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 deciding to invest in our securities.

Risks Relating to Our Business and Industry

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

We depend on a small number of customers and partners for the majority of our revenues from our drug delivery technologies. Those customers that individually generated more than 10% of our revenue in 2011 include GlaxoSmithKline plc (GSK) 67.6% and Merck Serono, S.A. (Merck Serono), 11.6%. The termination of our relationship with any of these customers or partners and our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

Our revenues from our drug delivery technology business primarily depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.

We market and sell our technologies to third parties who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GSK, Merck Serono, Theralpha SAS, Digna Biotech SL, Eagle Pharmaceuticals, Inc. and other pharmaceutical and biotechnology companies whose identities remain confidential.

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

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

- our collaborative partners may enter bankruptcy or otherwise dissolve.

Although products that incorporate our drug delivery technologies and development products acquired from Éclat may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.

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

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

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

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

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

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

- our pharmaceutical and biotechnology company partners may find that certain products using our technologies cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;

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

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

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products. In 2011, we spent $25.1 million on research and development. Our ongoing investments in research and development for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The research and development process is lengthy and carries a substantial risk of product failure. If our research and development does not yield sufficient new products that achieve commercial success, our future operating results will be adversely affected.

We must comply with various covenants and obligations under the note agreement with Éclat Holdings, and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities.

Flamel and its subsidiaries are subject to financial and non-financial restrictive covenants under the note agreement with Éclat Holdings that may impair our ability and reduce our flexibility to operate and finance our business, plan for or react to changes in our business, the economy or the markets, or limit our ability to engage in activities that may be in our long term best interest. These covenants include, without limitation, restrictive covenants with respect to (i) establishment of new subsidiaries, (ii) liquidation, dissolution, mergers, consolidations or other corporate reorganizations, (iii) prior to March 13, 2015, engaging someone other than Mr. Anderson to manage a substantial part of Flamel's business, unless Mr. Anderson's employment agreement is terminated before such date other than as a result of Flamel's breach, (iv) making restricted payments (such as dividends or distributions) to any Flamel shareholder, (v) creating or incurring any lien on the assets of Flamel or its subsidiaries, subject to certain permitted exceptions; and (vi) creating, incurring, assuming or guaranteeing any indebtedness, subject to certain permitted exceptions. If we were to default under the Éclat note by violating these covenants or otherwise, Éclat Holdings' remedies would include the ability to, among other things, accelerate payment of all or a substantial portion of the amounts payable under the note. Our largest shareholder Deerfield Capital has a controlling interest, and our Chief Executive Officer, Mr. Anderson, has a minority interest in Éclat Holdings. As a result, their interest may differ from those of our other shareholders. Defaults under the Éclat note, if not cured or waived, could have a material adverse effect on our business, financial condition, and results of operations.

Management transition to a new Chief Executive Officer may be disruptive to our business and personnel.

Mr. Anderson is Flamel's first new Chief Executive Officer in six years. The transition in leadership from Mr. Willard to Mr. Anderson may bring about changes to our business plans and operations that could be disruptive and distracting to our personnel and business. These changes may require time to adjust. In addition, the covenants related to Mr. Anderson's employment as CEO could restrict the ability of our Board of Directors to make a change to the CEO position without incurring, in addition to any severance payments, a financial cost to make acceleration payments under the note with Éclat Holdings or negotiating a waiver or modification of such provisions.

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

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

We depend on a limited number of suppliers for certain raw materials used in our drug delivery technologies, and any failure to deliver sufficient supplies could interrupt our production process and could have a material adverse effect on our business.

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

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

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

If our competitors develop and market technologies or products that are more effective than ours, or obtain regulatory approval and market such technology 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 systems. Some of these competitors are also our business partners. Our Medusa technology competes with technologies from companies such as Alkermes, Inc., Enzon Pharmaceuticals, Human Genome Sciences, Nektar Therapeutics, Ambrx and SkyePharma, plc. Companies with oral drug delivery technology that can compete with our Micropump technology include Durect, Depomed and Tris Pharma. We also compete with companies seeking to develop controlled release formulations of scheduled drugs such as Pain Therapeutics as well as generally with other drug delivery, biotechnology and pharmaceutical and biotechnology companies that develop alternative drug delivery technologies or new drug research and testing. The Éclat business competes with companies such as Covidien, Hi-Tech, and others. If we are successful in expanding our marketed products, we will encounter more competitors.

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

Additionally, new chemical entities could be developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the United States and in Europe, there may be some that we do not now know of that may compete with our drug delivery systems or products in the future. These chemical entities and new products may be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery system to use with their drugs instead of one of our drug delivery systems.

We may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of pipeline products.

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

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

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

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

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

If we cannot adequately protect our technology 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 technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

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

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

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 and advisors. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or techniques, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation 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), which was signed into law on September 16, 2011, includes several provisions that may impact our business and patent protection in the United States. The AIA may increase our patents' post grant reviews before the U.S. Patent and Trademark Office, which may result in changing the scope of the patent protection in an unfavorable manner. The scope of the issuing patent protection may not be sufficiently broad to cover our products or to exclude competing products. The AIA amends patent litigation procedures in the United States, which may result in litigation being more complex and expensive. These litigation changes could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel.

Even if we and our partners obtain necessary regulatory approvals, our products and technologies may not gain market acceptance.

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

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

If any of our products or technologies fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

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

Our business is dependent on our ability to work with customers and partners in collaborative relationships to develop products using our technologies. We have in the past and expect that in the future we will enter into collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements. Collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products and can lead to lengthy, expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs.

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

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

The development of some of our products may require the use of technology developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses. These fees would reduce the revenues and royalties we may receive on commercialized products that incorporate our technologies.

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

Third parties may claim that the manufacture, use, import, offer for sale or sale of our drug delivery technologies 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 patents in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in 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, United States and foreign patents that pose a risk of potential infringement claims.

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

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

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

Some of our third party collaborative partners may utilize our drug delivery technologies in products with exclusive rights secured by patents or other means. These rights are limited in time and do not always provide effective protection for their products. If our collaborative partners are unable to protect their products' exclusivity or patent rights, generic competition may erode their market share, undermine the profitability of their products and limit the royalties we could collect from product sales. The expiration of the Hatch Waxman exclusivity for Coreg CR in April 2010 could open Coreg CR to generic competition, which may negatively affect the royalties we could collect in the future. Abbreviated New Drug Applications (ANDA) have been submitted to the FDA by Mutual Pharmaceuticals and Lupin Pharmaceuticals requesting marketing approval of generic formulations of Coreg CR and by Anchen Pharmaceuticals regarding only 40 mg dosage strength. Should the FDA grant approval to either or both of these applications, our royalty income from sales of Coreg CR would be negatively affected (See Item 4 – Information on the Company – General Overview). To date, we have generated $42.5 million in royalty revenue from Coreg CR, the only product sold using our drug delivery technology.

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 will reimburse consumers for the cost of these products, which affects 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 United States 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.

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

For the year ended December 31, 2011, we derived 36% of our total revenues from transactions in U.S. dollars, but have 75% of our cash and cash equivalents, all of our marketable securities, and the majority of our expenses denominated in Euros. Our functional currency is the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although we do, from time to time, purchase Euros against invoiced dollar receivables.

Recent developments in the European Union have created uncertainty about the ability of certain EU Member States to continue to service their sovereign debt obligations. This debt crisis and the related financial restructuring efforts may cause the value of the Euro to deteriorate, reducing the value of the Euro relative to the U.S. dollar. Any strengthening in the U.S. dollar relative to the Euro would have a negative effect on our balance sheet while a weakening in the U.S. dollar relative to the Euro would have a positive effect. See ‘Quantitative and Qualitative Disclosures About Market Risk’ on page 78 for more information on the impact of currency exchange rate fluctuations. In addition, the sovereign debt crisis affecting some EU Member States is contributing to instability in global credit markets. If global economic and market conditions, or economic conditions in the European Union, the U.S. or other key markets, remain uncertain, persist or deteriorate further, our business, financial condition, results of operations and cash flows may be adversely affected.

The audit report included in this annual report is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, you are deprived of the benefits of such inspection.

Auditors of companies that are registered with the US Securities and Exchange Commission and traded publicly in the United States, including our independent registered public accounting firm, must be registered with the US Public Company Accounting Oversight Board (United States) (“the “PCAOB”) and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Because our auditors are located in France, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditors are not currently inspected by the PCAOB.

This lack of PCAOB inspections in France prevents the PCAOB from regularly evaluating audits and quality control procedures of any auditors operating in France, including our auditors As a result, investors may be deprived of the benefits of PCAOB inspections.

The inability of the PCAOB to conduct inspections of auditors in France makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of France that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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

In the ordinary course of our business, we collect and store sensitive 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 EU Member States, disruption to our operations and damage to our reputation, which could adversely affect our business.

Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery technologies and development products acquired from Éclat 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.

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

Applicants for FDA approval often must submit extensive clinical and pre-clinical data as well as information about product manufacturing processes and facilities and other supporting information to the FDA. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us or our partners to conduct additional pre-clinical studies or clinical trials. For instance, we do not anticipate the necessity to conduct individual toxicity and carcinogenicity tests for each product that we develop using the Medusa nano-particulate technology. Due to their special properties, however, nanoparticle formulations may pose different issues of safety or effectiveness than non-nanoscale products. With that in mind, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of product candidates using the Medusa technology, which would impact development plans for product candidates. Similarly, although we anticipate submitting applications for approval for the development products acquired from Éclat that rely on existing data to demonstrate safety and effectiveness, FDA may determine that additional studies particular to our products are necessary. If FDA requires such additional data, it would impact development plans for those products.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 (FDAAA), we or our partners may be required to develop risk evaluations and mitigation strategies, or REMS, to ensure the safe use of their product candidates. If the FDA disagrees with our or our partners' REMS proposals, it may be more difficult and costly for us or our partners to obtain regulatory approval for their 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 can 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.

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

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

If our products or products that incorporate our technologies are marketed in other jurisdictions, we and the partners with whom we are developing our technologies must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety, quality and efficacy. These related obligations are frequently as demanding as those imposed by the FDA, the EMA or the competent authorities of EU Member States. If approvals to market our products or our partners' products are delayed, or if we or our partners fail to receive these approvals or previously received approvals are withdrawn, our revenues would be reduced. We may be required to incur significant costs to obtain or maintain foreign regulatory approvals.

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

We and our pharmaceutical and biotechnology company partners will continue to be subject to extensive regulatory requirements for products and product candidates that incorporate our technologies, even if the products receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required post-marketing studies or clinical trials;
- authorization renewal procedures;
- authorization variation procedures;
- compliance with any required REMS;

- updating safety and efficacy information;
- processing of personal data;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

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

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

We are subject to 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 federal and state laws and regulations, including but not limited to, health care "fraud and abuse" laws, such as anti-kickback and false claims laws and regulations. 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 Office of Inspector General of the Department of Health and Human Services that it intends to continue to vigorously pursue fraud and abuse violations by pharmaceutical companies, including through the potential to impose criminal penalties on pharmaceutical company executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

It is possible, however, that such changes could have a significant impact on the path to approval of products incorporating our technologies or of competing products, and to our obligations and those of our partner pharmaceutical and biotechnology companies. For example, the FDAAA contains a number of provisions that strengthen the FDA's regulatory authority in various areas, including clinical trial registration and results reporting, pharmacovigilance and other safety-related issues and post-approval clinical study requirements. As another example, with adoption of the Biologics Price Competition and Innovation Act of 2009 (BPCIA), enacted in March 2010, biological products incorporating our technologies may face competition from "biosimilar" products that are approved via an abbreviated process on the basis of a showing that the product is highly similar to the approved 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. The BPCIA provides periods of exclusivity during which abbreviated applications may not be submitted to, or approved by, FDA, but the statute then allows approval by an abbreviated pathway and, if certain standards are met, a finding by FDA that the biosimilar product is interchangeable with the reference product. If competitors are able to obtain marketing approval for biosimilars under an abbreviated regulatory approval process in the U.S. or the European Union, biotechnology products incorporating our technologies may become subject to additional competition with the attendant pricing pressure. Because the BPCIA is a highly complicated statute that has only recently been enacted, there is uncertainty as to how many important components of the new law will be implemented. Some issues may be resolved by three draft guidances that FDA issued in February 2012 or by issuance of regulations or other guidances, but other positions may develop on an ad hoc basis as FDA confronts them in the context of specific applications. The recent modifications to the provisions of the Community Code on medicinal product governing pharmacovigilance also impose further reporting and surveillance obligations on our partner pharmaceutical and biotechnology companies and grant greater supervisory powers to the European Commission and the competent authorities of EU Member States.

Companies to which we have licensed our technology are subject to extensive regulation by the FDA and other regulatory authorities. Their failure to meet strict regulatory requirements could adversely affect our business.

Several companies to which we have licensed our technology 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 companies' facilities to monitor compliance with applicable regulatory standards. If the FDA or another regulatory authority finds that a company has failed to comply with applicable regulations, the authority can 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 those companies' ability to produce and market their products, which could significantly impact the royalties that we receive from them.

We may face product liability claims related to participation in clinical trials or the use or misuse of our products or products that incorporate our technologies.

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

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

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

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

Risks Relating to Ownership of Our Securities

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

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2011, the closing sale price of our ADSs as reported on the NASDAQ Global Market ranged from $3.85 to $6.97. During the year ended December 31, 2010, the closing sale price of our ADSs as reported on the NASDAQ Global Market ranged from $6.02 to $9.60. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery systems developed by us or drugs developed others;
- 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 technologies;
- 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, investors in our shares may have difficulty evaluating our prospects.

We recorded the first commercial sales of products using one of our polymer technologies through our partner, Corning, in 1999. Our first commercial sales of a pharmaceutical compound incorporating our Micropump technology occurred in March 2007 with the launch of Coreg CR. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited history of commercial sales, which may make it difficult to evaluate our prospects. The difficulty investors may have in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors react to information about our prospects. Since 1995, we have generated revenues from product development fees and licensing arrangements and royalties. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with limited commercial sales of products and only two currently marketed products, one of which, Hycet, we consider a niche product.

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 $189 million through December 31, 2011. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for research and product development of our drug delivery technologies and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our technologies and products;

- the level of product and price competition;

- our ability to develop new collaborative partnerships and additional commercial applications for our products;

- our ability to control our costs;

- our ability to broaden our customer base;

- the effectiveness of our marketing strategy;

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

- general economic conditions.

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

We may require additional financing to fund the development and possible acquisition of new drug products and delivery technologies 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 technologies. We also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and technologies;

- the progress of our research and product development programs;

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

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

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

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

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

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

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

We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act, relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-United States issuers under the Exchange Act is more limited than the periodic disclosure required of United States issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

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

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

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

An investor in the United States may find it difficult to:

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

At March 31, 2012, Deerfield Capital and certain of its affiliates beneficially owned approximately 17.2% of our ADRs, BVF, Inc. and certain of its affiliates beneficially owned approximately 7.8% of our ADRs and Visium Asset Management, LP certain of its affiliates beneficially owned approximately 7.7% of our 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

We are a biopharmaceutical company principally engaged in (1) the development and licensing of two unique polymer-based drug delivery technologies and (2) as a result of our acquisition of Éclat Pharmaceuticals, LLC, or Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S.

Our drug delivery technology business is built primarily on two technologies—Medusa and Micropump. Our hydrogel Medusa technology is designed to provide controlled release following injection of therapeutic proteins, peptides and other large and small molecules. We also have developed a microparticle adaptation of the Medusa platform which we believe offers important advantages in the delivery of smaller proteins and peptides. Both the hydrogel and microparticle adaptations of Medusa have been demonstrated to solve threshold problems commonly affecting the development of biologics such as poor solubility, poor stability, and the tendency of certain biologics to aggregate, which can provoke an immune response in the body. The Medusa platform may be used to deliver multiple therapeutic agents simultaneously, which is of particular interest in the field of vaccines, among other examples. Our Micropump technology is a microparticle technology for oral administration of small molecule drugs with applications in controlled-release, taste-masking and bioavailability enhancement. The Micropump technology has been demonstrated in a clinical trial to apply to the extended, controlled release of small molecule drugs in liquid suspension formulations. We refer to this application as LiquiTime®. Our Trigger Lock™ technology is an adaptation based on our Micropump technology that is designed to minimize the misuse and abuse of medications subject to abuse. A Trigger Lock formulation has been tested in a clinical trial to achieve the controlled release of a narcotic that qualifies as a controlled substance, or Schedule II drug, under the Controlled Substances Act (CSA), Title II of the U.S. Comprehensive Drug Abuse Prevention and Control Act of 1970. Testing of this formulation as well as other formulations with respect to a broad range of commonly employed methods of tampering has confirmed that Trigger Lock may substantially prevent such tampering, and that it is applicable to a wide range of molecules.

Our Éclat specialty pharmaceuticals business, acquired in March 2012, is focused on the development, approval and commercialization of niche branded and generic pharmaceutical products. We acquired Éclat after the conclusion of the year ended December 31, 2011. Accordingly, this Report on Form 20-F does not fully explain the effects or impacts of the acquisition of Éclat, and the financial results for 2011 do not include any of the operations of Éclat.

Our Business Model

We develop specific applications of our controlled release technologies in partnership with biotechnology and pharmaceutical companies. Our business model enables us to focus on our comparative advantages in polymer chemistry and drug delivery while leveraging the resources and expertise of partner companies in specific indications, clinical and regulatory development, marketing, and sales. We generate revenues through license payments from our partners to develop products using our drug delivery technologies, milestone payments for achieving certain objectives in getting products to market and royalty payments based on product sales. Currently we are working with six of the top twenty-five pharmaceutical companies in the world, based on annual healthcare revenue: our joint development programs comprise seventeen feasibility or license and development projects. These projects are being conducted across a wide range of indications and involve new formulations of both novel and already-marketed molecules. Nine of these apply the Medusa platform and eight are Micropump formulations, including several Trigger Lock formulations.

The addition of Éclat Pharmaceuticals, acquired in March 2012, brings with it one licensed and marketed product, Hycet® and its generic equivalent, and a product portfolio in various stages of development, creating a vertically integrated business model. Through this acquisition, we have enhanced our development and commercial experience, providing us with increased knowledge and understanding of the markets in which we operate and product candidates which we believe will help us identify and leverage new opportunities for application of our drug delivery platforms. Éclat, which has focused on pursuing FDA approvals through the 505(b)(2) mechanism (See *Item 4. Information on the Company — New Drug and Biological Product Development and Approval Process — Patent Restoration and Exclusivity*), adds knowledge of the commercial and regulatory process in the U.S., which we believe will enhance the ability of the company to identify potential product candidates for development, marketing and licensing in the United States. In light of the recent acquisition, we are currently evaluating the potential synergies and complementary opportunities created by the combined business, and we may adapt our business model in the future.