fund II, L.P. shall contribute to the Company all of their rights, title and interest in all of the Affiliated Company Indebtedness and (iii) the Company shall contribute to FSC Labs and FSC Therapeutics as applicable, all of its rights, title and interest in the Affiliated Company Indebtedness, with the effect that at Closing there shall be no outstanding Affiliated Company Indebtedness (whether principal, interest or otherwise), all documents related to the Affiliated Company Indebtedness shall be terminated with no residual Liability on the part of any Company Party and all Encumbrances thereunder shall be released (the foregoing transactions, the ***"Affiliated Company Indebtedness Termination"***). Immediately after the Affiliated Company Indebtedness Termination but immediately prior to the Closing, Deerfield Private Design International II, L.P. and Deerfield Private Design Fund II, L.P. shall contribute all of their Units to Deerfield CSF, LLC.

(b) There shall be no outstanding Company Indebtedness, including Affiliated Company Indebtedness, at the Effective Time and neither the Buyer nor any of its Affiliates (including the Company Parties after the Closing) shall have any responsibility for any Company Indebtedness. If there shall be any outstanding Company Indebtedness at the Effective Time, Sellers shall pay all such Company Indebtedness at the Closing and, if the Sellers do not pay, Buyer shall be entitled to deduct such outstanding amount from the amount of Fixed Payments payable pursuant to **Section 1.2(a)** and Buyer shall use such amount to directly repay such Company Indebtedness.

(c) There shall be no outstanding Transaction Expenses at the Effective Time and neither the Buyer nor any of its Affiliates (including the Company Parties after the Closing) shall have any responsibility for any Transaction Expenses. If there shall be any outstanding Transaction Expenses at the Effective Time, Sellers shall pay all such Transaction Expenses at the Closing and, if the Sellers do not pay, Buyer shall be entitled to deduct such outstanding amount from the amount of Fixed Payments payable pursuant to **Section 1.2(a)** and Buyer shall use such amount to directly pay the Transaction Expenses.

(d) After payment by the Company Parties of all Company Indebtedness, Transaction Expenses and other obligations of the Company Parties, the Company shall be entitled to make a distribution to the Sellers of all freely available and unrestricted cash held by the Company Parties as of immediately prior to the Closing, excluding cash needed to pay any checks or other drafts that are issued by the Company Parties but not deposited by the recipient thereof as of the Closing Date, or any other obligations of the Company Parties arising prior to the Closing for which such cash would be used as payment.

(e) Within 120 days after the Closing, Buyer shall notify the Sellers whether (i) the actual amount of outstanding Company Indebtedness and/or Transaction Expenses at Closing exceeded the respective amounts determined pursuant to **Sections 1.3(b)** and **1.3(c)** and/or (ii) the Closing Working Capital was less than the Lower Target Amount or more than the Upper Target Amount. The Sellers shall have twenty Business Days after delivery by Buyer of its notice to object in writing to the statements made in Buyer's notice. If the Sellers timely deliver such an objection notice, Buyer and the Sellers shall cooperate in good faith to resolve such disputes as promptly as practicable. If no such resolution is achieved within 30 days after delivery by the Sellers of their objection notice, Buyer and the Sellers shall be obligated to submit the remaining disputes to the Reviewing Accountant, which shall be engaged only to resolve the remaining disputes. If the resolution of such disputes, whether by agreement of Buyer and the Sellers or determination of the Reviewing Accountant, results in a determination that the actual amount of outstanding Company Indebtedness and/or Transaction Expenses at Closing exceeded the respective amounts determined pursuant to **Sections 1.3(b)** and **1.3(c)** or that the Lower Target Amount exceeded the Closing Working Capital, or if the Sellers do not timely deliver an objection notice under this **Section 1.3(d)**, the Sellers shall, within five Business Days thereafter, pay to Buyer the applicable amount owed to Buyer (which shall be equal to (x) the amount by which the outstanding Company Indebtedness at Closing exceeds the amounts determined pursuant to **Section 1.3(b)**, plus (y) the amounts by which the outstanding Transaction Expenses at Closing exceeds the amount determined pursuant to **Section 1.3(c)**, plus (z) the difference between the Closing Working Capital, as finally determined pursuant to this **Section 1.3(e)**, and $0). To the extent such amount owed by Sellers to Buyer is not paid on or prior to the date Buyer is to make any Fixed Payment or Deferred Payment to Sellers, Buyer may deduct from such Fixed Payment or Deferred Payment, as the case may be, and, to the extent necessary, any subsequent Fixed Payment or Deferred Payment, the amount owed to it by Sellers pursuant to this **Section 1.3(e)**. If the Closing Working Capital as finally determined hereunder was more than the Upper Target Amount, the Buyer shall promptly pay to the Sellers the amount by which such finally determined Closing Working Capital amount exceeds $0. The costs, fees and expenses charged by the Reviewing Accountant for its engagement pursuant to this **Section 1.3(e)** shall be allocated equally amount Buyer and Sellers.

1.4 **Purchase Price Allocation**. The consideration described in **Section 1.2** shall be allocated 55.0% to FSC Labs and 45.0% to FSC Therapeutics for U.S. income tax purposes according to **Schedule 1.4** (the "***Purchase Price Allocation Schedule***"). The portion of the consideration described in **Section 1.2** allocated to FSC Therapeutics, LLC shall be further allocated among its assets for U.S. income tax purposes in accordance with the methodology set forth on the Purchase Price Allocation Schedule. The parties will follow the methodology set forth on the Purchase Price Allocation Schedule and shall not (and shall not permit any Affiliates to) take any U.S. federal income tax position, or file any Tax Return for U.S. federal income tax purposes, inconsistent therewith, unless otherwise required by a change of law after the date hereof, a closing agreement with the IRS, or a decision of a court of competent jurisdiction. Each of the Buyer and the Sellers shall notify the other parties if the IRS challenges the Purchase Price allocations and shall keep the other parties reasonably informed of the status and progress of such challenge.

1.5 **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 by the Sellers. At or prior to the Closing, the Sellers shall have delivered to the Buyer:

(i) Resignation letters, in form and substance reasonably acceptable to Buyer, of each of the directors, managers and certain officers of the Company Parties specified by the Buyer, effective as of the Effective Time;

(ii) A certificate executed by the Secretary of each Company Party certifying that (A) attached thereto is a true and complete copy of such Company Party's certificate of formation or certificate of incorporation and all amendments thereto and then in effect, in each case certified by the Secretary of State of the State of Delaware; (B) attached thereto are certificates of good standing of such Company Party 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 such Company Party's bylaws or limited liability company agreement and all amendments thereto and then in effect; (D) for just the Company, 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 Transaction Agreements and the transactions contemplated hereby, and (E) for just the Company, as to the incumbency and signatures of each individual who will execute documents at the Closing on behalf of the Company;

(iii) Documentation from the Company evidencing the Affiliated 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 Affiliated Company Indebtedness are terminated, (2) all obligations related to the Affiliated Company Indebtedness are deemed paid in full, and (3) all Encumbrances related to the Affiliated Company Indebtedness are released and (B) the Sellers which are lenders and the Company authorize the Buyer to file any UCC termination statements deemed appropriate by the Buyer to effect the Affiliated Company Indebtedness Termination;

(iv) Payoff letters for all other Company Indebtedness outstanding as of the Closing Date, setting forth the amount required to pay off in full all such Company Indebtedness and otherwise providing for the complete satisfaction and/or release as of the Closing Date of all of such Company Indebtedness to the Persons to whom such Company Indebtedness is owed, and the complete release of any Encumbrances or guarantees any such Person may have against any Company Party or any of their respective assets or properties, along with supporting documentation, all in customary form reasonably satisfactory to the Buyer;

(v) (A) a certificate executed by each Seller in accordance with the requirements of Treasury Regulation Section 1.1445-2(b)(2) certifying that such Seller is not a foreign person (as such term is defined in the Code and the Treasury Regulations promulgated in connection therewith) and (B) two (2) original copies of IRS Form W-9 from each Seller, each such copy duly executed by such Seller;

(vi) Unit transfer powers, each in form and substance reasonably acceptable to the Buyer, evidencing the transfer and assignment of the Units from the applicable Seller to the Buyer hereunder, together with any other documents that are necessary to transfer to Buyer good and valid title to the Units, free and clear of all Encumbrances;

(vii) Copies of all Company Approvals, duly executed by the applicable consenting party (if applicable), and, in the case of the Company Approvals relating to the Leases, together with certificates of estoppel reasonably satisfactory to Buyer;

(viii) Releases from each of the Sellers, each in form and substance reasonably acceptable to the Buyer, of all claims such Seller may have against any Company Party, Buyer or any of their respective Affiliates;

(ix) Non-competition and non-solicitation agreements from Peter Steelman and James Flynn, in form and substance reasonably acceptable to Buyer; and

(x) The contents of the electronic data room maintained by the Sellers in connection with the transactions contemplated by this Agreement.

1.6 **Deferred Consideration**.

(a) Deferred Payments. The Buyer shall pay (or cause to be paid) to the Sellers (or their successors and assigns) quarterly deferred payments (each, a "***Deferred Payment***") equal to 15.0% of Net Sales of the Products in such quarter (collectively, the "***Deferred Consideration***"), subject to Section 1.6(b).

(b) Payment of the Deferred Payments. The Deferred Payments described in **Section 1.6(a)** shall be paid quarterly in arrears and shall accrue daily for each quarter from and after the Closing until the earlier of (i) the tenth anniversary of the Closing Date or (ii) $12,500,000 in the aggregate of Deferred Payments have been paid to the Sellers. No later than three Business Days following the date the Buyer 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 Sellers the Deferred Payment for such quarter. On the same day it makes a Deferred Payment, the Buyer shall deliver or cause to be delivered to the Sellers a written statement showing all Net Sales of Products during such quarter and the corresponding Deferred Payment (each a "***Deferred Payment Calculation***"). All Deferred Payments shall be made among the Sellers in the amounts designated in Exhibit B by wire transfer of immediately available funds to the account(s) designated in Exhibit B or otherwise designated by the Sellers in writing no later than five Business Days prior to the date such Deferred Payment shall be due. For the avoidance of doubt, the accrual of Deferred Payments shall terminate on the tenth anniversary of the Closing Date even if less than $12,500,000 of aggregate Deferred Payments shall have accrued as of such tenth anniversary.

(c) Delinquent Deferred Payments. Any 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, from the date such payment was due until the date paid.

(d) Audit Right. Upon not less than ten Business Days written notice (the "***Audit Notice***"), the Sellers shall have the right to audit the books and records of the Company Parties for the purpose of determining the correctness of their computation and payment of any 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 1.6**. Such audit may not be conducted more than once in any calendar year and shall be conducted during normal business hours at the Sellers' 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 Sellers and their advisors with reasonable access to all pertinent books and records of the Company related to the Products and shall reasonably cooperate with the Sellers' and their advisors' efforts to conduct such audits. The Sellers 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 the Sellers and shall describe in reasonable detail the basis for such objection, as well as the amount in dispute. If the Sellers deliver a Deferred Payment Calculation Objection Notice, Buyer and the Sellers shall negotiate in good faith for up to ten Business Days to resolve the disputed items and agree upon the resulting amount of the Deferred Payment that is the subject of the Deferred Payment Calculation Objection Notice. If Buyer and the Sellers 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 the Sellers 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 the Sellers, 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 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 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 Sellers for the reasonable out-of-pocket costs (including Reviewing Accountants' fees) incurred by the Sellers pursuant to this **Section 1.6(d)**.

(e) Assignment or Sublicense by the Buyer. The Buyer shall continue to be obligated to pay the Deferred Payments, subject to the aggregate maximum amount and time period set forth in **Section 1.6(b)**, on all sales by all direct or indirect licensees and assignees of any rights to sell, market or otherwise distribute the Products, and the provisions of this **Section 1.6** shall apply to all such sales as if made directly by a Company Party.

(f) Credit Facility Restrictions. The Buyer represents and warrants that there are no restrictions or limitations on the Buyer's ability to make the payments that are or may be required to be paid to the Sellers under this Agreement in any Contract of the Buyer or any of its Subsidiaries (excluding the Company Parties), including in any loan agreement, note debenture or other document evidencing any indebtedness of the Buyer and any of its Subsidiaries (excluding the Company Parties). The Buyer 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 the Buyer's or the Company Parties' ability to make the payments that are or may be required to be paid to the Sellers under this Agreement.

(g) Acceleration. Notwithstanding anything to the contrary contained in this **Section 1.6** (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 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 (except for any notice contemplated in the definition of Acceleration Trigger Event, if applicable), all of which are hereby knowingly and expressly waived by the Buyer, and (y) the Sellers may exercise any and all other rights and remedies available to it under this Agreement and applicable law to enforce its right to receive payment of the Accelerated Value (plus any applicable accrued interest).

(h) No Security. The parties hereto understand and agree that (i) the contingent rights to receive any 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 any Company Party, (ii) Sellers shall not have any rights as securityholders of Buyer or of any Company Party as a result of Sellers' contingent right to receive any Deferred Payment hereunder, and (iii) no interest is payable with respect to any Deferred Payment except as provided in **Section 1.6(c)**.

(i) Tax Treatment. The Sellers and the Buyer agree that the Deferred Payments represent part of the consideration for the sale of the Units to the Buyer. Buyer shall not claim, and shall not permit any of its Affiliates or any transferee that assumes the obligation to make any Deferred Payment to claim, any deduction for income tax purposes under Section 162(a) of the U.S. Internal Revenue Code of 1986, as amended (the "***Code***"), or any comparable provision of state or local Tax law, or take any U.S. federal income tax position (or position under comparable state or local income tax law) inconsistent therewith, on account of any Deferred Payment (or portion thereof) unless otherwise required by a change of law after the date hereof, a closing agreement with an applicable Taxing authority or a decision of a court of competent jurisdiction. Each of the Buyer and the Sellers shall notify the other parties if a Taxing authority challenges the tax treatment of the Deferred Consideration and shall keep the other parties reasonably informed of the status and progress of such challenge.

(j) Other Covenants. Until the Deferred Payments are paid in full:

(i) Buyer and the Company shall not, and shall cause the Company Parties after Closing not to, take any action or fail to take any action that would waive, breach, terminate or materially amend any of the following contracts in a manner that would adversely affect the sale of Products or the right of the Sellers to the Deferred Payments in connection therewith: (A) the Supply and Distribution Agreement dated August 9, 2013 between FSC Laboratories, Inc. and Tris Pharma, Inc., (B) the License and Assignment Agreement between Eisai Inc. and FSC Therapeutics, LLC dated June 12, 2014, (C) the Supply Agreement between Eisai Inc. and FSC Laboratories, Inc. dated June 12, 2014 and (D) the License, Supply & Distribution Agreement dated March 17, 2015 by and among Yung Shin Pharm. Ind. Co., Ltd., FSC Therapeutics, LLC, FSC Laboratories, Inc., and Rising Pharmaceuticals, Inc. In addition, Buyer and the Company shall not, and shall cause the Company Parties after Closing not to, take any action or fail to take any action that would waive, breach, terminate or materially amend in any way any of the following specific provisions of the following contracts: (A) Section 4.3 and/or the definition of "Minimum Unit Sales Commitment" in the Supply and Distribution Agreement dated August 9, 2013 between FSC Laboratories, Inc. and Tris Pharma, Inc., (B) Section 3.3(a)(ii) of the License and Assignment Agreement between Eisai Inc. and FSC Therapeutics, LLC dated June 12, 2014, and (C) Section 2.7 and/or Section 3.2(d) of the License, Supply & Distribution Agreement dated March 17, 2015 by and among Yung Shin Pharm. Ind. Co., Ltd., FSC Therapeutics, LLC, FSC Laboratories, Inc., and Rising Pharmaceuticals, Inc.

(ii) During each calendar year beginning in 2016, Buyer and the Company shall, and shall cause the Company Parties after Closing to, cause the sales representatives of the Company Parties to complete no fewer than 60,000 P1 Product Details and no fewer than 50,000 P2 Product Details for the Products; provided, however, that in the event that new generic products are launched after Closing that compete with three or more of the Products, then the annual P1 Product Detail requirement shall be reduced to 45,000 and the annual P2 Product Detail requirement shall be eliminated. For purposes of clarification, the Buyer and the Company Parties shall have full and sole discretion to direct the required Product Details toward any Product.

1.7 **Guarantees; Security Interest.**

(a) Each of the Company, FSC Labs, FSC Therapeutics and Flamel SA (such Persons in such capacity, "***Guarantors***") hereby, jointly and severally, unconditionally and irrevocably, as a primary obligor and not only a surety, guarantees to the Sellers the prompt and complete payment and performance by Buyer when due of the Buyer's obligations under this Agreement, including, without limitation, the obligation to pay to the Sellers the Fixed Payments and the Deferred Payments (the "***Guaranteed Obligations***"). Each of the Company, FSC Labs and FSC Therapeutics waives any and all notice of the creation, renewal, extension or accrual of any of the Guaranteed Obligations and notice of or proof of reliance by any Seller upon the guarantee contained in this **Section 1.7(a)** or acceptance of the guarantee contained in this **Section 1.7(a)**; the Guaranteed Obligations, and any of them, shall conclusively be deemed to have been created, contracted or incurred, or renewed, extended, amended or waived, in reliance upon the guarantee contained in this **Section 1.7(a)**. Each of the Company, FSC Labs and FSC Therapeutics waives (a) diligence, presentment, protest, demand for payment and notice of default or nonpayment to or upon Buyer or any of the them with respect to the Guaranteed Obligations, (b) notice of the existence or creation or non-payment of all or any of the Guaranteed Obligations, and (c) all diligence in collection or protection of or realization upon any Guaranteed Obligations or any guaranty of any Guaranteed Obligations.

(b) Each of FSC Labs and FSC Therapeutics hereby pledges, assigns, hypothecates, transfers and grants to Sellers, a first priority lien upon and security interest in, all of their right, title and interest in and to the following property and assets, in each case whether now owned or existing or hereafter acquired or arising and wherever located, but in each case only relating to the Products (collectively, the "***FSC Assets Collateral***"): all inventory, all owned Proprietary Rights other than domain names and websites and all owned Governmental Authorizations. The FSC Assets Collateral shall secure the full and prompt payment, at any time and from time to time as and when due (whether at the stated payment date, by acceleration or otherwise), of the Guaranteed Obligations.

(c) If Buyer defaults on any of the Guaranteed Obligations and does not cure such default within ten Business Days after the due date thereof, Sellers shall be entitled to exercise in respect of the FSC Assets Collateral all of its rights, powers and remedies provided for herein or otherwise available to it under any law, in equity or otherwise, including all rights and remedies of a secured party under the Delaware Uniform Commercial Code. Buyer, FSC Labs and FSC Therapeutics to the greatest extent not prohibited by applicable law, hereby (i) agrees that it will not invoke, claim or assert the benefit of any rule of law or statute now or hereafter in effect (including, without limitation, any right to prior notice or judicial hearing in connection with Sellers' possession, custody or disposition of any FSC Assets Collateral or any appraisal, valuation, stay, extension, moratorium or redemption law), or take or omit to take any other action, that would or could reasonably be expected to have the effect of delaying, impeding or preventing the exercise of any rights and remedies in respect of the FSC Assets Collateral, the absolute sale of any of the FSC Assets Collateral or the possession thereof by any purchaser at any sale thereof, and waives the benefit of all such laws and further agrees that it will not hinder, delay or impede the execution of any power granted hereunder to the Sellers, but that it will permit the execution of every such power as though no such laws were in effect, (ii) waives all rights that it has or may have under any rule of law or statute now existing or hereafter adopted to require the Sellers to marshal any FSC Assets Collateral or any other party or against or in payment of any or all of the obligations hereunder, and (iii) waives all rights that it has or may have under any rule of law or statute now existing or hereafter adopted to demand, presentment, protest, advertisement or notice of any kind (except notices expressly provided for herein). In addition, Buyer, FSC Labs and FSC Therapeutics waives any and all rights of contribution or subrogation upon the sale or disposition of all or any portion of the FSC Assets Collateral. Buyer and the Company Parties shall be permitted to transfer, sell and/or assign any of the FSC Assets Collateral to an Affiliate so long as such Affiliate executes a joinder to this **Section 1.7** of the Agreement in order to guarantee the Guaranteed Obligations and grant a security interest in the FSC Assets Collateral on the same terms agreed to by the Company Parties set forth herein. For purposes of clarification, nothing in this Agreement shall be interpreted to restrict Buyer's or Guarantors' right to sell any inventory that is part of the FSC Assets Collateral or otherwise in the ordinary course of business.

(d) In the event that Flamel SA undertakes a "reincorporation" transaction under which either a new parent company is established or any material assets are transferred from Flamel SA to an Affiliate, Flamel SA shall cause such new parent entity or transferee to execute a joinder to this **Section 1.7** of the Agreement in order to guarantee the Guaranteed Obligations on the same terms as Flamel SA.

(e) All terms in this **Section 1.7** that are not capitalized shall, unless the context otherwise requires, have the meanings provided by the Delaware Uniform Commercial Code to the extent the same are used or defined therein.

1.8 **Withholding**. Any and all payments due to Sellers pursuant to this Agreement shall be made free and clear of and without deduction for any Taxes except as required by applicable Tax law. If any Person (whether the Buyer, a Guarantor or an Affiliate to which the Buyer elects to assign its rights and/or obligations under this Agreement) shall be required by Tax law to deduct any non-U.S. Taxes from any payments due to any Seller hereunder (other than any such non-U.S. Taxes that are imposed as a result of (x) a present or former connection between a Seller and the jurisdiction imposing such Tax (other than any such connection arising from such Seller having executed, delivered, become a party to, performed its obligations under, received payments under, or enforced its rights under, a Transaction Agreement), or (y) the failure (other than as a result of a change in law or because the requested document is inconsistent with the Seller's actual circumstances or Tax status when requested) of a Seller to provide the Buyer with any Tax form, certification or information reasonably requested by the Buyer (any such Tax described in clause (x) or (y), an "Excluded Tax")), then notwithstanding any provisions to the contrary, (i) the sum payable hereunder by such Person shall be increased by as much as shall be necessary so that after making all required deductions (including deductions for Taxes (other than Excluded Taxes) applicable to additional sums payable under this Section 1.8) for such non-U.S. Taxes, each Seller shall receive an amount equal to the sum it would have received had no such deductions been made (any and all such additional amounts payable shall hereafter be referred to as the "***Additional Amounts***"), (ii) such Person shall make such deductions, and (iii) such Person shall pay the full amount deducted to the relevant Governmental Body in accordance with applicable Tax law and shall provide to the applicable Seller the original or a certified copy of a receipt evidencing payment thereof or other reasonably satisfactory evidence of such payment. Except as otherwise provided in this **Section 1.8**, to the extent that amounts are so deducted and withheld by the Buyer, such amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of which the Buyer made such deduction and withholding. The Buyer shall provide the Sellers with five (5) Business Days' advance notice of any such required withholding and shall reasonably cooperate with the Sellers to mitigate or reduce such withholding. All payments of Additional Amounts, once made by Buyer pursuant to this **Section 1.8,** shall be treated as indemnification payments made pursuant to Section 6.3 for all purposes of this Agreement.

2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Each Company Party and the Sellers, severally and not jointly, represents and warrants to the Buyer:

2.1 Organization; Good Standing; Enforceability.

(a) Each Company Party is a corporation or limited liability company, as applicable, duly organized, validly existing and in good standing under the laws of the state of its incorporation or 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 each 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.

(b) Accurate and complete copies of (i) the certificate of formation, certificate of incorporation or similar formation documents; (ii) bylaws, operating agreement or other similar governance documents; (ii) minutes of meetings, or written consents in lieu of meetings, of the members, boards of directors or managers (or similar governing bodies) and committees of the boards of directors or managers (or similar governing bodies); (iii) equity transfer ledgers and (iv) other organizational documents (in each case, together with all amendments thereto) of each Company Party have been delivered or made available to Buyer. None of the Company Parties is in default under or in violation of any provision of its organizational documents. All transfer Taxes levied or payable with respect to all transfers of securities of each Company Party prior to the date hereof have been paid and, if applicable, all applicable transfer Tax stamps have been affixed.

(c) The Company and each Seller has all requisite power and authority to execute and deliver the Transaction Agreements to which the Company and/or such Seller is a party, to perform its or his respective obligations thereunder and to consummate the transactions contemplated thereby. The execution and delivery of the Transaction Agreements, the performance of its obligations thereunder and the consummation of the transactions contemplated thereby have been duly and validly authorized by all necessary limited liability company or other action on the part of the Company. The Transaction Agreements have been duly executed and delivered by the Company and each Seller and (assuming due execution by the Buyer) constitute legal, valid and binding obligations of the Company and each Seller, enforceable against them in accordance with their terms.

(d) No registrations, filings, applications, notices, consents, approvals, orders, qualifications, authorizations or waivers are required to be made, filed, given or obtained by any Company Party or any Seller with, to or from any Person, including any Governmental Body, in connection with the execution and delivery of the Transaction Agreements or the consummation of the transactions contemplated hereby or thereby, except as set forth on **Schedule 2.1(d)** (the "Company Approvals").

2.2 **Consents and Approvals; No Violation**. Except as disclosed in **Schedule 2.2**, neither the execution and delivery of the Transaction Agreements by the Sellers or the Company, nor the performance of their respective obligations hereunder or thereunder, nor the consummation by the Sellers or the Company of the transactions contemplated hereby or thereby will: (a) conflict with or result in a breach, violation, or default of or under the certificate of formation, certificate of incorporation or other governing or organizational document of any Company Party, (b) conflict with, result in a violation or breach of, result in the creation of any obligation or loss of any benefit under, 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 Sellers or any Company Party is a party or by which Sellers 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 Sellers or the Company Parties.

2.3 **Units; Subsidiaries**.

(a) The authorized, issued and outstanding membership interests of the Company consist of 1,000 Preferred Units and 1,000 Common Units. The Units transferred to the Buyer pursuant to this Agreement represent 100% of the issued and outstanding Equity Interests of the Company. The Sellers are the sole record and beneficial owners and holders, free and clear of all Encumbrances, of all of the Units, as more particularly described in **Schedule 2.3(a)**, 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 validly issued and are fully paid, and were issued in compliance with all applicable Legal Requirements and pursuant to an exemption from registration under all applicable federal and state securities laws and regulations. None of the Units were issued in violation of any agreement, arrangement or commitment to which Sellers or any Company Party is a party or is subject to or was issued in violation of any preemptive, right of first refusal or offer, or similar rights of any Person. There are no outstanding warrants, options, calls, rights of first refusal, convertible or exchangeable securities or other rights, agreements, arrangements or commitments of any character pursuant to which the Company or any Seller is or may become obligated to issue, sell, transfer, purchase, return or redeem, or cause to be done any of the foregoing, 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. There are no voting trusts, irrevocable proxies or other Contracts or understandings to which the Company or any Seller is a party or is bound with respect to voting or consent of any Units.

(b) The only Persons in which the Company or any Company Party owns or holds any Equity Interest are set forth on **Schedule 2.3(b)**. The record and beneficial owners and holders, free and clear of all Encumbrances, of all of the Subsidiaries of the Company are set forth on **Schedule 2.3(b)**. All of the Equity Interests set forth on **Schedule 2.3(b)** were validly issued and fully paid, and were issued in compliance with all applicable Legal Requirements and pursuant to an exemption from registration under all applicable federal and state securities laws and regulations. None of the Equity Interests of any Company Party were issued in violation of any agreement, arrangement or commitment to which Sellers or any Company Party is a party or is subject to or was issued in violation of any preemptive, right of first refusal or offer, or similar rights of any Person. There are no outstanding warrants, options, calls, rights of first refusal, convertible or exchangeable securities or other rights, agreements, arrangements or commitments of any character pursuant to which any Subsidiary is or may become obligated to issue, sell, transfer, purchase, return or redeem, or cause to be done any of the foregoing, 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. Other than as set forth in the operating agreements listed on **Schedule 2.3(b)**, there are no voting trusts, irrevocable proxies or other Contracts or understandings to which any Company Party or any Seller is a party or is bound with respect to voting or consent of any Equity Interests of any Subsidiary.

(c) There are no phantom equity rights, equity appreciation rights or other agreements or arrangements of any character that provide for or grant any right to share in the equity, income, revenue or cash flow of any Company Party. No Company Party has ever adopted, sponsored or maintained any equity option plan or any other plan or agreement providing for equity compensation to any person.

2.4 **Financial Statements**.

(a) **Schedule 2.4** contains accurate and complete copies of (a) the consolidated, audited balance sheets of the Company Parties as of December 31, 2014 (the "***Balance Sheet***", and such date the "***Balance Sheet Date***"); (b) the consolidated, audited statement of income for the Company Parties for the year then ended; (c) the consolidated, unaudited balance sheet of the Company Parties as of December 31, 2015 and (d) the consolidated, unaudited statement of income for the Company Parties as of the fiscal years 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 consistently applied throughout the periods covered thereby, subject, in the case of the Financial Statements that are unaudited, to (x) the absence of notes, and (y) normal year-end audit adjustments, none of which is material.

(b) **Schedule 2.4(b)** sets forth an accurate and complete list of all Company Indebtedness. For the avoidance of doubt, none of the Company Parties has any (i) obligations evidenced by notes, bonds, debentures or similar instruments, or pursuant to any guaranty or arrangements having the economic effect of a guarantee (excluding trade payables), or that are secured by a lien on property or assets; (ii) obligations under interest rate protection agreements; (iii) obligations under capital leases; (iv) obligations issued or assumed as the deferred purchase price of property or services; (v) accrued but unpaid milestone or royalty obligations that are not accrued in Closing Working Capital; (vi) obligations in respect of interest rate, currency or commodity derivatives, swaps, hedges or similar arrangements; (vii) asset retirement obligations and similar obligations; or (viii) obligations evidenced by any securitization or factoring arrangements.

(c) None of the Company Parties has any liability of any nature that would be required to be reflected or reserved against on a balance sheet of the Company's business prepared in accordance with GAAP, except for (i) liabilities reflected in or reserved against the Balance Sheet or the notes thereto, (ii) liabilities incurred in the Ordinary Course of Business since the Balance Sheet Date, and (iii) liabilities set forth on **Schedule 2.4(c)**.

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 or otherwise, and has not repurchased, redeemed or otherwise reacquired any of its Equity Interests.

(b) there has been no amendment to the certificate of incorporation, certificate of formation, bylaws, operating agreement or other governing or organizational document of any Company Party, and no Company Party has adopted, effected or been a party to any merger or business combination or recapitalization or reclassification of its Equity Interests;

(c) no Company Party has adopted any plan of consolidation, reorganization, liquidation or dissolution, applied for relief of debt or moratorium on payments, filed a petition in bankruptcy or insolvency under any provisions of federal or state bankruptcy law, or consented to the filing of any bankruptcy petition against it under any similar law, and, to the Knowledge of the Company, no third party has done any of the foregoing with respect to any Company Party;

(d) no Company Party has formed any Subsidiary, made any equity or debt investment in or acquired any equity interest in any other Entity;

(e) no Company Party has made or committed to make capital expenditures that exceed $25,000 individually or $50,000 in the aggregate, or $75,000 in the aggregate for all of the Company Parties;

(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 by or to such Company Party in an amount or having a value in excess of $50,000 in the aggregate or that involves obligations lasting longer than 12 months, 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 $50,000 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, and there has been no Material Adverse Effect on 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 Encumbrance other than Permitted Encumbrances;

(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 in any material respect, or any of its methods of collection, payment, accounting or accounting practices in any material respect, including accelerating collection of receivables or payment of payables;

(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, (iii) taken any action to grant, vest or pay, or accelerate the granting, vesting or payment of, any compensation or benefit for any employee, officer, director, independent contractor or consultant, or (iv) entered into any employment, deferred compensation, severance, special pay, consulting, non-competition or similar agreement (or amended any such agreement to which a Company Party is a party);

(m) no Company Party has made any loan or advance to (or forgiven, canceled or compromised any loan to) any Person, other than ordinary course expense advancements to its employees, and no Company Party has entered into any 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 Tax election, or adopted or changed any 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 Financial Statements, (iii) consented to any extension or waiver of any limitation period with respect to any claim or assessment for Taxes, or (iv) amended any Tax Return or filed any claim for a refund of 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 income and other material Taxes that are due and payable by any of them prior to the Closing Date (whether or not shown on any Tax Return) (c) all income and other material Taxes not yet due and payable of the Company Parties for any Pre-Closing Period that are not accrued as liabilities in the Financial Statements have been properly accrued on the books and records of the Company Parties, (d) with respect to each Company Party, no claim has ever been made by a Tax Authority in writing in any jurisdiction where such Company Party does not file Tax Returns claiming that such Company Party is or may be subject to taxation in that jurisdiction, (e) the Company Parties have withheld and timely paid to the appropriate taxing authority all material Taxes required to be withheld and paid in connection with amounts paid or owing to any employee, member, shareholder, independent contractor, creditor or other third party, (f) there are no Liens for Taxes (other than Permitted Encumbrances) upon any assets of any Company Party, (g) no deficiencies have been asserted in writing or assessed by any taxing authority against any Company Party, (h) 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) or extensions of the time to assess any Taxes of the Company Parties, (i) no Company Party has participated in any "listed transaction" within the meaning of Treasury Regulation Section 1.6011-4(b)(2) or, to the Sellers' Knowledge any transaction that did not have economic substance for purposes of Section 7701(o) of the Code or that, when entered into, was a "reportable transaction" within the meaning of Treasury Regulation Section 1.6011-4(b)(1), (j) the Company is classified as a partnership and FSC Therapeutics, LLC is classified as a disregarded entity of the Company, in each case, for U.S. federal income tax purposes, (k) no Company Party is a party to any Tax allocation, Tax sharing, Tax indemnification or similar agreement or has been a member of an affiliated, combined, consolidated or unitary group of companies of which a Company Party is not the common parent or has any liability for the Taxes of any other person under Treasury Reg. Section 1.1502-6 (or any similar provision of any Tax law or regulation) as a transferee or successor, by contract, or otherwise, (l) 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 Section 481 of the Code (or any similar provision of any Tax law or regulation) occurring prior to the Closing, (ii) a "closing agreement" as described in Section 7121 of the Code entered into prior to the Closing or (iii) an election under Section 108(i) of the Code made prior to the Closing or (iv) an installment sale or open sale transaction occurring before the Closing Date, (m) 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, (n) no Company Party is a "United States real property holding corporation" within the meaning of Section 897(c)(2) of the Code, (o) no Company Party has been the subject of an audit or other examination in respect of Taxes, (p) no Company Party has granted a power of attorney relating to Tax matters that will be in effect after Closing to any person, (q) no tax rulings or requests for rulings have been applied for or obtained by any Company Party, (r) the Company has delivered or made available to Buyer copies of each of the Tax Returns filed by each Company Party since January 1, 2013, and (s) no entity has merged with or been liquidated into any Company Party.

Notwithstanding anything to the contrary in this Agreement, (i) the representations and warranties set forth in this Section 2.6 and Section 2.9 shall be the only representations or warranties in this Agreement with respect to Taxes, and (ii) the Sellers make no representations or warranties regarding the amount, value or condition of, or any limitations on, any Tax asset or attribute (e.g., net operating losses) (each, a "Tax Attribute") of the Company Parties arising in any Pre-Closing Period, the ability of the Buyer or any Company Party to use any Tax Attributes after the Closing or any Tax positions that Buyer or its Affiliates (including the Company Parties) may take in or in respect of a taxable period (or portion thereof) beginning after the Closing Date.

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. To the Company's Knowledge there are no claims or Legal Proceedings against any director, officer or employee of any Company Party (in their capacities as such). There are no claims or Legal Proceedings pending in which a Company Party is a plaintiff or in which a Company Party is otherwise seeking recovery. No Company Party is subject to any Order, settlement agreement or stipulation, nor is any Company Party in breach or violation of any Order, settlement agreement or stipulation.

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 in the last three years any written notice from any Governmental Body or any other Person regarding (i) any actual, alleged or potential violation of or liability under any Legal Requirement, or (ii) any actual, alleged, or potential obligation of such Company Party to undertake or pay for any response action required by any Legal Requirement. To the Company's Knowledge, no Company Party is under investigation or inquiry with respect to the violation of any Legal Requirement.

(b) Schedule 2.8(b) sets forth all material Governmental Authorizations held by the Company Parties, which constitute all material Governmental Authorizations required for each Company Party to conduct its business as currently conducted. All such Governmental Authorizations are valid and in full force and effect and no Company Party is in default under or violation of (and no event has occurred that, with notice or the lapse of time or both, would constitute a default under or violation of) any term, condition or provision of any Permit held by it. All material fees and charges with respect to such Governmental Authorizations due and payable as of the date hereof have been paid in full. 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. No Company Party has received written notice in the last two years of any loss of or refusal to renew any Governmental Authorization held by it.

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 and total compensation in 2015 (including bonus), accrued vacation and severance pay of each officer, director and employee of the Company Parties. **Schedule 2.9(a)** lists each Contract (i) for the employment of any individual or (ii) relating to the payment of any severance or termination payment to any current of former employee or independent contractor. Each Company Party has complied in all material respects with all Legal Requirements relating to employment and terms and conditions of employment, immigration, wages, occupational safety and health.

(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 each independent contractor who currently provides services to any Company Party. Each Company Party has properly classified for all purposes (including for all Tax purposes and for purposes of determining eligibility to participate in any Employee Plan) all employees and independent contractors of the Company Party.

(d) Since January 1, 2014, no Company Party has effectuated (a) a "plant closing" as defined in the WARN Act affecting any site of employment or one or more facilities or operating units within any site of employment or facility, or (b) a "mass layoff" as defined in the WARN Act affecting any site of employment or facility.

(e) **Schedule 2.9(e)** sets forth a list of each "employee benefit plan" (as defined in Section 3(3) of ERISA) and each bonus, equity rights, deferred compensation, change in control, profit sharing, vacation, cafeteria, fringe benefit or welfare benefit plan, program or arrangement (whether qualified or nonqualified) to which any Company Party is a party, with respect to which any Company Party has or may reasonably be expected to have any obligation or liability, or which is maintained, contributed to or sponsored by any Company Party (each of the foregoing, an "***Employee Plan***"). Except as required by Section 4980B of the Code, none of the Employee Plans provides welfare benefits following termination of employment of an employee of any Company Party.

(f) The Company has made available to the Buyer with respect to each Employee Plan, to the extent applicable, (i) a true and complete copy of each governing plan document, all amendments thereto, and each summary plan description, (ii) each trust agreement, insurance Contract, the latest financial statements and documents governing funding of the Employee Plan, (iii) the most recent IRS Form 5500, and (iv) if the Employee Plan is unwritten, a written description of the material terms thereof. Each Employee Plan has been operated in material compliance with its terms and the requirements of ERISA, the Code and other applicable Legal Requirements. Each Employee Plan intended to be qualified under Code Section 401(a) is so qualified, and the Company has received a favorable determination letter from the IRS or is entitled to rely on a favorable opinion letter from the IRS with respect to such Employee Plan. All contributions with respect to each Employee Plan relating to the period prior to and including the Closing Date have been made by the Company.

(g) 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***").

(h) 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.

2.10 **Insurance**. The Company Parties maintain the insurance coverage set forth on **Schedule 2.10**. Each insurance policy is in full force and effect and provides coverage as may be required by applicable Legal Requirements or by the Contracts to which the Company Parties are parties. All premiums due and payable under all policies have been paid, and the Company Parties are otherwise in compliance with the terms and conditions of such policies. There is no claim pending under any such policy and 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 or has ever owned any real property and no Company Party has ever been a lessor or sublessor of real property. The Leased Real Property constitute all interests in real property and all facilities currently occupied, used or held for use in connection with the businesses of the Company Parties. The Company Parties enjoy quiet and undisturbed possession of each applicable Leased Real Property. No party to any Lease has exercised any right of termination, extension, renewal, purchase option, expansion or right of first refusal with respect to any Lease. There is no Person other than the applicable Company Party that is in possession of or uses or occupies any portion of any Leased Real Property. To the Knowledge of the Company, there is no condemnation, expropriation, environmental, zoning or other land-use regulation proceeding pending or threatened with respect to any Leased Real Property.

2.12 **Bank Accounts**. **Schedule 2.12** lists each bank account or safety deposit box 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) Each of the Products is set forth on **Schedule 2.13(a)** and is subject to the Governmental Authorization set forth opposite the name of such Product on **Schedule 2.13(a)**. Each Product's Drug Master Files, as defined in 21 C.F.R. Section 314.420 ("DMFs"), in the possession of the FDA, and each equivalent file in the possession of any other Governmental Body, is complete, accurate and up to date in all material respects, and the subject of each such DMF and equivalent file can be legally manufactured or utilized in compliance with the pertinent DMF or equivalent file. Each of the Products manufactured and tested for use in a product whose regulatory submission references a DMF or equivalent file is being manufactured and tested in compliance with the terms of the current version of such applicable file. To the Knowledge of the Company, all Persons involved in the manufacturing, warehousing, distributing and testing of the Products on behalf of the Company Parties are and have been for the last two years in compliance in all material respects with all applicable Legal Requirements, including the rules and regulations of all applicable Governmental Bodies, including U.S. Current Good Manufacturing Practice Regulations and equivalent foreign rules and regulations.

(b) No Company Party has received any notices or correspondence from the FDA or any Governmental Body exercising comparable authority requiring the recall, withdrawal, termination or suspension of sale of the Products or otherwise alleging that any Company Party or any Product is not in compliance in all material respects with all applicable Legal Requirements. No Legal Proceeding seeking the recall, withdrawal, suspension or seizure of any of the Products has ever been pending or, to the Company's Knowledge, threatened. None of the Products has been (i) adulterated within the meaning of 21 U.S.C. Section 351 (or any equivalent Legal Requirement); (ii) misbranded within the meaning of 21 U.S.C. Section 352 (or any equivalent Legal Requirement); or (iii) produced in violation of 21 U.S.C. Section 355 (or any equivalent Legal Requirement).

(c) None of the Company Parties, nor any of their respective directors, managers, officers or employees, nor, to the Company's Knowledge, any of their respective agents or contractors is or has been the subject of any pending or threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, or by any other comparable Governmental Body pursuant to 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 its policies regarding such matters, such as the FDA's "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy.

(d) None of the Company Parties, nor any of their respective directors, managers, officers or employees, nor, to the Company's Knowledge, any of their respective agents or contractors has been debarred or convicted of any crime or engaged in any conduct that did or could result in debarment under 21 U.S.C. § 335a, exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7, disqualification as a clinical investigator under 21 C.F.R. § 312.70 or similar consequence under any similar Legal Requirements, and none of such Persons has engaged in any conduct that would reasonably be expected to result in debarment, exclusion, or disqualification from U.S. federal health care programs.

(e) None of the Company Parties, nor any of their respective directors, managers, officers or employees has received any written notice or communication from the FDA, DEA, or other Governmental Body relating to (i) adverse inspection, investigation or corrective or remedial action with respect to the Persons engaged in manufacturing, warehousing, testing or distributing the Products; or (ii) termination or suspension of sale of the Products or alleging noncompliance with any applicable FDA Law, DEA Law, or other applicable Legal Requirements with regard to the Products. Neither the Company nor any of its officers has been or is subject to any enforcement proceedings (including seizure or injunction) by the FDA, DEA, or other Governmental Body and, to the Company's Knowledge, no such proceedings have been threatened. None of the Company Parties has received any written notice in the last two years that any Governmental Body has commenced, or threatened to commence, any Legal Proceeding to withdraw its approval, registration or licensure of any Product.

(f) Each Company Party is duly authorized to sell the Products in each of the jurisdictions in which it is currently selling the Products. To the extent that any of the Products is intended for export from the United States or import into any country, each Company Party is in compliance in all material respects with the applicable Legal Requirements of such country.

(g) The Company Parties have provided to the Buyer all material documents in their possession or control concerning communications from or to any Governmental Body in the last two years relating to (i) establishment inspection reports and (ii) warning letters relating to the Products.

(h) The Company Parties have provided to the Buyer accurate and complete copies of all Periodic Adverse Experience Reports filed by or on behalf of, and all Periodic Safety Update Reports generated by or on behalf of, the Company Parties for the last two years.

(i) None of the Company Parties nor any of their respective officers, directors or managers is a Prohibited Person. No Company Party has engaged in a transaction involving, directly or indirectly, a Prohibited Person or Iran, Sudan, Syria or any other country against which the United States imposes a trade embargo.

(j) None of the Company Parties nor any of their respective officers, directors, managers, employees, or to the Knowledge of the Company its agents or consultants or any other Person acting for or on behalf of any Company Party has:

(i) made, undertaken, offered to make, promised to make or authorized the payment or giving of any bribe, rebate, payoff, influence payment, kickback or other payment or gift of money or anything of value (including meals or entertainment), to any officer, employee or ceremonial office holder of any government or instrumentality thereof, any political party or supra-national organization (such as the United Nations), any political candidate, any royal family member or any other person who is connected or associated personally with any of the foregoing for the purpose of influencing any act or decision of such payee in his official capacity, inducing such payee to do or omit to do any act in violation of his lawful duty, securing any improper advantage or inducing such payee to use his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality ("Prohibited Payments");

(ii) been subject to any investigation by any Governmental Body with regard to any actual or alleged Prohibited Payment;

(iii) used funds or other assets, or made any promise or undertaking in such regard, for the establishment or maintenance of a secret or unrecorded fund (a "Prohibited Fund"); or

(iv) made any false or fictitious entries in any books or records of any Company Party relating to any Prohibited Payment or Prohibited Fund.

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 a valid and enforceable right to use (which right will remain in full force and effect immediately upon consummation of the Transactions) all of the Proprietary Rights that the Company Parties use in their business as of the date hereof (the "***Company Proprietary Rights***"). 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. The Company Parties have complied in all material respects with their respective duties of disclosure to the U.S. Patent and Trademark Office regarding each applicable item of registered Company Proprietary Rights. None of the Sellers nor any officer, director, manager, employee or independent contractor of any Company Party, or any of their respective Affiliates (other than the Company Parties), has any ownership, royalty or other right to or interest in any of the Company Proprietary Rights.

(b) **Schedule 2.15(b)** sets forth a true and complete list or description of all Contracts under which a Company Party has licensed or assigned any Company Proprietary Rights to a third party. Neither the applicable Company Party nor, to the Knowledge of the Company, the applicable third party is in default in the performance, observance or fulfillment of any obligation, covenant or condition contained in any Contract pursuant to which the Company Party licenses to or from a third party the right to use any Company Proprietary Right.

(c) To the Knowledge of the Company: (i) no Company Party is infringing upon, violating or misappropriating any Proprietary Right of any other Person, and (ii) no Person is infringing upon, violating or misappropriating any Company Proprietary Right. No Seller or Company Party has received in the last two years any written claim of any infringement, violation, misappropriation or dilution by, or other possible conflict with, any third party with respect to any of the Products, the Company Proprietary Rights, or activities necessary to conduct the businesses of the Company Parties as currently conducted. No claims are pending or, to the Company's Knowledge, threatened against any Company Party by any Person: (A) contesting the validity, enforceability, use or ownership of any Company Proprietary Right; (B) that such Person has any right, title or interest in or to any of the Company Proprietary Rights; (B) that such Person has the right to use any of the Company Proprietary Rights; or (C) to the effect that any action by any Company Party infringes any Proprietary Right of such Person. No loss, expiration, reexamination, reissue, opposition, or declaratory judgment action pertaining to any Company Proprietary Right is pending or, to the Company's Knowledge, threatened.

(d) All employees, contractors and consultants retained or hired by the Company Parties have executed and delivered to the applicable Company Party (i) confidentiality, proprietary information, non-competition, non-use, non-disparagement, non-solicitation and non-disclosure agreements and (ii) intellectual property assignment agreements, in each case in form and substance reasonably acceptable to the Buyer, and no employee, contractor or consultant of any Company Party is in violation of any such agreement.

(e) The Company Parties have not developed any Proprietary Rights using any funding provided by any college or university or any Governmental Body.

(f) All necessary registration, maintenance, renewal and other relevant filing fees in connection with any registered Company Proprietary Rights have been timely paid, and all necessary documents, certificates and other relevant filings in connection with such Company Proprietary Rights have been timely filed with the relevant Governmental Authorities in the United States or foreign jurisdictions, as the case may be, for the purpose of maintaining such Company Proprietary Rights and all issuances, registrations and applications therefor.

(g) All data, including personally identifiable information and other information relating to Persons that is protected by Legal Requirements, that has been collected, imported, exported, stored, maintained, disclosed or otherwise used by the Company Parties have been collected, imported, exported, stored, maintained, disclosed and used in accordance with all applicable Legal Requirements. To the Knowledge of the Company, there have been no security breaches compromising the confidentiality or integrity of such information. No Company Party has received in the last two years a written notice of noncompliance with applicable data protection Legal Requirements.

2.16 **Supply Arrangement**. **Schedule 2.17** sets forth a list of all supply agreements for goods or services related to the 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, to otherwise terminate or materially reduce its relationship with such Company Party, or, except as set forth in a Contract of a Company Party, to increase its prices for such goods and services.

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 sale or delivery of goods or materials by or to a Company Party of an amount or value in excess of **$**25,000 per year or that has obligations that continue for longer than 12 months and, in either case, is not cancelable without penalty on 30 days' notice or less;

(ii) is a Contract that is or relates to the grant or receipt by a Company Party of any license of Proprietary Rights;

(iii) is a Contract that is a lease agreement with respect to real property ("***Leases***");

(iv) is a Contract of any Company Party with any other Company Party, any Seller or any Affiliate of any Seller, or any officer, director or employee of such Company Party or any other Company Party;

(v) is a Contract with investment bankers, financial advisors, attorneys, accountants or other advisors retained by any Company Party, or that involves a sale or license of assets of a Company Party outside the Ordinary Course of Business;

(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 relating to any Company Indebtedness (excluding trade payables in the Ordinary Course of Business) or that grants any Encumbrance on any of the assets of any Company Party;

(viii) is a partnership, joint venture agreement, strategic alliance agreement or other similar agreement involving co-investment with a third party to which any Company Party is a party, or is a Contract involving a merger, business combination or other fundamental business transaction involving a Company Party;

(ix) is a Contract with a Governmental Body; or

(x) is a Contract that (A) contains non-competition, exclusivity, or other covenants limiting or restricting the ability of a Company Party or any Affiliate of a Company Party to engage directly or indirectly in any business, including with respect to geographic areas. (B) grant rights of first refusal, rights of first negotiation or similar rights or terms to any Company Party or any Person, (C) limits the ability of any Company Party or any Affiliate of a Company Party to solicit any customers, employees or clients of any other Person, (D) requires a Company Party or any Affiliate of any Company Party to provide to any other Person "most favored nation" pricing, or (F) requires a Company Party or an Affiliate of a Company Party to market or co-market any products or services of a third party.

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, or detailed descriptions of any oral 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, and 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; and no event has occurred that with the lapse of time or the giving of notice or both would constitute a breach or default by a Company Party or any other party thereunder. No Company Party has received in the last two years written notice from a counterparty to any Material Contract (i) alleging a breach or default under such Material Contract, (ii) alleging termination, rescission, invalidity or unenforceability of such Material Contract, or (iii) of any intention to terminate such Material Contract or to exercise (other than in the normal course of performance) any right or remedy exercisable on breach or default under such Material Contract.

2.18 **Title to Assets**. Each Company Party has good and valid title to, or a valid leasehold interest in, all real property and personal property used by it in connection with its business as presently conducted, in each case free and clear of any Encumbrance, and all 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. The molds for production of the Flexichamber are in satisfactory operating condition and free from material defects, in each case subject to ordinary wear and tear, and are suitable for the purposes used.

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 operate the Company Parties' respective businesses as conducted on the date of this Agreement and 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 any 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 **Related Party Transactions**. No employee, officer, director, manager or member of any Company Party, or any member of any such Person's immediate family ("Related Persons"), directly or indirectly, (a) owes any amount to any Company Party or is owed any amount by a Company Party, (b) is involved in any business arrangement or other relationship with any Company Party (whether written or oral), (c) owns any property or right, tangible or intangible, that is used by a Company Party, (d) has any claim or cause of action against a Company Party or (e) owns or holds any direct or indirect interest of any kind in, or controls or is a director, officer, employee or partner of, equity holder in, consultant to, or lender to or borrower from, or otherwise has the right to participate in the profits of, any Person that is a competitor, supplier, customer, landlord, tenant, creditor or debtor of a Company Party.

2.24 **Distributions to Sellers**. Since the Balance Sheet Date, no Company Party has made any dividend or distribution of cash or other assets to any Seller except for repayments of Company Indebtedness.

2.25 **No Other Representations or Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 2 AND SECTION 3, NEITHER THE SELLERS 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.

3. **REPRESENTATIONS AND WARRANTIES OF THE SELLERS**

Each Seller severally represents and warrants to the Buyer as follows.

3.1 **Organization; Good Standing**. If not a natural person, such Seller is duly organized, validly existing and in good standing under the laws of the state of its formation.

3.2 **Authority; Enforceability**. Such 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 such 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 such Seller. Each Seller Document has been duly and validly executed and delivered by such 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 such Seller nor the performance of its obligations thereunder nor the consummation by such 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 **Title to Units**. Such Seller is the sole owner of the Units reflected next to such Seller's name on **Schedule 2.3** and has, and will have as of the Closing, good, valid and marketable title to such Units free and clear of any Encumbrances. Such Seller represents that such Seller has full right, power and authority to sell, transfer and deliver such Units to Purchaser, and, at the Closing, will transfer to Purchaser good, valid and marketable title thereto free and clear of any Encumbrances. Other than the operating agreement of the Company, such Seller is not party to any voting trust agreement or arrangement affecting the exercise of the voting rights of such Seller's Units. There is no Legal Proceeding against such Seller or such Seller's assets or properties pending or, to such Seller's knowledge, threatened, at law or in equity, or before any court, arbitrator or other tribunal, or before any administrative law judge, hearing officer or administrative agency relating to or in any manner affecting upon the Units held by such Seller.

3.5 **Consents and Approvals; No Violation**. Neither the execution and delivery of the Seller Documents by such 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 assets of such Seller 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 such Seller, if applicable, (B) any Contract to which such Seller is a party, or (C) any Legal Requirement or Order.

3.6 **No Other Representations or Warranties**. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 3 AND SECTION 2, NEITHER THE SELLERS 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 Sellers as follows.

4.1 **Organization; Good Standing**. The Buyer is duly organized, validly existing and in good standing under the laws of France. 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 them 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, as a Company Transaction 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. Such policy shall cover only those persons who are currently covered by the Company's existing directors' and officers' liability policy in effect as of the Closing Date and, in each case, only for matters occurring at or prior to the Closing.

(b) Subject to the Buyer's rights to indemnification as provided in **Section 6.2**, which shall supersede this Section 5.1(b), 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 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, accountants or co-investors (including outside auditors and legal counsel of such Party's accountants and co-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 current investor of such Party, in connection with investment decisions with respect to such Party or otherwise in connection with customary reports to such 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, Sellers 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 Sellers 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 Sellers 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, any attorney-client or other privilege or any confidentiality undertaking by such party, or in connection with a dispute between the requesting party and the providing party.

5.4 **Tax Return Matters**.

(a) The Company Parties shall (and the Buyer shall cause the Company Parties to), at the Seller's expense, engage and direct the Company's existing accounting firm, Susan S. Hooper, CPA, to prepare any and all Tax Returns for the Company Parties for all Tax periods that end on or before the Closing Date. Such Tax Returns shall be prepared in a manner consistent with past practices for Tax Returns (unless otherwise required by applicable Legal Requirements) for periods prior to the Closing.

(b) The Buyer shall prepare, at the Buyer's expense, any and all Tax Returns for the Company Parties for all Straddle Periods. Such Tax Returns shall be prepared in a manner consistent with past practices of the Company Parties for Tax Returns (unless otherwise required by applicable Legal Requirements) for periods prior to the Closing. At least 20 days prior to the due date for filing any Tax Return for any Straddle Period, the Buyer shall deliver, or caused to be delivered, to the Sellers such Tax Return for their review and approval (not to be unreasonably withheld, conditioned or delayed). Unless any Seller gives written notice to the Buyer 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 Sellers shall be deemed to have accepted and agreed to such Tax Return. The Sellers shall be responsible for paying, and shall pay to Buyer at least two (2) days prior to the due date for filing of any Straddle Period Tax Returns pursuant to this Section 5.4(b), the Taxes shown on such Tax Returns that are attributable to the period ending on and including the Closing Date (as determined pursuant to Section 5.4(d)), but excluding any such Taxes that were taken into account as liabilities in the calculation of the Closing Working Capital, and the Buyer shall be responsible for paying the portion of the Taxes shown on such Tax Returns that are attributable to the period beginning on the day after the Closing Date (as determined pursuant to Section 5.4(d)).

(c) If any Seller timely notifies the Company of its objection to any Straddle Period Tax Return prepared hereunder for any taxable period that includes (but does not end on) the Closing Date, the Buyer, the Company and the Sellers 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 Straddle Period Tax Return is subject to an ongoing dispute under this **Section 5.4(c)** 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 Sellers 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. Any overpayment of Taxes by Sellers pursuant to Section 5.4(b) based on the revised Straddle Period Tax Return liability shall be promptly refunded by Buyer to the Sellers.

(d) If the Parties are permitted to treat the Closing Date as the last day of a taxable period, the Sellers and the Buyer shall treat (and cause their respective Affiliates to treat) the Closing Date as the last day of a taxable period. All Taxes of the Company Parties for any Straddle Period shall be apportioned between the Pre-Closing Period and the period beginning on the day after the Closing Date as follows: the portion of any such Tax that is allocable to the portion of the period ending on or before the Closing Date shall be paid by the Sellers, and such portion shall (i) in the case of Taxes based upon or related to income, sales or receipts, be the amount which would be payable if the taxable year ended on (and included) the Closing Date; and (ii) in the case of all other Taxes, be the amount of such Taxes for the Straddle Period (or, in the case of such Taxes determined on an arrears basis, the amount of such Taxes for the immediately preceding period) multiplied by a fraction the numerator of which is the number of calendar days in the portion of the Straddle Period ending on (and including) the Closing Date and the denominator of which is the number of calendar days in the entire Straddle Period. The federal (and, if applicable, state) income Tax Return for FSC Labs shall include an election under Treas. Reg Section 1.382-6(b)(1) to close its books on the Closing Date and/or any prior ownership change date occurring during the same taxable year as the Closing Date. Notwithstanding anything in this Section 5.4 to the contrary, the Sellers will pay, or cause to be paid, one-half, and the Buyer will pay, or cause to be paid, one-half of all applicable transfer Taxes, sales and/or use Taxes, real property transfer or excise Taxes, recording, deed, stamp, and other similar Taxes, fees and duties under applicable law incurred in connection with the transfer of the Units to the Buyer. The Sellers and the Buyer agree to jointly prepare or cause to be prepared and file or cause to be filed in a timely manner, all Tax Returns required to be filed with respect to such Taxes.

(e) After the Closing, upon reasonable written notice, the Buyer (or the Company Parties) and the Sellers 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 for a period of at least seven (7) years following the Closing Date, provided however, that the Buyer shall give the Sellers reasonable written notice prior to transferring, destroying or discarding any such books and records and shall allow the Sellers to take possession of such books and records.

(f) Neither the Buyer nor any Company Party may amend a Tax Return of any of the Company Parties with respect to a Pre-Closing Period, or file or amend any tax election with respect to any of the Company Parties with respect to a Pre-Closing Period, in each case, without the prior written consent of the Sellers (which consent may not be unreasonably withheld, conditioned or delayed).

(g) 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 Pre-Closing Period, the Buyer shall cause the applicable Company Parties to promptly pay any such refund or credit, and any interest received thereon, to the Sellers upon receipt or realization thereof; provided, that, except as otherwise provided in **Section 6.4(i)**, 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.

5.5 **FSC Name**. Sellers acknowledge and agree that as of the Effective Time, the Sellers shall retain no right, title or interest in or to the "FSC" 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, that from and after the Effective Time, Buyer and the Company Parties shall have the sole right to the name "FSC" and all similar names and all such trademarks, service marks, etc. After the Closing Date, Sellers further acknowledge and agree not to use the name "FSC" or any variation thereof or confusingly similar name or mark as or in a company or subsidiary name or in connection with any of Sellers' or their affiliates' future products, services or businesses, and further agree not 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 this Agreement.

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 for twenty years after the Closing Date 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 90 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 and other provisions set forth in this **Section 6**, the Buyer and its Affiliates (including the Company Parties from and after the Closing) and each of their respective officers, directors, managers, agents, employees, successors and assigns (collectively, "***Buyer Indemnified Parties***") shall be entitled to be indemnified and held harmless, solely out of a right of set off against amounts due under the Deferred Payments 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 (collectively, "***Damages***"), arising out of, resulting from or relating to:

(a) any inaccuracy in or breach of any representation or warranty contained in **Section 2** or **Section 3** of this Agreement;

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Sellers pursuant to this Agreement; and

(c) without duplication, (i) Pre-Closing Taxes (excluding Buyer's share of any Transfer Taxes under Section 5.4(d)); (ii) Taxes for which any Seller is liable under applicable U.S. federal, state or local Tax law that are imposed on any Buyer Indemnified Party as a result of the Closing transactions (excluding Buyer's share of any Transfer Taxes under Section 5.4(d)); and (iii) Taxes imposed on the Buyer or any Company party as a result of any Company Party being or having been a member of an affiliated, combined, consolidated or unitary group of companies of which a Company Party is not the common parent; provided, however, that no Buyer Indemnified Party shall be entitled to indemnity under this clause for Taxes resulting from any action or event outside the ordinary course of business occurring on the Closing Date but after the Closing or for Taxes taken into account as liabilities in the calculation of the Closing Working Capital or for Taxes arising from any breach by Buyer or any of its Affiliates of any covenant or agreement in this Agreement.

6.3 **Buyer Indemnification**. The Buyer shall indemnify and hold harmless the Sellers and their respective officers, directors, managers, agents, employees, successors and assigns (collectively, "***Seller Indemnified Parties***") for, and shall pay to the Sellers, any and all Damages arising out of, resulting from or relating to:

(a) any inaccuracy in or breach of any representation or warranty contained in **Section 4** of this Agreement;

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Buyer pursuant to this Agreement;

(c) without duplication of any obligation of the Buyer or a Guarantor under **Section 1.8**, Taxes imposed on any Seller Indemnified Party as a result of any assignment or other transfer of any payment obligations of the Buyer or any Guarantor; and

(d) without duplication of any obligation of the Buyer under **Section 1.8**, all present or future non-U.S. stamp or documentary Taxes or any other excise or property Taxes, duties, other charges or similar levies, arising from any payment due to any Seller hereunder or from the execution, delivery, registration or enforcement of any Transaction Agreement or any security interest in the FSC Assets Collateral (excluding any such Taxes, duties, other charges or levies incurred in connection with the transfer of the Units to the Buyer, which are addressed in Section 5.4(d)).

6.4 **Limitations**. Notwithstanding anything set forth in this Agreement to the contrary:

(a) Subject to Section 6.4(h) and Section 6.7, (i) the Sellers shall not have any liability under this Agreement other than in connection with the right of the Buyer to set-off Damages against amounts due under the Deferred Payments in accordance with **Section 6.6** and (ii) except in connection with any breach of a representation or warranty set forth in **Section 2.22**, Sellers shall not have any liability in the aggregate in excess of the aggregate amount of Deferred Payments made by the Buyer hereunder.

(b) Buyer Indemnified Parties shall not be entitled to recovery under **Section 6.2(a)** unless the amount of Damages suffered or incurred by the Buyer Indemnified Parties in connection with breaches of the representations and warranties exceeds $15,000.

(c) Except in connection with breaches of any Fundamental Representations or any representation or warranty contained in **Section 2.6**, the Buyer Indemnified Parties shall not be entitled to recovery under **Section 6.2(a)** unless and until the aggregate amount of the Damages suffered or incurred by the Buyer Indemnified Parties exceeds $150,000, in which event the Buyer Indemnified Parties 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) All Damages recoverable by the Buyer as a right of the Buyer to set-off against amounts due under the Deferred Payments 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 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.

(f) Notwithstanding any other provision in this Agreement to the contrary, except in connection with Third Party Claims, the Buyer shall not be entitled to a right of set-off against amounts due under the Deferred Payments 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 of the business or the Units (but not diminution in value of any particular asset of the business).

(g) All amounts recovered by the Buyer as a right of set-off against amounts due under the Deferred Payments in accordance with **Section 6.6** shall be treated by the Parties as an adjustment to the Purchase Price.

(h) Notwithstanding the foregoing, none of the limitations set forth in this **Section 6**, whether time-based, monetary or otherwise, including the survival periods set forth in Section 6.1 and the limitations in **Section 6.4(a)**, shall apply to any Damages resulting from the willful misconduct, criminal act or fraud of a Party hereto.

(i) To the extent that a Tax Benefit is actually realized by an Indemnified Party as a result of Damages recovered by such Indemnified Party pursuant to Section 6.2 or Section 6.3, the Indemnified Party shall refund to the Indemnifying Party the amount of such Tax Benefit promptly after the Tax Return reflecting such Tax Benefit is filed with the applicable Taxing authority. For purposes of this Section 6.4(i), a "Tax Benefit" means an amount by which the Tax liability of an Indemnified Party is actually reduced by a deduction, reduction of income or entitlement to refund (including through a carry back to a prior taxable period) or credit. This Section 6.4(i) shall not be construed to require any Indemnified Party to (x) amend any Tax Return (y) pay any amount to an Indemnifying Party the payment of which would place the Indemnified Party in a less favorable net after-Tax position than the Indemnified Party would have been in if the Damages subject to indemnification and giving rise to the Tax Benefit had not been incurred and the indemnification payments with respect to such Damages had never been paid, or (z) make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the Indemnifying Party or any other Person. The Indemnifying Party shall, upon the request of the Indemnified Party, repay to the Indemnified Party the amount paid to such Indemnifying Party pursuant to this paragraph (i) (plus any penalties, interest or other charges imposed by the relevant Taxing authority) in the event that the Indemnified Party is required to repay a related Tax Benefit to such Taxing authority

6.5 **Procedure for Indemnification – Third-Party Claims**.

(a) If the Buyer shall claim a right of set-off against amounts due under the Deferred Payments in accordance with **Section 6.6** hereunder, or a Seller Indemnified Party shall make a claim for indemnification pursuant to **Section 6.3**, in each case, arising from any claim or demand of a third party (a "***Third Party Claim***"), the Indemnified Party shall notify the Indemnifying Party 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 an Indemnified Party and the Indemnified Party gives notice to the Sellers pursuant to **Section 6.5(a)**, the Indemnifying Party shall be entitled to participate in such Legal Proceeding and, to the extent that they wish, to assume the defense of such Legal Proceeding if (i) the Indemnifying Party provides written notice to the Indemnified Party that the Indemnifying Party intends to undertake such defense and (ii) the Indemnifying Party conducts the defense of the third-party claim diligently and with reputable counsel. The Indemnified Party shall, in its sole discretion, have the right to employ separate counsel (who may be selected by the Indemnified Party 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 Indemnified Party, unless the Indemnified Party has been advised by counsel that there exists a conflict of interest between the Indemnified Party and counsel chosen by the Indemnifying Party, in which case the fees and expenses of one separate counsel engaged by the Indemnified Party shall be paid by the Indemnifying Party. The Indemnified Party shall cooperate in all reasonable respects with the Indemnifying Party and their counsel in the defense or compromise of such claim or demand. If the Indemnifying Party assumes the defense of a Legal Proceeding, no compromise or settlement of such claims may be effected by the Indemnifying Party without the Indemnified Party'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 adverse effect on the Indemnified Party with respect to any other claims that may be made against it, and (B) the sole relief provided is monetary damages that, in the case of a claim made in accordance with **Section 6.6,** are paid in full as a right of set-off against amounts due under the Deferred Payments in accordance with **Section 6.6**.

(c) If (i) notice is given to the Indemnifying Party of the commencement of any third-party Legal Proceeding and the Indemnifying Party does not, within thirty days after the Indemnified Party's notice is given (or such shorter period as may be necessary to respond to the relevant complaint), give notice to the Indemnified Party 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 Indemnified Party shall (upon notice to the Indemnifying Party) have the right to undertake the defense, compromise or settlement of such claim, the costs of which shall be included in the calculation of Damages of the Indemnified Party; provided that no compromise or settlement of such claim may be affected by the Indemnified Party without the Indemnifying Party's consent, which shall not be unreasonably withheld or delayed, if (A) the Indemnified Party will seek indemnification for any amounts to be paid to compromise or settle the claim, (B) there is a finding or admission of any violation by the Indemnifying Party of any Legal Requirement or the rights of any Person, or (C) the compromise or settlement would have a material adverse effect on the Indemnifying Party with respect to any other claims that may be made against it.

(d) For the avoidance of doubt, this **Section 6.5** shall not prevent any Indemnified Person from making a claim for indemnification or recovering Damages in connection with any event or occurrence that does not involve a claim by a third party.

(e) Notwithstanding the foregoing provisions of this **Section 6.5**, any non-U.S. Taxes described in **Section 6.3(d)** shall be paid when due without any right of contest if the non-payment of such Taxes would involve any risk of the sale, forfeiture or loss of, or the creation of any lien on all or any part of the FSC Assets Collateral or any risk of criminal liability to any Seller.

6.6 **Right of Set-Off**. The Buyer shall be entitled to withhold from the amount to be paid under one or more Deferred Payments (but not the Fixed Payments) any amount it in good faith believes a Buyer Indemnified Party is or may be entitled to recover under **Section 1.3(e)** or **Section 6.2** (subject to the limitations set forth in this **Section 6**). If Buyer elects to exercise such right hereunder, it shall promptly notify Sellers specifying in reasonable detail the basis of its claim and such withholding. Upon final determination of the claim made by the Buyer Indemnified Parties hereunder, whether by a court order or final settlement of the dispute, Buyer shall be entitled to retain that portion of the withheld amount required to satisfy the claim in full and shall pay the remainder of amounts that were withheld but not due to Buyer, if any, together with interest at 7.0% per annum, to the Sellers. Neither the exercise of nor the failure to exercise such right of set off shall limit the right of Buyer to exercise any other remedies that may be available to it.

6.7 **Exclusive Remedy**. Except with respect to claims of fraud, criminal activity or willful misconduct, the right of the Buyer to indemnification in accordance with **Section 6.2** and the right of Buyer to set-off in accordance with **Section 6.6** shall constitute the Buyer's sole and exclusive remedies 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.

6.8 **No Right of Contribution**. No Seller shall make any claim for contribution from any Company Party or any Company Party's current or former Affiliates, officers, directors, managers or employees with respect to any indemnity claims arising under or in connection with this Agreement, and the Sellers hereby waive any such right of contribution from the Company Parties and their respective current and former Affiliates, officers, directors, managers and employees.

6.9 **Effect of Investigation; Reliance**. The right to indemnification, recovery of Damages or any other remedy will not be affected by any investigation conducted with respect to, or any knowledge acquired (or capable of being acquired) at any time, whether before or after the execution and delivery of this Agreement or the Closing Date, with respect to the accuracy or inaccuracy of or compliance with any representation, warranty, covenant or agreement made by the party seeking indemnification or recovery. The waiver of any condition based on the accuracy of any such representation or warranty, or on the performance of or compliance with any such covenant or agreement, will not affect the right to indemnification, recovery of Damages or any other remedy based on any such representation, warranty, covenant or agreement. No party seeking indemnification or recovery under this Agreement shall be required to show reliance on any representation, warranty, certificate or other agreement in order for such party to be entitled to indemnification or recovery hereunder.

7. **MISCELLANEOUS PROVISIONS**

7.1 **Amendment**. This Agreement may not be amended except by an instrument in writing signed on behalf of each 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. The Buyer 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. Each Party waives any right it may have to trial by jury in any Legal Proceeding commenced in connection with this Agreement, whether such Party is a plaintiff or defendant in such Legal Proceeding. 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 (which consent shall not be unreasonably withheld, conditioned or delayed), 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 1.6** of this Agreement to any other Person without the prior written consent of the Buyer or any other Party; and provided that the Buyer may assign its rights and/or obligations under this Agreement to an Affiliate without the prior written consent of the Sellers or the Company so long as it remains directly liable for all of its obligations under this Agreement. 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, by facsimile or by e-mail to the address, facsimile telephone number or e-mail address set forth beneath the name of such Party below (or to such other address, facsimile telephone number or e-mail address as such Party shall have specified in a written notice given to the other Parties):

if to the Sellers:

780 Third Avenue
37th Floor
New York, NY 10017
Fax: (212) 573-8111
E-mail:
Attention: James E. Flynn
Peter Steelman
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
E-mail:
Attention: Mark O. Henry

if to the Buyer or the Company:

Flamel Technologies S.A.
Parc club du Moulin a Vent
33, avenue du Docteur Georges Levy
69693 Vennissieux Cedex France
Attention:

with a copy to (which shall not constitute notice):

Orrick, Herrington & Sutcliffe LLP
51 W. 52nd St.
New York, NY 10019
Fax: (212) 506-5151
Email: kmilling@orrick.com
thacohen@orrick.com
Attention: R. King Milling, Jr.
Tal Hacohen

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 **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 7.9** 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.

7.10 **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.

FSC HOLDING COMPANY, LLC

By: /s/ Peter Steelman
Name: Peter Steelman
Title: President and CEO

FSC THERAPEUTICS, LLC

By: /s/ Peter Steelman
Name: Peter Steelman
Title: President and CEO

FSC LABORATORIES, INC.

By: /s/ Peter Steelman
Name: Peter Steelman
Title: President and CEO

DEERFIELD CSF, LLC

By: /s/ David J. Clark
Name: David J. Clark
Title: Authorized Signatory

/s/ Peter Steelman
Peter Steelman

/s/ James Flynn
James Flynn

FLAMEL TECHNOLOGIES SA,
solely for purposes of Section 1.7

By: /s/ Michael S. Anderson
Name: Michael S. Anderson
Title: Chief Executive Officer

FLAMEL US HOLDINGS, INC.

By: _____
Name:
Title: Authorized Signatory

EXHIBIT A

CAPITALIZED TERMS

For purposes of the Agreement (including this **Exhibit A**):

"***Accelerated Value***" shall mean as of any date of determination, (i) all of the remaining unpaid Fixed Payments plus (ii) $12,500,000 minus (iii) the amount of Deferred Payments paid by the Buyer to the date of determination.

"***Acceleration Trigger Event***" shall mean the occurrence of any one or more of the following events:

(a) The Buyer shall, on its own behalf, (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 the Buyer 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;

(c) The Company transfers (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 other than in a Reincorporation Transaction (in which case this provision shall apply thereafter to New Subsidiary); 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 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 Products; or

(d) The material breach of any of the covenants set forth in **Section 1.6(j)**, which breach is not cured within ten Business Days after notice of such breach is delivered to Buyer.

"***Affiliated Company Indebtedness***" means all Company Indebtedness owed by the Company Parties to Deerfield PDI Financing II, L.P. and/or Deerfield Private Design Fund II, L.P. that remains outstanding as of the Closing Date.

"***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.

"***Closing Working Capital***" means the consolidated current assets of the Company Parties less the consolidated current liabilities of the Company Parties, prepared from the books and records of the Company and calculated in accordance with GAAP and the Company's accounting policies and procedures, consistently applied.

"***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, or pursuant to any guaranty or arrangements having the economic effect and interest (including default interest), premiums, penalties (including prepayment and early termination penalties and default penalties or judgments), breakage fees and other amounts owing in respect of such obligations or guarantees.

"***Company Party***" means the Company or any 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, and shall include all amendments and modifications thereto.

"***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%, or, if lower, the highest maximum rate permitted by law.

"***DGCL***" shall mean the General Corporation Law of the State of Delaware.

"***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 the Buyer is obligated to file reports under the provisions of the Securities Exchange Act of 1934, the Form 6-K filed by the Buyer containing its financial information for such quarter and (ii) during any period when the 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, profits 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.

"***Fundamental Representations***" means those representations and warranties set forth in **Sections 2.1** (Organization; Good Standing; Enforceability), **2.2** (Consents and Approvals; No Violation), **2.3** (Capital Stock; Subsidiaries), **2.5(a)** (No Distributions), **2.18** (Title to Assets), 2.21 (Brokers), **2.22** (Transaction Payments), **2.24** (Distributions to Sellers) and all of Article 3.

"***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).

"***Indemnified Party***" shall mean a Seller Indemnified Party or a Buyer Indemnified Party, as the case may be.

"***Indemnifying Party***" shall mean the Sellers pursuant to Section 6.2 or the Buyer pursuant to Section 6.3, as the case may be.

"***IRS***" shall mean the United States Internal Revenue Service or any successor agency thereto.

"***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 of the Company***" means the knowledge, after due inquiry, of Peter Steelman or Bryan Sendrowski.

"***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, Order, rule, regulation or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

"***Licensed Professional***" means a health care practitioner who has pharmaceutical product prescribing authority in the United States and includes medical doctors, doctors of osteopathy, nurse practitioners and physician assistants.

"***Lower Target Amount***" means -$50,000 (negative fifty thousand dollars).

"***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.

"***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 Products, sold globally in *bona fide*, arm's length transactions, less customary deductions determined without duplication in accordance with the selling Person's customary accounting methods as generally and consistently applied for: (i) cash or terms discounts, (ii) sales, use and value added taxes (if and only to the extent included in the gross invoice amount), (iii) reasonable and customary accruals for third party rebates and chargebacks, (iv) returns, and (v) recalls.

"***New Parent***" shall mean an entity organized under the Laws of the Republic of Ireland which is the surviving or resulting entity of a Reincorporation Transaction.

"***New Subsidiary***" means a wholly-owned subsidiary of the New Parent that owns all of the FSC Assets.

"***NPA***" shall mean the Note Purchase Agreement substantially in the form attached hereto as **Exhibit B**.

"***Order***" means any order, injunction, judgment, doctrine, decree, ruling, writ, assessment or arbitration award of a Governmental Authority.

"***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.

"***P1***" means a Product Detail where the presentation of a Product during the Product Detail is the first presentation made or is the presentation that lasts longer than any other presentation during a meeting with a Licensed Professional.

"***P2***" means a Product Detail where the presentation of a Product during the Product Detail is the second presentation made or is the presentation that is shorter than the P1 Product Detail but lasts longer than any other presentation during a meeting with a Licensed Professional.

"***Party***" or "***Parties***" shall mean the Buyer, the Company and the Sellers.

"***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 and with respect to which adequate reserves have been established in the Company's financial statements in accordance with GAAP; (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.

"***Person***" shall mean any individual, Entity or Governmental Body.

"Pre-Closing Period" shall mean any taxable year or other taxable period of a Company Party ending on or prior to the Closing Date (including the portion of any Straddle Period ending on and including the Closing Date).

"Pre-Closing Taxes" shall mean all Taxes imposed on the Company Parties for any Pre-Closing Period.

"***Products***" means the products set forth on Schedule A-1(whether sold under the brand name set forth on Schedule A-1 or otherwise under the Governmental Authorization set forth on Schedule A-1).

"***Product Detail***" means a face-to-face meeting between a professional, trained, and qualified representative of a Company Party and a health care professional, during which a presentation of one or more of the Products is orally presented.

"***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 Products.

"***Product Regulatory Rights***" shall mean each and every investigational new drug application or new drug application and/or state license or registration that is held or obtained (if any) that is necessary to develop, conduct clinical trials relating to, manufacture, have manufactured, distribute, promote, market or sell the Products.

"***Prohibited Person***" means (i) a Person on the List of Specially Designated Nationals and Blocked Persons administered by the U.S. Department of the Treasury or the Denied Persons List or Entity List administered by the U.S. Department of Commerce; (ii) a Person on any list of sanctioned Persons administered by the European Union or Member of the European Union; (iii) the government of any nation against which the United States imposes a trade embargo, including any agency or instrumentality thereof; or (iv) a Person acting or purporting to act, directly or indirectly, on behalf of, or an entity that is majority owned or controlled by, any of the Persons covered by subparagraphs (i), (ii) or (iii).

"***Proprietary Rights***" means, with respect to a Person, all Copyrights, Marks, Trade Names, Trade Secrets, Patents, intellectual property rights in inventions and discoveries, intellectual property rights in internet web sites and internet domain names and subdomain names and intellectual property rights in Know-How, owned or used by such Person.

"***Representatives***" shall mean directors, officers, other employees, agents, attorneys, accountants, advisors and representatives.

"***Reviewing Accountant***" means one of the "Big Four" accounting firms or another nationally-recognized accounting firm mutually agreeable to the Buyer and the Sellers.

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.

"***Straddle Period***" shall mean any taxable year or other taxable period beginning before and ending after the Closing Date.

"***Tax***" shall mean (i) any federal, state, local, foreign or other taxes, levies, charges and fees or other similar governmental assessments or liabilities, 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 and (ii) any liability in respect of items described in clause (i) by reason of contract, assumption, transferee liability, operation of law, U.S. Treasury Regulations Section 1.1502-6 (or any predecessor or successor thereof or any analogous or similar provision under any law or regulation) or otherwise.

"***Tax Return***" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, disclosure, 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.

"***Transaction Agreements***" means this Agreement and each other agreement and document to be executed and delivered by a Party in connection with this Agreement.

"***Transaction Expenses***" means all fees and expenses incurred by Sellers or any Company Party at or prior to the Closing in connection with the transactions contemplated by this Agreement and the other Transaction Agreements (including preliminary discussions, term sheet negotiations and discussions with third parties), including any legal, accounting, broker's, investment banker, dataroom provider, financial printer and any other third party service provider fees and expenses, and including any change of control, severance, transaction bonus or similar payment committed to any officer, director or employee of a Company Party in connection with the execution of this Agreement or the consummation of the transactions contemplated hereby.

"***Upper Target Amount***" means $50,000 (fifty thousand dollars).

"***WARN Act***" means the Worker Adjustment and Retraining Notification Act of 1988, as amended, and any similar federal, state or local law.

ADDITIONAL DEFINITIONS

Each of the following definitions is set forth in the section of the Agreement indicated below:

Definition	Section
Audit Notice	1.6(d)
Balance Sheet	2.4
Balance Sheet Date	2.4
Buyer	Preamble
Buyer Documents	4.2
Closing	1.5(a)
Closing Date	1.5(a)
Company	Recitals
Company Transaction Payments	2.22
Deferred Consideration	1.6(a)
Deferred Payment	1.6(a)
Disclosure Schedule	2
Deferred Payment Calculation	1.6(b)
Deferred Payment Calculation Objection Notice	1.6(d)
Effective Time	1.5(a)
Financial Statements	2.4
Foreign Plan	2.9(d)
Leased Real Property	2.11
Material Contract	2.17(a)
Pension Plan	2.9(d)
Product Suppliers	2.16
Sellers	Preamble
Seller Documents	3.2
Units	Recitals

Brand Name	API	Governmental Authorization
Flexichamber	NA	510(k) – K140062
Karbinal ER	Cabinoxamine maleate	NDA – N022556
	Cefaclor	ANDAS – A065412 or A065146
AcipHex Sprinkle	Rabeprazole sodium	NDA – N204736
E-Z Spacer	NA	510(k) – K933090

FLAMEL TECHNOLOGIES

SOCIETE ANONYME AU CAPITAL DE 4 636 011 EUROS

SIEGE SOCIAL :

PARC CLUB DU MOULIN A VENT
33, AVENUE DU DOCTEUR GEORGES LÉVY
69200 VENISSIEUX

R.C.S. LYON 379.001.530

RULES GOVERNING THE FREE SHARE PLAN DECEMBER 2014

With respects to the applicable laws and regulations relating to free shares and under the authorization granted to the Board of Directors of Flamel Technologies (hereinafter the "**Board**") by the Shareholders' Meeting held on June 24, 2014, the Board, during its meeting held on December 11, 2014, has caused a plan for grant of free shares for the benefit of some members of the company's staff and affiliated companies' staff as well as their official company representatives, subject to certain terms and conditions as provided herein.

The present allocation rules reproduce the terms and conditions of the allocation decided by the Board and supplement the letter sent to each beneficiary designated by the Board.

Main characteristics of the grant of free shares

· Grant Date	Dec 11, 2014
· Continue employment Condition*	Dec 12, 2016 (1)
· Effective allocation date	Dec 12, 2018 (2)
· Earliest trading date	**Dec 13, 2018**

** provided that the allocation conditions are satisfied on the said date.*

(1) Effective allocation date for French tax resident beneficiaries
(2) Non French tax resident beneficiaries

I - DEFINITIONS AND LEGAL FRAMEWORK

1.1. DEFINITION

A plan for grant of free shares is a legal shareholder regime under which a company may offer, subject to certain conditions, to members of its staff or certain categories of such employees as well as staff of affiliated companies, the possibility of becoming the owner of a given number of shares to be created by FLAMEL TECHNOLOGIES. Executive officers ("*mandataires sociaux*") of those companies are also eligible under this plan (Article L225-197-1 II of the Commercial Code).

1.2. LEGAL FRAMEWORK

The grant of free shares by FLAMEL TECHNOLOGIES is governed by Articles L.225-197-1 to L.225-197-5 of the French Commercial Code, Articles 80 quaterdecies and 200 A of the General Tax Code, and Article L.242-1 of the Social Security Code.

II - CHARACTERISTICS OF THE FREE SHARE PLAN ON DECEMBER 2013

2.1. BENEFICIARIES

The beneficiaries eligible for the 2013 free shares plan (hereinafter the "**Beneficiaries**") were determined by the Board meeting held on **December 11, 2014(**hereinafter the "**Grant Date**") from among the following:

- Employees of FLAMEL TECHNOLOGIES or of any company which is directly or indirectly controlled by FLAMEL TECHNOLOGIES through at least a fifty ten (10%) ownership of the voting stock or similar (hereinafter "**Employees**"), and/or,

- Executive officers of FLAMEL TECHNOLOGIES (hereinafter "**Executive Officers**")

2.2. NUMBER OF FREE SHARES GRANTED

For each beneficiary, the Board determined the number of shares to be freely granted. The specific number is indicated in the notice letter sent to each beneficiary.

Since the grants are irrevocable, the specific number may not be modified during the Vesting Period (as defined in Article 2-4 below), except in the events listed in Article 2.9.

Further grant of free shares can only be made following a Board's decision.

2.3. RIGHTS RESULTING FROM THE GRANT

Rights resulting from the grant of free shares are non-transferable, but if the beneficiary dies during the Vesting Period, his inheritors may apply for allocation of the shares in the six months following the date of his death. After that time, the allocation right shall irrevocably lapse.

2.4. VESTING PERIOD

The Vesting Period is the period at the end of which the Beneficiary definitely owns the shares.

For French tax resident beneficiaries at the time of the initial grant, the Vesting Period is a two-year period starting from the Grant Date and ending on **December 12, 2016**.

For non-French tax resident beneficiaries at the time of the initial grant, the Vesting Period is a four-year period starting from the Grant Date and ending on **December 12, 2018**.

2.5. CONDITION OF CONTINUED EMPLOYMENT

Allocations are conditional. Beneficiary shall become owner of the shares at the end of the Vesting Period, as defined in Article 2-4, provided that the Beneficiary is still on continued employment with, or an official company representative of, the Company and/or its affiliated companies, as the case may be, at the end of the two- year period starting on the Grant Date, i.e. on **December 12, 2016**.

Free shares rights granted to a Beneficiary who no longer satisfies the condition at the end of a two- year period from the Date of Grant i.e. **December 12, 2016** shall lapse by right and without any formalities (except for the exceptions mentioned below).

So, except for the exceptions mentioned below, any Beneficiary who no longer satisfies the condition of continued employment on **December 12, 2016** shall not claim any benefit from the initial grant, even in the event of later reinstatement into the Company for any reason.

It is specified that rights relative to free shares will lapse as follow:

- Regarding lay-off and resignation, the day when the employee leaves the staff of the Company,
- Regarding revocation of an Executive Officer, the day when the Board of Directors takes the decision, if the beneficiary attends the said meeting, or the day the beneficiary receives the notification if he has not attended the meeting,
- Regarding non-renewal of the mandate of an Executive Officer, the day when his mandate expires.

Exceptions

As an exception, although no longer employed by the company at the end of a two-year period from the grant date, beneficiaries shall be entitled to retain their allocation right in the event of retirement, disability (2nd or 3rd category), redundancy for economic reasons or transfer of their employment agreements linked to transfer by the company of its operating business ("*cession de fonds de commerce*"), in whole or in part.

Notwithstanding the rules laid down above, the Board of Directors may decide, in certain circumstances, to make an exception to the aforementioned allocation condition and authorize a beneficiary to retain his rights on departure for reasons other than those covered by the exceptions mentioned above.

2.6. PRESERVATION OF THE BENEFICIARIES' INTERESTS

If the Company transmits its assets under merger during the acquisition period, its obligations to the beneficiaries shall be taken over by the absorbing company and the number of shares allocated shall be corrected in line with the exchange ratio.

Moreover, a change of control of the Company during the Retention Period, that is, if a person comes to hold, alone or in concert, directly or indirectly, more than half of the Company's capital or voting rights, could bring the possibility to sell shares without respect of the retention period.

2.7. DATE AND PROCEDURES REGARDING DEFINITIVE GRANT OF SHARES

Shares allocated freely to Beneficiaries at the end of the Vesting Period will be new ordinary shares (common stock) to be issued by way of a capital increase by incorporation of reserves.

The Board will meet on the date of definitive grant of the free shares at the latest, in order to:

- record the compliance with the continued employment condition for definitive grant as per Article 2.5,
- record the capital increase related to the issue of the new shares allocated freely, paid-up by incorporation of reserves.

III - Rights oF New shareholders

3.1. RIGHTS RELATED TO GRANTED SHARES

As of their definitive grant, the shares will bear dividend rights, thus entitling the holder to all dividends paid starting as of their definitive grant.

3.2. FORM AND REGISTRATION OF THE GRANTED SHARES

The free shares definitely granted will be registered in a pure registered account (*"nominatif pur")* by the company acting as custody account keeper. Each Beneficiary will receive a certificate of registration of shares.

Regarding French tax resident beneficiaries at Grant Date who shall retain the shares (as per the provisions of Article 3.3 below), the custody account keeper will make an entry in a special account stating the unavailability of the shares, and no request for modification of the said entry may be made before expiry of the Freeze Period.

Moreover, with respect to official company representatives, the custody account keeper will enforce the restrictions of rights to sell shares decided by the Board of Directors in accordance with article L.225-197-1 II of the Code de Commerce and stated in article 2-10 below.

3.3. RETENTION PERIOD

Regarding French tax resident beneficiaries at Grant Date, the free shares definitely granted may only be transferred or sold at the end of a two-year "Freeze Period" following the Vesting Period, i.e. on **December 13, 2018**.

Regarding non-French tax residents at Grant Date, free shares definitely granted may be disposed of freely on **December 13, 2018**, being the end of the acquisition period.

Hence the Beneficiary shall be entitled to dispose of the shares starting on **December 13, 2018,** subject to the conditions set forth in article 3.4.

3.4. SALE AND DISPOSAL OF SHARES

As long as the Beneficiary is still on continued employment with, or a corporate officer of the Company and/or its affiliated companies, sale and disposal of shares must comply with the Company's Insider stock trading policy, and of which a copy was made available to the Beneficiaries.

Therefore, the shares may be transferred only under the following transaction windows:

- For the first three quarters during which the quarterly earnings are released, the window is defined as the period beginning two trading days after publication of the quarterly earnings and ending on the fifth day prior to the end of the last month of each quarter (the transaction windows therefore having a duration of six to seven weeks).

- For the quarter during which the annual earnings are released, the window is defined as the period beginning two business days after publication and ending on the fifth day preceding the end of the of the last month of the first quarter.

The transaction windows may be closed from time to time in the event that, in the opinion of the Chairman, Chief Executive Officer or Chief Financial Officer, there is confidential information making transfers of the shares undesirable.

In addition, and by application of articles L.225-197-1 II of the Commercial code, during all the term of office in which a beneficiary is an official company representative ("mandataire social"), he/she will be required to hold 50% of the shares that are definitively acquired.

IV - PLAN MANAGEMENT

The plan is managed, for the time being, by FLAMEL TECHNOLOGIES.

The Company reserves the right to assign the management to a third party. The beneficiaries will be informed in due time and individually of any modification.

Each beneficiary receives a copy of the present rules, and must return a signed copy to the Company with the following marked by hand "lu et approuvé" [read and approved].

V - RULES MODIFICATIONS

Any legislative or regulatory modifications affecting the present rules, retroactively or for the future, will automatically be binding on all beneficiaries of free shares.

Nevertheless, such modifications will be the object of an amendment that will need to be signed and returned to the company.

Return one signed copy containing the handwritten indication "lu et approuvé" [read and approved].

Beneficiaries Surname/ firstname

Fait à _____

Le_____

Signature

Exhibit 10.22

[xxxx]

Vénissieux, ……., 2015

Objet : Free shares

Dear [xxxx],

We are pleased to inform you that, on proposal of your hierarchy, the Board meeting of Flamel Technologies held on December 11, 2014 granted to you

[xxxx] free shares of the Company,

according to the authorization provides by the Shareholders' Meeting on June 24, 2014 and according to the rules governing the plan for allocation of free shares of December 2014 (attached document).

We remind you that, as a non-French resident, you will become the owner of the shares at the end of a **four-year acquisition period** subject to the condition that there will be an employment contract between you and the Company at the end of a two-year period starting on the date of grant. You will find details of these rules in the attached document.

As a consequence, you will become the owner of the shares allocated to you as of December 12, 2018 if you are still in employment with Flamel Technologies on December 12, 2016.

As an exception, you will notice that you shall be entitled to retain your allocation right in the event of retirement, disability (2nd and 3rd category) and redundancy for economical reasons, although no longer employed by the Company at the end of this two-year period.

The [xxxx] shares of which you will be the owner as of December 12, 2018, will be entered in a pure registered account by the establishment acting as the account-keeper and custodian.

You will be able to dispose of the free shares allocated to you, **as of December 13, 2018**.

We thank you in advance to duly sign and state "Lu et approuvé", **the present letter and the attached document "Rules governing the free share plan - December 2014**" and return them to the HR Department (Nadine Vidou).

Yours sincerely,

The BENEFICIARY: **FLAMEL TECHNOLOGIES**
[xxxx] ***Michael S. Anderson***

Exhibit 10.23

FLAMEL TECHNOLOGIES

SOCIETE ANONYME AU CAPITAL DE 4 636 011 EUROS

SIÈGE SOCIAL :

PARC CLUB DU MOULIN A VENT
33, AVENUE DU DOCTEUR GEORGES LÉVY
69200 VENISSIEUX

R.C.S. LYON 379.001.530

JUNE 2015 STOCK WARRANT RULES

The present allocation rules reproduce the terms and conditions of the allocation of warrants decided by the Board, subject to authorization granted to the Board of Directors of Flamel Technologies (hereinafter the "**Board**") by the Shareholders' Meetings held on June 26, 2015.

Main characteristics of the grant of stock warrants

· Grant Date	June 26, 2015
· Subscription price	1.80€
· End of Subscription period	**Sept 1st, 2015**
· Exercise Price	$21.67
· Start of exercise period *	June 26, 2016
· End of Exercise period*	**June 26, 2019**

** provided that the warrants' holder is still a member of the Board of Directors of the Company on the day of such exercise.*

I - REMINDER OF THE CONTEXT

In accordance with the provisions of Articles L. 225-138 and L. 228-91 et seq. of the Commercial Code, the combined ordinary and extraordinary General Shareholders Meeting of June 26, 2016 decided, in its fourteenth and Thirteenth resolutions, to authorize the Board to issue 350,000 stock warrants, representing 350,000 new ordinary shares to the benefit of Directors of the Company who are not officers and/or employees of the Company, but including the Chairman of the Board of Directors.

The shareholders decided that the subscription price of each stock warrants will be valued by the Board of Directors at the time of warrants' issue based on the Company's share price. This subscription price shall be equal to, per one stock warrant, one tenth (10%) of the average market price of the share, in the form of ADS, on the NASDAQ, on the closing of the trades on the twenty days preceding the decision of the Board to issue such stock warrants.

The subscription price of stock warrants have to be fully paid up on the date of their subscription in cash or by off-set against outstanding receivables, as provided by law and as determined by the Board.

The shareholders decided that each stock warrant will give its holder, subject to the terms and conditions set forth hereafter and in the Board's decision to issue the stock warrants, the right to subscribe to one (1) ordinary share of the Company for an exercise price which shall be valued by the Board of Directors based on the Company's share price. This exercise price shall be equal to the closing trading price of a share, on the NASDAQ Global Market, on the trading days preceding the date of the Board of Directors' meeting, subject to such price is no less than 80% of the average closing trading prices of the share on the NASDAQ Global Market, in the form of ADS, during the last twenty trading days preceding the date of such Board of Directors' meeting. In that case, the price of the share shall be equal to 80% of the average closing trading prices of the share on the NASDAQ, in the form of ADS, during the last twenty trading days preceding the date of such Board of Directors' decision

The shares thus subscribed upon exercise of the stock warrants will have to be fully paid up on the date of their exercise in cash or by off-set against outstanding receivables, as provided by law and as determined by the Board.;

II - Decision of Board of June 26, 2015

By use of the powers granted by the twelfth and the thirteenth resolutions of the combined shareholders meeting of June 26, 2015, and described henceforth, the Board unanimously decided to issue the warrants according to the terms and conditions set forth below.

2.1. BENEFICIARIES

The subscription of these warrants (BSA) is notably reserved, among the following category of beneficiaries "Directors of the Company who are not legal representatives and/or employees of the Company, but including the Chairman", to the following persons, with the following proportions:

2.2. SUBSCRIPTION OF THE WARRANTS

The warrants will be issued at a subscription price of **€1.80**, being one tenth 10% the average market price of the share, in the form of ADS, on the NASDAQ, on the closing of the trades on the twenty days preceding the decision by the Board of Directors to issue warrants, according to the Twelfth Resolution Of The Combined Ordinary And Extraordinary General Shareholders Meeting of June 26, 2015, and converted in Euros on the basis of the average of European Central Bank's (ECB) exchange rate on the twenty days preceding the decision of the Board to issue such stock warrants.

The Board decided that the subscription price shall be fully paid up on the subscription date in cash or by off-set against outstanding receivables, as provided by law.

Each Beneficiary will subscribe the warrants under the terms and conditions of this plan by recorded delivery of **the subscription form duly completed along the subscription price addressed to the Company headquarters up to and including Sept 1st, 2015**.

The subscription period will be anticipatory closed as soon as all warrants have been subscribed for and in accordance with the conditions set out herein. Should a Director gives up in advance his rights to the warrants (BSA), the remaining BSA will be redistributed to the others Directors by the Board of Directors, on the same terms and conditions. The warrants (BSA) which have not been subscribed at the end of the subscription period will be redistributed by the Board of Directors, on terms and conditions further defined, subject to the current authorization of the shareholders and with respects to the limits provided by their authorization and the applicable law.

2.3. RIGHTS RESULTING FROM THE GRANT

Each warrant granted by the Board shall entitle the recipient to subscribe for one share in the Company.

The stock warrants will be issued on a registered form, will not be the object of an application for admission to trading on any market and will be not transferable.

2.4. VESTING PERIOD AND CONDITIONS OF EXERCISE

The warrants (BSA) can be exercised, in whole or part, as of June 26, 2016 and up to and including June 26, 2019, on the condition that the holder is still a member of the Board of Directors of the Company on the day of such exercise; being specified that the BSA holders will have the right to retain the possibility to exercise their BSA even if they are no longer a Director of the Company, provided they notify the Company within three (3) months of having left their position as a Director and in paying simultaneously to the Company an additional subscription price of EUR 0.01 per BSA.

The Board retains the right to suspend, for a maximum period of three months, the exercise of warrants in the event there is an operation giving rise to an adjustment of the share price or capital transaction.

2.5. UNEXERCISED WARRANTS

If its holder fails to exercise the warrant in whole or in part at the expiry of the above mentioned exercise period, the warrant (BSA) and the attached right to subscribe will automatically be void and null and accordingly, cannot be re-allocated.

2.6. EXERCISE PRICE

The warrants, authorized for subscription on June 26, 2015, are exercisable to purchase shares for a price of **$21.67 per share** (as determined by the Board of Directors, with reference to the share price on the closing of trades on the day preceding the decision of the Board to issue such warrants (BSA), this price being no less than 80% of the average of the market price for the share on the NASDAQ, in the form of ADS, during the last twenty trading days preceding such Board's decision). As far as necessary, the exercise price may be converted in Euros on the basis of the latest European Central Bank's (ECB) exchange rate published as at the date of the exercise.

The shares thus subscribed upon exercise of the warrants (BSA) shall be fully paid up on the date of their subscription, in cash or by off-set against outstanding receivables.

2.7. RIGHTS OF THE WARRANTS' HOLDERS

Pursuant to the provisions of Article L. 228-103 et seq. of the Commercial Code, the warrants' holders will all be grouped together in order to defend their common interests, in an assembly (a "masse") with a civil personality. General warrants holders meetings will be convened to authorize any changes in the issuance terms and conditions and to decide on any decision regarding the conditions of subscription or allocation of the shares as set forth at the time issuance took place. Each warrant will give access to one voting right. The conditions regarding the quorum and the majority will be those determined in the second and third paragraph of Article L. 225-96 of the Commercial Code. The expenses incurred in connection with such meetings, as well as, generally, any expenses in connection with the assembly ("masse") will be borne by the Company.

Upon issuance of the stock warrants, the Company shall be entitled to modify its form or its business purpose, modify the rules regarding the distribution of its profits, redeem its capital, create preferred shares resulting in such a change or redemption, subject to meeting the obligations of Article L.228-99 of the French Commercial Code. The shareholders during their meeting in June 24, 2014 decided that, in the case of a capital reduction, whether or not motivated by losses, and conducted through either a decrease of the shares' value of or a decrease of the shares' number, the rights of the holders of the stock warrants will be decreased accordingly as if they had been exercised before the date on which the capital decrease has become final;

The Board of Directors is granted with all necessary powers to take any steps to ensure protection of the holder(s) of stock warrants in case of a financial operation concerning the Company, this pursuant to the legal and regulatory provisions in effect.

3.1. RIGHTS RELATED TO SUBSCRIBED SHARES

Once the warrants have been exercised and the shares registered in an account, the Beneficiaries may exercise all rights associated with the shares received. As of the time the shares are recorded, the shares will bear dividends paid in the financial year during which the options have been exercised.

3.2. FORM AND REGISTRATION OF THE SHARES SUBSCRIBED

The shares will be recorded, in the Beneficiary's name, in a pure registered account ("nominative pur") by the company acting as custody account keeper. Each beneficiary will receive a certificate of registration of shares.

They will be freely transferable immediately after their registration and after payment of the exercise price, subject to the conditions set forth in article 3.3.

3.3. SALE AND DISPOSAL OF SHARES ISSUED FROM EXERCISE OF STOCK WARRANTS

As long as the Beneficiary is still a director of the Company, sale and disposal of shares issued from exercise of stock warrants must comply with the Company's Insider stock trading policy, and of which a copy was made available to the Beneficiaries.

Therefore, the shares may be transferred only under the following transaction windows:

- For the first three quarters during which the quarterly earnings are released, the window is defined as the period beginning two trading days after publication of the quarterly earnings and ending on the fifth day prior to the end of the last month of each quarter (the transaction windows therefore having a duration of six to seven weeks).

- For the quarter during which the annual earnings are released, the window is defined as the period beginning two business days after publication and ending on the fifth day preceding the end of the of the last month of the first quarter.

The transaction windows may be closed from time to time in the event that, in the opinion of the Chairman, Chief Executive Officer or Chief Financial Officer, there is confidential information making transfers of the shares undesirable.

IV - PLAN MANAGEMENT

The terms and conditions of this stock warrant plan will be communicated to Beneficiaries by recorded delivery post or delivered by hand in exchange for a receipt.

The plan is managed, for the time being, by FLAMEL TECHNOLOGIES.

The Company reserves the right to assign the management to a third party. The beneficiaries will be informed in due time and individually of any modification.

Each beneficiary receives a copy of the present rules, and must return a signed copy to the Company with the following marked by hand “lu et approuvé” [read and approved].

V - RULES MODIFICATIONS

Any legislative or regulatory modifications affecting the present rules, retroactively or for the future, will automatically be binding on all Beneficiaries.

Nevertheless, such modifications will be the object of an amendment that will need to be signed and returned to the company.

Return one signed copy containing the handwritten indication “lu et approuvé” [read and approved].

Beneficiaries Surname/ firstname

Fait à _____

Le_____

Signature

Exhibit 10.24

FLAMEL TECHNOLOGIES

SOCIÉTÉ ANONYME AU CAPITAL DE 4 901 727 EUROS

SIÈGE SOCIAL :

PARC CLUB DU MOULIN À VENT
33, AVENUE DU DOCTEUR GEORGES LÉVY
69200 VENISSIEUX

R.C.S. LYON 379.001.530

SUBSCRIPTION FORM OF STOCK WARRANT

I the undersigned, (full name)....., residing at

…….,

Certify hereby:

I have been informed that, in accordance with the terms and conditions relative of the twelfth and thirteenth resolutions of the Combined Ordinary and Extraordinary General Meeting of Shareholders on June 26, 2015 and enacted upon by the meeting of the Board of Directors of June 26, 2015, the Board of Directors of June 26, 2015 allocated to me ..... stock warrants

Main characteristics of the grant of stock warrants

- Grant Date
- Subscription price
- End of Subscription period
- Exercise Price
- Start of exercise period *
- End of Exercise period*

Declare to subscribe, using this subscription form, for .....stock warrants at a subscription price of 1.80€,

In support of this subscription pay a total of ..... €, corresponding to the total value of the warrants as subscribed,

☐ by off-set against the attendance fees granted to me by the Board of Directors of June 26, 2015, which represent an amount of ..... €

And/or any remaining amounts, by means of

☐ a cheque payable to Flamel Technologies, or

☐ a wire transfer to the HSBC bank account held by the company:

Bank and Branch:
Bank Code:
Branch Code:
Account Number:
IBAN:
BIC:

Declare to renounce any possibility of resale of the warrants as subscribed and this for a period as of today until their expiration on _____.

Agree to comply with the Stock warrant rules of June 2015 and with the Company stock trading policy and

Declare to retain a copy of the present document and its attachments

Date: **By:** _____

_____

(full name)

Signature of subscriber preceeded by 'bon pour souscription formelle et irrévocable de……..BSA'

FLAMEL TECHNOLOGIES

SOCIETE ANONYME WITH A STATED CAPITAL OF 5,029,783 EUROS

REGISTERED OFFICE:

PARC CLUB DU MOULIN A VENT
33, AVENUE DU DOCTEUR GEORGES LÉVY
69200 VENISSIEUX

R.C.S. LYON 379.001.530

DECEMBER 2015 STOCK OPTION RULES

With respects to the applicable laws and regulations relating to stock options and under the authorization granted to the Board of Directors of Flamel Technologies (hereinafter the "**Board**") by the Shareholders' Meetings held on June 24, 2014, the Board, during its meeting held on December 10, 2015, has caused a plan for grant of stock options for the benefit of some members of the company's staff and affiliated companies' staff as well as its official company representatives, subject to certain terms and conditions as provided herein.

The present allocation rules reproduce the terms and conditions of the allocation decided by the Board and supplement the letter sent to each beneficiary designated by the Board.

Main characteristics of the grant of stock options

· Grant Date	December 10, 2015
· Exercise Price	$14.35
· Vesting dates *	December 10, 2016 (25%)
	December 10, 2017 (25%)
	December 10, 2018 (25%)
	December 10, 2019 (25%)
· End of Exercise period*	**December 10, 2025**

** provided that the condition of continued employment is satisfied on the said date.*

I - DEFINITIONS AND LEGAL FRAMEWORK

1.1. DEFINITION

A plan for grant of stock options is a legal shareholder regime under which a company may offer, subject to certain conditions, to members of its staff or certain categories of such employees as well as staff of affiliated companies, the possibility of becoming the owner of a given number of shares, existing or to be created by the Company, for a determined price. Executive officers of the Company are also eligible under this plan (Article L. 225-185 paragraph 4 of the French Commercial Code).

1.2. LEGAL FRAMEWORK

This stock option plan is governed by Articles L 225-177 to L 225-186-1 of the French Code de Commerce, Articles 80 quaterdecies and 200 A of the General Tax Code, and Article L 242-1 of the Social Security Code.

II - CHARACTERISTICS OF THE STOCK OPTIONS PLAN

2.1. BENEFICIARIES

The beneficiaries eligible for the 2015-4 stock option plan (hereinafter the "**Beneficiaries**") were determined by the Board meeting held on **December 10, 2015** (hereinafter the "**Grant Date**") from among the following:

- Employees of FLAMEL TECHNOLOGIES or of any company which is directly or indirectly controlled by FLAMEL TECHNOLOGIES through at least a fifty percent (50%) ownership of the voting stock or similar (hereinafter "**Employees**") and/or,

- Executive officers of FLAMEL TECHNOLOGIES (including the Chairman of the Board), (hereinafter "**Executive Officers**")

In accordance with the law, options cannot be granted to Executive Officers or Employees who directly or indirectly own more than ten percent (10%) of the voting stock or similar in the Company.

2.2. NUMBER OF STOCK OPTIONS GRANTED

The Board freely determines the beneficiaries of the stock options, subject to the terms and conditions set forth by the Shareholders' Meeting, and grants them based on a proposal from the Chairman. The number of options granted is mentioned in the notice letter addressed to each beneficiary.

2.3. RIGHTS RESULTING FROM THE GRANT

Each option granted by the Board shall entitle the recipient to subscribe for one share in the Company.

Rights associated with the stock options are non-transferable.

2.4. VESTING PERIOD AND CONDITIONS OF EXERCISE

Provided that the beneficiary is still on continued employment, as defined in Article 2.5, the quarter (25%) of the total stock option granted is vested each year starting from the first year after the grant date or, in the case of conditional grants, the date that the defined condition has been met. The corresponding dates are mentioned in the notification letter.

Each Beneficiary will be able to exercise his/her rights under the terms and conditions of this plan by recorded delivery accompanied by the exercise price addressed to the Company within a period of ten years from Grant Date provided that the Beneficiary is still on continued employment, as defined in Article 2.5.

The Board retains the right to suspend, for a maximum period of three months, the exercise of options in the event there is an operation giving rise to an adjustment of the share price or capital transaction.

Exceptions

In any case, in the event of a transfer of goodwill or of a change in control of the Company, i.e. if a person comes to hold, individually or collectively, directly or indirectly, more than half of the Company's capital or voting rights, the options will vest immediately subject to the Beneficiary making a formal written request within 60 days of the effective date of a change in control. In absence of a request, the options will vest according to the terms and conditions set forth when initially granted.

2.5. CONDITION OF CONTINUED EMPLOYMENT

The options will be vested as defined in article 2.4 and the Beneficiary may exercise it according to section 2.4, provided that is still

- the Beneficiary still is an Executive Officer or an Employee of the Company or;
- the Beneficiary has ceased to be an Executive Officer or an Employee of the Company in the last (60) days. This condition shall not apply in the event that an Executive Officer is revoked for mismanagement.

The 60-day period is deemed to commence as follows:

- Regarding dismissal, resignation or transfer of the employment contract linked to transfer by the company of its operating business ("*cession de fonds de commerce*"), the day the Beneficiary's employment contract terminates and he/she is no longer considered to be included in the official headcount of the Company,
- Regarding the revocation of an Executive Officers' mandate, the day the Board decides to revoke the nomination if the beneficiary attends the meeting, or the day the beneficiary receives notification of such decision, if he/she does not attend the meeting,
- With regards to the non-renewal of an Executive Officer's term of office, the expiration date of the original term of office.

So, except for the exceptions mentioned below, any beneficiary who no longer satisfies the condition of continued employment shall not claim any benefit from the options, even in the event of later reinstatement into the Company for any reason.

Exceptions

In the event of the Beneficiary's death, his/her heirs may exercise, for a period of six months from the date of death, the number of options that the Beneficiary had the right to exercise at the time of his death.

In addition, in the event of retirement or disability (2nd or 3rd category), the Beneficiary may exercise the number of options that the Beneficiary had the right to exercise the day the Beneficiary's employment contract terminates and he/she is no longer considered to be included in the official headcount of the Company, within a period of ten years from Grant Date.

Notwithstanding the rules laid down above, the Board of Directors may decide, in certain circumstances, to make an exception to the aforementioned allocation condition and authorize a beneficiary to retain his rights on departure for reasons other than those covered by the exceptions mentioned above.

2.6. UNEXERCISED OPTIONS

In the event a Beneficiary is unable to exercise his/her options since he/she is no longer an Employee or Executive Officer, such options will become, by right and without any formality, null and void. They will become available and the Board may grant them in whole or in part to one or more other beneficiaries.

2.7. EXERCISE PRICE

The exercise price of the options is set by the Board on the date when such options are granted by the Board, in accordance with the terms and conditions determined by the Extraordinary General Shareholders' Meeting, as follows:

The subscription price of each share by the beneficiaries of the options, will be the closing market price for the share, in the form of ADS, on the NASDAQ Global Market, on the day preceding the date of the meeting of the Board of Directors, provided that such price shall not be less than 80% of the average of the closing market price for the share on the NASDAQ Global Market, in the form of ADS, during the last twenty trading days preceding the meeting. In this case, the price for the share shall be equal or superior to 80% of the average of the closing market price for the share on the NASDAQ Global Market, in the form of ADS, during the last twenty trading days preceding the meeting.

The exercise price of the options granted on December 10, 2015 is $14.35.

For fiscal and other declarations as of the grant date, the exercise price is translated into euros at the rate provided by the European Central Bank's (ECB) (0.9140) on the date preceding the Board of Directors meeting and represents €13.12.

The exercise price must be paid in full on the date the beneficiary decides to exercise the stock option, in USD or in EURO, upon beneficiary's choice. As far as necessary, the exercise price may be converted in Euros on the basis of the latest European Central Bank's (ECB) exchange rate published as at the date of the valid exercise, according to the present rules.

2.8. MODIFICATIONS OF THE EXERCISE PRICE

The price of the shares, as determined by the Board of Directors, may not be subsequently modified during the option period.

However, in accordance with Article L. 225-181 paragraph 2 of the French Commercial Code, if the Company conducts one of the specific matters detailed, the Board shall take all necessary measures to protect the interests of the options beneficiaries pursuant to the applicable laws and regulations and adjust the number and price of the shares on which the stock options have been granted.

III - Rights oF New shareholders

3.1. RIGHTS RELATED TO SUBSCRIBED SHARES

Once the options have been exercised and the shares registered in an account, the Beneficiaries may exercise all rights associated with the shares received. As of the time the shares are recorded, the shares will bear dividends paid in the financial year during which the options have been exercised.

3.2. FORM AND REGISTRATION OF THE SHARES SUBSCRIBED

The shares will be recorded, in the Beneficiary's name, in a pure registered account ("nominative pur") by the company acting as custody account keeper. Each beneficiary will receive a certificate of registration of shares.

They will be freely transferable immediately after their registration and after payment of the exercise price, subject to the conditions set forth in article 3.3.

3.3. SALE AND DISPOSAL OF SHARES ISSUED FROM EXERCISE OF STOCK OPTIONS

As long as the Beneficiary is still on continued employment with, or a corporate officer of the Company and/or its affiliated companies, sale and disposal of shares issued from exercise of stock options must comply with the Company's Insider Stock Trading Policy, and of which a copy was made available to the Beneficiaries.

Therefore, the shares may be transferred only under the following transaction windows:

- For the first three quarters during which the quarterly earnings are released, the window is defined as the period beginning two trading days after publication of the quarterly earnings and ending on the fifth day prior to the end of the last month of each quarter (the transaction windows therefore having a duration of six to seven weeks).

- For the quarter during which the annual earnings are released, the window is defined as the period beginning two business days after publication and ending on the fifth day preceding the end of the of the last month of the first quarter.

The transaction windows may be closed from time to time in the event that, in the opinion of the Chairman, Chief Executive Officer or Chief Financial Officer, there is confidential information making transfers of the shares undesirable.

In addition, according to article L.225-185 al4 of the French Commercial code, during the period in which a beneficiary is an official company representative (“mandataire social”), he will be required to hold 50% of the shares resulting from the exercise of stock option during the whole term of his office.

IV - PLAN MANAGEMENT

The terms and conditions of this stock option plan will be communicated to Beneficiaries by recorded delivery post or delivered by hand in exchange for a receipt.

The plan is managed, for the time being, by FLAMEL TECHNOLOGIES.

The Company reserves the right to assign the management to a third party. The beneficiaries will be informed in due time and individually of any modification.

Each beneficiary receives a copy of the present rules, and must return a signed copy to the Company with the following marked by hand “*lu et approuvé*” [read and approved].

V - RULES MODIFICATIONS

Any legislative or regulatory modifications affecting the present rules, retroactively or for the future, will automatically be binding on all Beneficiaries.

Nevertheless, such modifications will be the object of an amendment that will need to be signed and returned to the company.

Return one signed copy containing the handwritten indication “lu et approuvé” [read and approved].

Beneficiaries Surname/ firstname

Fait à _____

Le_____

Signature

Exhibit 10.26

[xxxx]

Vénissieux, January [●] 2016

Objet : Stock options

Dear [xxxx],

We are pleased to inform you that, you were granted [xxxx] stock options in the Company at the Board meeting of Flamel Technologies held on December 10, 2015, according to authorizations provided by the shareholders Meetings on June 24, 2014 and according to the rules governing the Stock Options plan of December 2015 (the "Rules 2015"), as attached.

Subject to condition of continued employment provided in Section 2.5 of the Rules 2015, these stock options will only be converted into shares according to the following detailed rules:

- [xxxx] (25%) exercisable options from 12/10/2016 to 12/10/2025 inclusive
- [xxxx] (25%) exercisable options from 12/10/2017 to 12/10/2025 inclusive
- [xxxx] (25%) exercisable options from 12/10/2018 to 12/10/2025 inclusive
- [xxxx] (25%) exercisable options from 12/10/2019 to 12/10/2025 inclusive

The exercise price of the options granted is **USD 14.35**.

These stocks options are not negotiable. We invite you to refer to the Rules 2015 for more detail with regard to the rules applicable to your options.

We thank you in advance to duly sign and write "Lu et approuvé", on **the present letter and attached document Rules 2015**" and return them to our HR Department (Evelyne Beauzon).

Yours sincerely,

The BENEFICIARY:	**FLAMEL TECHNOLOGIES**
[xxxx]	***Michael S. Anderson***

Attachement: Rules governing the Stock Option plan of December 2015

Exhibit 21.1

List of Subsidiaries

Name	Jurisdiction
Flamel Technologies S.A. (the Registrant):	France
1) Fccml Limited	Ireland
A) Flamel Ireland Limited	Ireland
2) Flamel U.S. Holdings, Inc.	United States (Delaware)
A) Eclat Pharmaceuticals, LLC	United States (Delaware)
i) Talec Pharmaceuticals, LLC	United States (Delaware)
B) FSC Holdings, LLC	United States (Delaware)
i) FSC Therapeutics, LLC	United States (Delaware)
ii) FSC Laboratories, Inc.	United States (Delaware)
a) FSC Pediatrics, Inc.	United States (Delaware)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-137844, 333-134638, 333-111725, 333-109693, 333-12542 and 333-177591) of Flamel Technologies S.A. of our report dated March 15, 2016 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

Lyon, France,
March 15, 2016

PricewaterhouseCoopers Audit

Represented by
/s/ Frederic Charcosset
Frederic Charcosset

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Michael S. Anderson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2016

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Michael F. Kanan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2016

/s/ Michael F. Kanan

Michael F. Kanan
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AND EXCHANGE ACT RULE 13a-14(b)

In connection with the annual report of Flamel Technologies S.A. (the "Company") on Form 10-K for the period ending December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael S. Anderson, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer
Flamel Technologies S.A.
March 15, 2016

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AND EXCHANGE ACT RULE 13a-14(b)

In connection with the annual report of Flamel Technologies S.A. (the "Company") on Form 10-K for the period ending December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael F. Kanan, Senior Vice President and Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael F. Kanan
Michael F. Kanan
Senior Vice President and Chief Financial Officer
Flamel Technologies S.A.
March 15, 2016