NOVADEL PHARMA INC
Form 10-K
March 29, 2011

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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the year ended December 31, 2010

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

COMMISSION FILE NO. 001-32177

NOVADEL PHARMA INC.

(Exact Name of registrant as specified in its charter)

Delaware	22-2407152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1200 ROUTE 22 EAST, SUITE 2000, BRIDGEWATER, NEW JERSEY 08807
(Address of principal executive offices) (Zip Code)

(908) 203-4640
Registrant’s telephone number, including area code

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

None

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

Common Stock, par value $0.001 per share
Title of class

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of June 30, 2010, the aggregate market value of the voting and non-voting common equity of the issuer held by non-affiliates of the registrant was approximately $12 million. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 21, 2011, the issuer had 113,523,192 shares of common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement to be filed pursuant to Regulation 14A within 120 days of the end of the fiscal year (December 31, 2010) are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes "forward-looking statements," including statements regarding NovaDel Pharma Inc.'s (the "Company," "we," "us" or "NovaDel") expectations, beliefs, intentions or strategies for the future and the Company's internal controls and procedures and outstanding financial reporting obligations and other accounting issues. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect the Company's views as of the date they are made with respect to future events and financial performance. In particular, the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section in Part II, Item 7 of this Annual Report includes forward-looking statements that reflect the Company's current views with respect to future events and financial performance. The Company uses words such as "expect," "anticipate," "believe," "intend" and similar expressions to identify forward-looking statements. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. A number of important risks and uncertainties could, individually or in the aggregate, cause actual results to differ materially from those expressed or implied in any forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the ability to develop products of the type the Company is developing (independently and through collaborative arrangements); the ability of third parties to commercialize the Company's products; the ability to complete clinical trials, including pilot pharmacokinetic feasibility studies; successful completion of preclinical studies; possible changes in the Company's financial condition; the progress of the Company's research and development; the ability to obtain adequate supplies of drug substance and drug product for clinical and preclinical studies, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in the Company's clinical trials; the impact of development of competing therapies and/or technologies by other companies; the Company's ability to obtain additional required financing to fund its research programs; the Company's ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with the Company; the progress of the U.S. Food and Drug Administration, or FDA, approvals in connection with the conduct of the Company's clinical trials and the marketing of the Company's products; the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; acceptance for filing by the FDA does not mean that the New Drug Application, or NDA, has been or will be approved, nor does it represent an evaluation of the adequacy of the data submitted; the risks related to the Company's internal controls and procedures; and the risks identified under the section entitled "Risk Factors" included as Item 1A in Part I of this Annual Report on Form 10-K and other reports, including this report and other filings filed with the Securities and Exchange Commission from time to time.

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PART I

In this report, all references to "NovaDel," "we," "our," "us" or the "Company" refer to NovaDel Pharma Inc., a Delaware corporation.

Item 1. Business.

Overview

NovaDel Pharma Inc. is a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products. Our patented oral spray drug delivery technology seeks to improve the efficacy, safety, patient compliance, and patient convenience for a broad range of prescription medications. Our products and product candidates are as follows:

	Active Ingredient	Indications	Stage of Development	Partner
Products				
NitroMist®	Nitroglycerin	Angina Pectoris	Market	Akrimax Pharmaceuticals
ZolpimistTM	Zolpidem	Insomnia	Market	Hi-Tech Pharmacal
Product Candidates				
DuromistTM	Sildenafil	Erectile Dysfunction	Clinical development	—
ZensanaTM	Ondansetron	Nausea/Vomiting	Clinical development	Talon Therapeutics Par Pharmaceuticals BioAlliance Pharma Kwang Dong Pharma
NVD-201	Sumatriptan	Migraine headache	Clinical development	—
NVD-301	Midazolam	Pre-Procedure Anxiety	Preclinical development	—

Products

NitroMist®

NitroMist, our oral spray formulation of nitroglycerin, has been approved by the United States Food and Drug Administration, or FDA, for acute relief of an attack of angina pectoris, or acute prophylaxis of angina pectoris, due to coronary artery disease. In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are

eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

ZolpimistTM

Zolpimist, our oral spray formulation of zolpidem, has been approved by the FDA for short-term treatment of insomnia. Zolpidem is the active ingredient in Ambien®, a leading prescription medication for the treatment of insomnia, marketed by Sanofi-Aventis. In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

Product Candidates

DuromistTM

Duromist, our oral spray formulation of sildenafil, is being developed for the treatment of erectile dysfunction. Sildenafil is the active ingredient in Viagra®, a leading prescription medication for the treatment of erectile dysfunction, marketed by Pfizer. The patent for Viagra is expected to expire in the second quarter of 2012. We believe that an oral spray version of sildenafil may afford faster onset of therapeutic action, and may allow for a lower dose compared to tablets.

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The preclinical work has been completed, and a prototype formulation with satisfactory stability has been developed. In July 2010, we initiated a non-IND pilot pharmacokinetic, or PK, clinical trial comparing Duromist to Viagra. The trial was designed to assess the relative bioavailability and safety of one, two and three doses of 10 mg/0.12ml of Duromist, compared to that of the 25 mg Viagra tablet. The trial was a single-center, open-label, single-dose, randomized, four-period, four-treatment, crossover study under fasting conditions. The total number of healthy adult male subjects enrolled in the study was 24. All subjects were required to stay at the clinical site for at least 24 hours after each treatment period.

In October 2010, we announced positive data from this trial. The preliminary data demonstrated that the 20 mg dose (two sprays) of Duromist is bioequivalent to the 25 mg Viagra tablet with respect to systemic exposure (AUC0-inf). The mean AUC0-inf for the 10 mg dose (one spray) was approximately 40% of the 25 mg Viagra tablet, as expected. The mean AUC0-inf for the 30 mg dose (three sprays) was approximately 40% higher than the 25 mg Viagra tablet, which is about 20% higher than expected. The increased systemic exposure observed with the 20 and 30 mg oral spray doses compared to the 25 mg Viagra tablet is suggestive of absorption of sildenafil via the oral transmucosal route.

A slightly lower maximum measured plasma concentration (Cmax) than that of the 25 mg Viagra tablet was observed with the 20 mg oral spray dose. The Tmax (or time point at Cmax) for the 20 mg oral spray dose was essentially the same as the 25 mg Viagra tablet (1.10 and 1.04 hours, respectively). Duromist demonstrated an excellent safety profile and was well tolerated in the pilot PK study.

In February 2011, we had a pre-IND meeting with the FDA. At that meeting we discussed the requirements for opening an IND, as well as the entire clinical and nonclinical development plan for a new drug application, or NDA, for Duromist. In 2011, we plan to open the IND, complete the required clinical and nonclinical work, and file a NDA. In order to do this we will need to secure additional funding or a development partner.

ZensanaTM

Zensana is our oral spray formulation of ondansetron. Ondansetron is the active ingredient in Zofran®, a leading prescription medication for the treatment of chemotherapy-induced nausea and vomiting, marketed by GlaxoSmithKline, or GSK. In October 2004, we entered into an exclusive license and development agreement with Talon Therapeutics, Inc. (formerly Hana Biosciences, Inc.), or Talon, to develop and market Zensana in the U.S. and Canada. In July 2007, we entered into an amended and restated license and development agreement with Talon and a product development and commercialization sublicense agreement with Talon and Par Pharmaceutical, Inc., or Par, pursuant to which Talon granted a sublicense to Par to develop and commercialize Zensana. Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. Par had previously announced that it expected to complete clinical development on the revised formulation of Zensana during 2008, and expected to submit a new NDA for Zensana by the end of 2008. However, in November 2008, Par announced that it had completed bioequivalency studies on Zensana with mixed results, and had ceased development of the product.

In January 2007, we entered into an exclusive license agreement with Kwang Dong Pharmaceuticals, or Kwang Dong, to develop and commercialize Zensana in South Korea. Under the terms of the agreement, we received an upfront fee of $100,000. We are eligible to receive additional milestone payments totaling $200,000, as well as royalty payments on net sales. Product development in South Korea is subject to the completion of product development in the U.S.

In May 2008, we entered into an exclusive license and supply agreement with BioAlliance Pharma SA, or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales. Product development in Europe is subject to the completion of

product development in the U.S.

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NVD-201

NVD-201 is our oral spray formulation of sumatriptan. Sumatriptan is the active ingredient in Imitrex®, a leading prescription medication for the treatment of migraine headache, marketed by GSK. We have completed a series of pilot pharmacokinetic clinical trials evaluating multiple doses of NVD-201 given to healthy adults. The results from these trials demonstrated that NVD-201 was well tolerated, achieved plasma concentrations in the therapeutic range, achieved a statistically significant increase in absorption rate when compared with Imitrex® tablets, and achieved up to a 50% increase in relative bioavailability in comparison with Imitrex® tablets. In September 2008, we announced the results from a pilot efficacy study for NVD-201. As previously announced, we believe this trial demonstrates that treatment with NVD-201 is safe and effective in relieving migraine headaches at a dose lower than that for sumatriptan tablets. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

NVD-301

NVD-301 is our oral spray formulation of midazolam. Midazolam is a leading prescription medication used for sedation during diagnostic, therapeutic and endoscopic procedures. We believe that NVD-301 has the potential to be an easy-to-use, rapid onset product, useful in the relief of pre-procedure anxiety suffered by many patients prior to undergoing a wide variety of procedures performed in hospitals, imaging centers, ambulatory surgery centers and dental offices. In order to pursue further clinical development of this product candidate, we will need to secure project financing, equity financing or a development partner.

Other Product Candidates

Our veterinary initiatives are being carried out by our partner, Velcera, Inc., or Velcera. In June 2004, we entered into an exclusive license and development agreement with Velcera. In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a canine pain management product. In August 2009 and March 2010, we received milestone payments from Velcera of $156,250 and $62,500, respectively. We are eligible to receive additional milestone payments, and royalty payments on sales.

In April 2003, we entered into an exclusive license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, for the development of propofol oral spray. Propofol is the active ingredient in Diprivan®, a leading intravenous anesthetic marketed by AstraZeneca. In July 2007, Manhattan announced its intention to pursue appropriate sub-licensing opportunities for this product candidate. In November 2010, the agreement was terminated.

Business Strategy

Our goal is to become a leading specialty pharmaceutical company that develops improved formulations of marketed prescription medications using our patented oral spray drug delivery technology. We believe that our technology has application to a broad range of therapeutic areas and product categories. Our strategy is to concentrate our product development activities primarily on pharmaceutical products which meet the following criteria:

- Significant prescription sales already exist;
- Regulatory approval using the 505(b)(2) pathway is available; and
- Our patented oral spray drug delivery technology will enhance the performance of the pharmaceutical product, potentially addressing unmet patient needs.

In today’s environment of escalating development costs and increased time to market, we believe that the ability to bring differentiated products with a competitive advantage to the marketplace, in a timely and cost-effective manner, is a viable strategy.

Strategic Alliance, License and Other Commercial Agreements

We intend to secure marketing partners for our marketed products and development and commercialization partners for our product candidates. Typically, we secure development and commercialization partners after we have generated sufficient clinical data to demonstrate the effectiveness of our product candidates. We anticipate these strategic partners will provide us with upfront payments, milestone payments and royalties on product sales.

Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC

In October 2009, we entered into an exclusive license and distribution agreement with Akrimax Pharmaceuticals LLC, through its affiliate Mist Acquisition LLC, to manufacture and commercialize NitroMist in North America. Under the terms of the agreement, we received an upfront payment of $1,000,000, a milestone payment of $500,000 in October 2010 and a milestone payment of $500,000 in January 2011. We are eligible to receive royalty payments of up to 17% of net sales. Akrimax Pharmaceuticals began marketing NitroMist in January 2011.

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Hi-Tech Pharmacal Co., Inc., through its subsidiary ECR Pharmaceuticals Company, Inc.
In November 2009, we entered into an exclusive license and distribution agreement with Hi-Tech Pharmacal Co., Inc., through its wholly owned subsidiary ECR Pharmaceuticals Company, Inc., to manufacture and commercialize Zolpimist in the U.S. and Canada. Under the terms of the agreement, we received an upfront payment of $3,000,000. We are eligible to receive royalty payments of up to 15% of net sales on branded products. ECR Pharmaceuticals began marketing Zolpimist in February 2011.

Talon Therapeutics, Inc. (formerly Hana BioSciences, Inc.) and Par Pharmaceutical, Inc.
In October 2004, we entered into a license and development agreement pursuant to which we granted to Talon Therapeutics, Inc. (formerly Hana Biosciences, Inc.), or Talon, an exclusive license to develop and market Zensana, our oral spray version of ondansetron, in the U.S. and Canada. Pursuant to the terms of the agreement, in exchange for $1,000,000, Talon purchased 400,000 shares of our common stock at a per share price equal to $2.50, a premium of $0.91 per share or $364,000 over the then market value of our common stock. We accounted for this premium as deferred revenue related to the license. In connection with the agreement, Talon issued to us $500,000 worth of common stock of Talon (73,121 shares based on a market value of $6.84 per share). The fair value of the common stock received from Talon was included in deferred revenue and was being recognized over the 20-year term of the agreement.

In July 2007, we entered into a sublicense agreement with Talon and Par Pharmaceutical, Inc., or Par, pursuant to which Talon granted a non-transferable, non-sublicenseable, royalty-bearing, exclusive sublicense to Par to develop and commercialize Zensana In connection therewith, Talon amended and restated their existing license and development agreement, as amended, with us relating to the development and commercialization of Zensana, to coordinate certain of the terms of the sublicense agreement. Under the terms of the sublicense agreement, Par is responsible for all development, regulatory, manufacturing and commercialization activities of Zensana in the United States and Canada. We retain our rights to Zensana outside of the United States and Canada.

In addition, under the terms of the amended and restated license agreement, Talon relinquished its right to pay reduced royalty rates to us until such time as Talon had recovered one-half of its costs and expenses incurred in developing Zensana from sales of Zensana, and we agreed to surrender for cancellation all 73,121 shares of the Talon common stock that had been acquired by us in connection with execution of the original license agreement with Talon.

We may receive milestone payments and royalties over the term of the agreement.

Kwang Dong Pharmaceuticals
In January 2007, we entered into an exclusive license agreement with Kwang Dong Pharmaceuticals, or Kwang Dong, to develop and commercialize Zensana in South Korea. Under the terms of the agreement, we received an upfront fee of $100,000. We are eligible to receive additional milestone payments totaling $200,000, as well as royalty payments on net sales. Product development in South Korea is subject to the completion of product development in the U.S.

BioAlliance Pharma SA
In May 2008, we entered into a 19.5-year exclusive license and supply agreement with BioAlliance Pharma SA or BioAlliance, to develop and commercialize Zensana in Europe. Under the terms of the agreement, we received an upfront fee of $3,000,000. We are eligible to receive additional milestone payments totaling approximately $24 million, as well as royalty payments on net sales. We anticipate collaborating with BioAlliance in the completion of development activities for Europe, with BioAlliance responsible for regulatory and pricing approvals and then commercialization throughout Europe. We will be responsible for supplying the product.

Velcera, Inc.

In June 2004, we entered into a 20-year exclusive license agreement with Velcera, Inc., or Velcera, to develop and commercialize our patented oral spray drug delivery technology in animals. Under the terms of the agreement, we received an upfront payment of $1,500,000, as well as 529,500 shares of common stock in Velcera. The value of the shares of common stock was de minimis, and was valued at $0. We are eligible to receive additional milestone payments, as well as royalty payments on sales.

In June 2007, Velcera announced that it had entered into a global license and development agreement with Novartis Animal Health to develop and commercialize a canine product. We received a milestone payment of $125,000 in connection with this agreement. In March 2008, Velcera announced that it had received notice from Novartis Animal Health that it was terminating the agreement, without cause.

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In June 2009, Velcera announced it had entered into a global licensing agreement with a multinational animal health company to develop a canine pain management product. In August 2009 and March 2010, we received milestone payments from Velcera of $156,250 and $62,500, respectively.

Manhattan Pharmaceuticals, Inc.
In April 2003, we entered into a 20-year exclusive license and development agreement with Manhattan Pharmaceuticals, Inc., or Manhattan, to develop propofol oral spray for the treatment of pre-procedural sedation. Under the terms of the agreement, we received a payment of $125,000 in June 2003, and a payment of $375,000 in November 2003. We are eligible to receive additional milestone payments, and royalty payments on sales. In July 2007, Manhattan announced that as part of a change in its strategic focus it intends to pursue appropriate sub-licensing opportunities for this product candidate. In November 2010, the agreement was terminated.

Intellectual Property
Our policy is to pursue patents, pursue trademarks, maintain trade secrets and use other means to protect our technology, inventions and improvements that are commercially important to the development of our business.

We have applied for U.S. and foreign patent protection for our oral spray drug delivery technology, which is the primary focus of our development activities. Currently, we own nine patents which have been issued in the U.S. and 53 patents which have been issued outside of the U.S. Additionally, we own 63 patents pending around the world. Additional patent applications may not be granted, or, if granted, may not provide adequate protection to us. We also intend to rely on whatever protection the law affords to trade secrets, including unpatented know-how. Other companies, however, may independently develop equivalent or superior technologies or processes and may obtain patents or similar rights with respect thereto.

Although we believe that we have developed our technology independently and have not infringed, and do not infringe, on the patents of others, third parties may make claims that our technology does infringe on their patents or other intellectual property. In the event of infringement, we may, under certain circumstances, be required to modify our infringing product or process or obtain a license. We may not be able to do either of those things in a timely manner if at all, and failure to do so could have a material adverse effect on our business. In addition, we may not have the financial or other resources necessary to enforce a patent infringement or proprietary rights violation action or to defend ourselves against such actions brought by others. If any of the products we develop infringe upon the patent or proprietary rights of others, we could, under certain circumstances, be enjoined or become liable for damages, which would have a material adverse effect on our business.

We also rely on confidentiality and nondisclosure agreements with our licensees and potential development candidates to protect our technology, intellectual property and other proprietary property. Pursuant to the foregoing and for other reasons, we face the risk that our competitors may acquire information which we consider to be proprietary, that such parties may breach such agreements or that such agreements will be inadequate or unenforceable.

Further, we own the registered trademark NITROMIST in the U.S. and Canada. In addition, we have applications for other trademarks pending around the world, which may or may not be granted.

Manufacturing and Clinical Supplies
We do not currently have in-house manufacturing capabilities. Our two approved products, NitroMist and Zolpimist, have been licensed to strategic partners, and these strategic partners are responsible for manufacturing. We rely on third party contract manufacturers to make the material used to support the development of our product candidates. We purchase the material used in our clinical trial activities from various companies and suppliers.

Sales and Marketing

We do not currently have sales or marketing capabilities. To date, we have chosen to license our approved products to strategic partners that have sales, marketing and distribution capabilities. In the future, we intend to pursue additional strategic alliances, as well as consider internal commercialization of our product candidates. Since we do not currently have the financial, and other, resources to undertake sales and marketing activities, if we are unable to enter into additional strategic alliances, we may not be able to successfully market our products or product candidates.

Customers and Distribution

We do not currently sell or distribute pharmaceutical products.

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Competition

We and our strategic partners face intense competition. We are in competition with organizations which are larger and or better capitalized than us. We will be competing against established pharmaceutical companies that currently market products which are equivalent or functionally similar to those we intend to market. Prices of pharmaceutical products are significantly affected by competitive factors and tend to decline as competition increases. In addition, numerous companies are developing or may, in the future, engage in the development of products competitive with our proposed products. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as enhanced delivery system technologies gain greater acceptance. Additionally, the markets for formulated products which we have targeted for development are intensely competitive, involving numerous competitors and products. We intend to enhance our competitive position by focusing our efforts on our novel dosage forms.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

Government Regulation

Pharmaceutical Regulation

The Food and Drug Administration, or FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution and export of pharmaceutical products, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these areas. We may be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied or marketed abroad. The approval process outside the U.S. varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Regulation in the United States

New Drug Applications

The FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act or FDCA. The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our products will ever obtain approval. The FDA approval process for new drugs generally includes the following to enable the FDA to evaluate the product’s safety and effectiveness:

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