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

Year Ended December 31, Euro to U.S. Dollar:	**High**	**Low**	**Average Rate[1]**
2004	1.367	1.176	1.248
2003	1.246	1.036	1.132
2002	1.0485	0.8594	0.9495
2001	0.9548	0.8388	0.8958
2000	1.0334	0.8269	0.9207

Previous Six Months, Euro to U.S. Dollar:	**High**	**Low**	**Average Rate**
May, 2005	1.2936	1.2349	1.2697
April, 2005	1.3093	1.2838	1.2943
March, 2005	1.347	1.288	1.319
February, 2005	1.327	1.277	1.301
January, 2005	1.348	1.296	1.312
December, 2004	1.363	1.325	1.341

The exchange rate for the Euro against the U.S. dollar as of May 31, 2005 was € 1.2349 to $1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into dollars at any of the exchange rates referred to herein as of a given date.

Risk Factors

Certain statements made in this Annual Report on Form 20-F are forward-looking statements based on our current expectations, assumptions, estimates and projections about our business and our industry. These forward-looking statements involve risks and uncertainties. Our business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements as a result of certain factors, as more fully described below and elsewhere in this Annual Report. The risks and uncertainties described below are not the only ones we face.

We depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.

We depend on a few customers and partners for the majority of our revenues, including GlaxoSmithKline and TAP. The termination of our relationship with any of these major 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 allow us to maintain profitability.

Our revenues 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 TAP, Servier, GlaxoSmithKline, Merck, and other pharmaceutical and biotechnology companies.

1 *Annual totals represent the average of the noon buying rates for Euros on the last business day of each month during the relevant period. Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month.*

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. 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 and adverse impact on our revenues and profits. 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 market any commercial 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; and
- our collaborative partners may terminate their relationships with us.

Although products that incorporate our drug delivery technologies 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.

Successful research and development of pharmaceutical products is difficult, expensive, and time consuming. Many product candidates fail to reach the market. Accordingly, it is possible that products that incorporate our technologies may never reach the commercial market for any number of reasons. 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. If products using our technologies fail to reach the commercial market, our revenues would be adversely affected, and we may be unable to increase our revenue.

Even if our technologies appear promising during various stages of development, there may not be successful commercial applications developed for them because:

- they may be found to be ineffective or cause harmful side effects, or they may fail during 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 cannot be manufactured on a commercial scale and, therefore, may not be economical to produce; or
- products that use our technologies also could fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties.

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 have employment agreements with any of our key personnel, nor do we maintain material key person life insurance for any of our key personnel. If we lose the services of Dr. Gerard Soula, our Chief Executive Officer, Stephen Willard, our Chief Financial Officer and General Counsel, or Raphael Jorda, our Director of Manufacturing, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel plays more than one role in respect of numerous components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

Products that incorporate our drug delivery technologies are subject to regulatory approval. If 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 U.S. Food and Drug Administration (FDA), and state and local government agencies regulate all pharmaceutical products, including existing products and those under development. 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 they 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.

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. 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. The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of such data and information 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, or may 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.

The FDA's statutes, regulations or policies may change and additional government regulations or statutes may be enacted which could prevent or delay regulatory approval of biological and other drugs or medical devices. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Manufacturers of drugs also must comply with applicable Good Manufacturing Practices (GMP) requirements. If we or our pharmaceutical and biotechnology company partners 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. We may not be able to comply with all of the applicable good manufacturing practices and other FDA regulatory requirements for manufacturing.

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 and quality. If approvals to market our products are delayed, if we fail to receive these approvals or if we lose previously received approvals, our revenues would be reduced. We may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals.

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 conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. 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.

Our commercial products are subject to continuing regulation and we may be subject to adverse consequences if we fail to comply with applicable regulations.

Even if our products receive regulatory approval, either in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

- adverse drug experience and other reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements;
- record keeping requirements;
- drug sampling and distribution requirements;
- electronic record and signature requirements; and
- product manufacturing and labeling changes or modifications.

If we fail to comply with these laws and regulations, we may be fined or barred from selling our products. If the FDA determines that we are not complying with the law, it can:

- issue warning letters;
- impose fines;
- seize products 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;
- suspend or limit our production;
- withdraw previously approved marketing applications; and
- initiate criminal prosecutions.

If our competitors develop and market drug delivery technologies or related 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 reduced 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. Our Medusa® technology competes with technologies from companies such as Alkermes, Inc., SkyePharma plc and Enzon Pharmaceuticals, Inc. Companies with oral drug delivery technology that can compete with our Micropump® technology include Eurand International S.p.A., Biovail and Andrx Corporation. We also compete generally with other drug delivery, biotechnology and pharmaceutical and biotechnology companies that develop alternative drug delivery technologies or new drug research and testing.

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, there could be new chemical entities that are being 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 turn out to 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.

If we cannot keep pace with the rapid technological change in our industry, we may lose business.

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 governmental 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.

Our products and technologies may not gain market acceptance.

The competitive nature of our industry could adversely affect market acceptance of our products or the use of our drug delivery technologies. Even if we and our pharmaceutical and biotechnology company partners obtain the necessary regulatory approval to market our products and products that incorporate our technologies, our products and technologies may not gain market acceptance among physicians, patients, healthcare payers and the medical community.

The degree of market acceptance of any product candidate or technology will depend on a number of factors, including:

- the effectiveness of our marketing strategy;
- demonstration of the clinical efficacy and safety of the product or technology;
- no evidence of undesirable side effects which delay or extend trials;
- no regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods; 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.

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 we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Our current patents may not be 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 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. Further, we may not have the necessary financial resources to enforce our patents.

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.

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 or sale of our drug delivery technologies infringe on their patent rights. If such claims are asserted, 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 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. and foreign patents that pose a risk of potential infringement claims.

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 the sale of products incorporating our technology and royalties. 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 company may be restricted or may cease.

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.

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 federal, state 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. We currently do not maintain insurance coverage for environmental liabilities. 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.

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

Our ability to successfully commercialize our products and technologies may depend in part on the extent to which the government health administration authorities, private health insurers and other third party payers will reimburse consumers for the cost of these 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. Adequate third party reimbursement may not be available for our 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 ability to commercialize that particular drug. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. Any such changes may adversely affect our business.

Because we have a limited operating history, 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. We have had no commercial sales to date of products incorporating either our Medusa® or Micropump® technologies. Accordingly, we have only a limited operating history, which may make it difficult to evaluate our prospects. The difficulty investors may have in evaluating our prospects may cause volatile fluctuations, including decreases, 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, therefore, must be evaluated in light of the risks and uncertainties of a company with a limited operating history and, in particular, one in the pharmaceutical industry.

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

We have accumulated aggregate net losses from inception of approximately $47.8 million through December 31, 2004. If we are unable to continue 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 losses in 2003, 2001 and 2000. Our ability to maintain profitable operations depends on 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 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; 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 your equity interest.

We may require additional financing to fund the development and possible acquisition of new drug delivery technologies and to increase our production capacity beyond what is currently anticipated. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to develop and possibly to acquire new drug delivery technologies or limit the expansion of our manufacturing capacity. We also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery technologies and expand manufacturing capacity beyond that currently planned. 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.

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. In the year ended December 31, 2004, the closing sale price for our ADSs as reported on the Nasdaq National Market ranged from $14.67 to $31.73. In the year ended December 31, 2003, the closing sale price of our ADSs as reported on the Nasdaq National Market ranged from $3.74 to $42.85. 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:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drugs developed by us or others;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA 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.

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 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 could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses.

Uncertainties related to potential changes in the structure of our board of directors and management at our annual shareholders' meeting may disrupt our business and put us at a disadvantage with respect to our competitors.

Mr. Oscar Schafer, a major shareholder of our Company, and affiliated shareholders proposed the nomination of three directors to our board of directors at our annual shareholders' meeting to be held on June 22, 2005 to replace the current board of directors as well as the slate of directors proposed by the current board of directors. Our board of directors unanimously recommended that our shareholders vote against these nominees and vote for the re-election of our current directors and for the election of our two applicants. We depend upon the continued service of our skilled executive officers and board of directors that is knowledgeable about our industry. Our founder, President and Chief Executive Officer, Dr. Soula, has indicated his intention to resign if our shareholders approve the nomination of the three candidates proposed by Mr. Schafer. The potential loss of our current experienced executives and directors may lead to a destabilization within our Company that may disrupt our business and put us at a disadvantage with respect to our competitors, which could harm our business.

ITEM 4. Information on the Company

General Overview

We are a biopharmaceutical company principally engaged in the development of two unique polymer-based delivery technologies for medical applications. Our Micropump® technology is a multiparticulate technology for oral administration of small molecule drugs with applications in controlled-release, tastemasking and bioavailability enhancement. Our Medusa® nano-particulate technology is designed to deliver therapeutic proteins, peptides and small molecules. Our expertise in polymer science has also been instrumental in the development of a photochromic eyeglass lens product that was launched by Corning in 1999. Additionally, we have developed a patented biomaterial, ColCys®.

Our Medusa® technology permits the long-acting controlled-release of proteins without the denaturation or other adverse effects on such proteins of certain other delivery systems. Our initial application of Medusa® is Basulin®, a long-acting insulin for the treatment of diabetes.

Beginning in 1999, we worked with Novo Nordisk A/S to optimize the Medusa® polymer and the insulin formulation to be delivered using our proprietary technology. As of March 12, 2002, we reacquired all rights to Basulin®. On August 27, 2003, we announced that we had entered into a license agreement with Bristol-Myers Squibb for Basulin®. The license agreement provided for an initial payment to us of $20 million and additional milestone payments that could have reached $145 million plus royalties on the sale of the product. Bristol-Myers Squibb also would assume all costs of future clinical trials, development, registration and marketing of the product. On September 16, 2004, we received a letter notifying us of Bristol-Myers Squibb's intention to cancel the partnership. On December 15, 2004, ninety days after receipt of the cancellation letter, we re-acquired the rights to Basulin. On January 31, 2005 Flamel Technologies and BMS entered into a termination agreement, with respect to the former licensing agreement. Under the terms of the January 31, 2005 agreement, we received a cash payment of $5,850,000.