Risk Factors

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

Risks Relating to Our Business and Industry

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

The majority of our revenues are or will be derived from the commercialization of two (2) products, Bloxiverz® and Vazculep™. Additionally, we depend on a small number of customers for the majority of our revenues from sales of these two drug products. Four customers, AmeriSource Bergen, Cardinal, McKesson and Morris & Dickson accounted for approximately 99% of revenues from sales of these products in 2014. These customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo consolidation marked by mergers and acquisitions among wholesale distributors and retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that continuing consolidation will increase pricing and other competitive pressures on pharmaceutical companies. The loss of any one of these products or the termination of our relationship with any of these customers or our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

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

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

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

Our products may not gain market acceptance.

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

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

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

Our products may not reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful Research and Development ("R&D) of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of previously Unapproved Marketed Drugs ("UMDs") products and development of products that utilize our drug delivery platforms. If the UMDs products and/or the products incorporating our drug delivery platforms fail to reach the commercial market, our future revenues would be adversely affected.

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

- the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the competent authority of an EU Member State or an Institutional Review Board ("IRB"), or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our current drug delivery platforms and drug products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find certain products cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;
- managed care providers may be unwilling or unable to reimburse patients at an economically attractive level for products under development; or
- our products could fail to obtain regulatory approval or, if approved, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to R&D in order to develop new products and enhance our technologies. In 2014, we spent $17.3 million on R&D. Our ongoing investments in R&D for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

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

As part of the divestiture of our development and manufacturing facility ("Pessac Facility") to Recipharm AB ("Recipharm"), we entered into certain agreements with Recipharm for the development, supply of clinical materials and potentially the supply of commercial batches for several of our products incorporating our drug delivery platforms, as well as our Medusa™ polymer(s); for details see "Item 4. *Information on the Company"*. Any disruption in the operations of Recipharm or if Recipharm fails to supply acceptable quantity and quality materials or services to us for any reason, such disruption or failure could delay our product development and could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory obligations.

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

Currently, we depend on a single manufacturer for both Bloxiverz® and Vazculep™. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. If the supplies of these products or materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current Good Manufacturing Practices ("cGMP") requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of our products by our contract, development, and manufacturing organizations ("CDMOs"). Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

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

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including other companies developing drug delivery platforms or niche brand or generic specialty pharmaceutical products. Some of these competitors may be also our business partners.

Our drug delivery platforms compete with technologies provided by several other companies (for details see "Item 4. *Competition and Market Opportunities*"). In particular, New Biological or Chemical Entities ("NBEs" or "NCEs") could be developed that, if successful, could compete against our drug delivery platforms or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These new biological or chemical products may be safer or may work better than our products.

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

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

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

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

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

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

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

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

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

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

Further, patent protection once obtained is limited in time, after which competitors may use the covered product or technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shortened.

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

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

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

Third parties may claim that our products infringe their rights, and we may incur significant costs resolving these claims.

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

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

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

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

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

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

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

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

Fluctuations in foreign currency exchange rates may cause fluctuations in our financial results.

For the year ended December 31, 2014, we derived 98.6% of our total revenues from continuing operations from transactions in U.S. dollars, but have 75% of our cash and cash equivalents, and 39% of our marketable securities, and the majority of our expenses denominated in Euros. Our functional currency is the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not currently engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, but we expect to implement hedging activities to manage exchange rate risk in the future.

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

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

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

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

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

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

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

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

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

Risks Relating to Regulatory and Legal Matters

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

Although products that incorporate our drug delivery platforms and other products we may develop, may appear promising, in particular at their early stages of development and in clinical trials, none of these potential platforms or products may gain regulatory approval and reach the commercial market for a variety of reasons.

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

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners, to conduct additional pre-clinical studies or clinical trials. For instance, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of Medusa-based product candidates, which would impact development plans for product candidates. In addition, although Flamel has submitted a Drug Master File (“DMF”) for its lead Medusa polymer, the FDA may require additional information prior to the conduct of clinical trials or for commercialization of any product that uses our Medusa polymer and cross-references our DMF.

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

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

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

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

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

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

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

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

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;

- withdraw or vary approval of marketing applications;

- order the competent authorities of EU Member States to withdraw or vary national authorization; and

- initiate criminal prosecutions.

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

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

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

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

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

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

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

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

We, and companies to which we license our products or drug delivery platforms, as well as, companies acting as subcontractors for our product developments, including but not limited to non-clinical, pre-clinical and clinical studies, and manufacturing, are subject to extensive regulation by the FDA, other domestic regulatory authorities and equivalent foreign regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including: warning letters or untitled letters; fines and civil penalties; delays in clearing or approving, or refusal to clear or approve, products; withdrawal, suspension or variation of approval of products; product recall or seizure; orders to the competent authorities of EU Member States to withdraw or vary national authorization; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair the ability to produce and market applicable products, which could significantly impact our revenues and royalties that we receive from our customers.

We may face product liability claims related to clinical trials for our products or their misuse.

The testing, including through clinical trials, manufacturing and marketing, and the use of our products may expose us to potential product liability and other claims. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from Contract Research Organizations (“CROs”) or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance with a limit of €8 million and product liability and recall insurance with a limit of €10 million for products incorporating our drug delivery platforms, and coverage of $10 million for products marketed by the US operations of the Company (Bloxiverz® and Vazculep™). We cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing, or will develop, our products may not protect us from product liability claims from the consumers of those products or from the costs of related litigation.

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

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

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

Risks Relating to Ownership of Our Securities

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

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2014, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $8.15 to $18.89. During the year ended December 31, 2013, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $3.25 to $8.21. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological partnerships, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery platforms developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery platforms;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA, the EMA or national authorities of EU Member States in connection with submissions related to the products incorporating our technologies;
- the perception by the market of biotechnology and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

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

Our primary commercial sales currently include only the Éclat products of Bloxiverz® and Vazculep™. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited history of commercial sales, which may make it difficult to evaluate our prospects. The difficulty in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors and holders react to information about our prospects. Since 1995 and up to December 1, 2014, we have generated revenues from product development fees and licensing arrangements and royalties associated with Coreg CR® classified as Discontinued Operations. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with limited commercial sales of products and only two currently marketed products, Bloxiverz® and Vazculep™.

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

We have a history of operating losses and have accumulated aggregate net loss from inception of approximately $320 million through December 31, 2014. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for R&D of our products and drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our drug delivery platforms and products;
- the level of product and price competition;
- our ability to develop new partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;

- the effectiveness of our marketing strategy;

- the effectiveness of our partners' marketing strategy for products that use our technology; and

- general economic conditions.

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

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

- the development and acquisition of new products and drug delivery platforms;

- the progress of our research and product development programs;

- results of our partnership efforts with potential pharmaceutical and biotechnology company partners; and

- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, we may choose to issue shares of our common stock or preferred stock, either through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to our stockholders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On March 31, 2015, Deerfield Capital and certain of its affiliates beneficially owned approximately 13.08% of our outstanding shares (in the form of ADRs) and Broadfin Capital and certain of its affiliates beneficially owned approximately 12.82% of our outstanding shares (in the form of ADRs). See "Item 7. *Major Shareholders and Related Party Transactions — A. Major Shareholders*". To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, including change of control transactions.

ITEM 4. Information on the Company

General Overview

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

Corporate Information

The Company was incorporated as a *Société Anonyme (or SA)*, a form of corporation under the laws of the Republic of France, in August 1990 as Flamel Technologies S.A. and its shares, represented by American Depositary Shares, began to be quoted on the NASDAQ National Market in 1996 and are now quoted on the NASDAQ Global Market. As per the Company's by-laws, its legal existence expires in 2099, unless extended. Flamel's principal place of business is located at Parc Club du Moulin à Vent, 33, avenue du Docteur Georges Lévy, 69200 Venissieux, France (a suburb of Lyon); phone number +33 472 78 34 34, fax number +33 472 78 34 35. Its website is www.flamel.com.

The Company currently has two direct wholly owned operating subsidiaries: Flamel US Holdings, Inc., and Flamel Irish Holdings, Ltd. Flamel US Holdings, Inc. is a Delaware corporation, created for the acquisition of Éclat in March 2012. Éclat Pharmaceuticals, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Flamel US Holdings, Inc. Talec Pharma, LLC, a Delaware limited liability company, is a wholly owned subsidiary of Éclat Pharmaceuticals, LLC. Flamel Irish Holdings, Ltd is a corporation duly organized under the laws of Ireland. Its wholly owned subsidiary, Flamel Ireland, Ltd., a corporation duly organized under the laws of Ireland, is where all intangible property was relocated on December 16, 2014 (see "Item 4. *Developments in 2014 and early 2015*"). A complete list of the Company's subsidiaries can be found in Exhibit 8.1 to this Annual Report.

Our Business Model

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

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

Business Strengths and Strategies

Éclat, which has focused on pursuing U.S. Food and Drug Administration ("FDA") approvals through the 505(b)(2) regulatory pathway (see "Item 4. *Patent Restoration and Exclusivity*"), adds to our Company marketing and licensing knowledge of the commercial and regulatory process in the U.S, which we believe enhances the ability of the Company to identify potential product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and to license and market products in both the U.S. and EU.