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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended September 30, 2010

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission File Number 001-33451

BIODEL INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**90-0136863**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
100 Saw Mill Road **Danbury, CT** *(Address of Principal Executive Offices)*	**06810** *(Zip Code)*

Registrant's telephone number, including area code
(203) 796-5000

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	The NASDAQ Global Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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 ☐ No ☐

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

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

Large accelerated filer ☐	Accelerated filer ☑
Non-accelerated filer ☐	Smaller reporting company ☐
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the common stock of the registrant held by non-affiliates was $81 million based on the last sales price at which the common stock was last sold on the NASDAQ Global Market on March 31, 2010.

The number of shares outstanding of the registrant's common stock, as of November 30, 2010 was 26,433,982.

Portions of the registrant's definitive Proxy Statement, or the 2011 Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2010, for its 2011 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report. With the exception of the portions of the 2011 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Annual Report on Form 10-K.

BIODEL INC.

INDEX TO REPORT ON FORM 10-K

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. Such forward-looking statements include statements about future activities related to the complete response letter regarding our new drug application, or NDA, for Linjeta™; the timing and adequacy our response to the complete response letter; the consequences of the complete response letter; and the company's focus, goals, strategy, research and development programs, and ability to develop and commercialize product candidates. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Our forward-looking statements in this Annual Report on Form 10-K are subject to a number of known and unknown risks and uncertainties that could cause actual results, performance or achievements to differ materially from those described or implied in the forward-looking statements, including:

- our ability to respond to the complete response letter regarding our NDA for Linjeta™ (formerly known as VIAject®) in a timely manner and the possibility that information we provide in response to the letter may not be sufficient for the approval of Linjeta™ or another rapid-acting insulin or insulin analog by the U.S. Food and Drug Administration, or FDA;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA, and the degree to which we are able to clarify with the FDA related regulatory requirements;
- our ability to conduct the additional pivotal clinical trials the FDA requested in the complete response letter or other tests or analyses required by the FDA to secure approval to commercialize Linjeta™;
- our ability to develop and commercialize formulations of Linjeta™ or other rapid-acting insulin or insulin analog formulations that may be associated with less injection site discomfort than the formulation that is the subject of the complete response letter we received from the FDA;
- the progress, timing or success of our product candidates, particularly Linjeta™, and that of our research, development and clinical programs, including any resulting data analyses;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves;
- our ability to enforce our patent for Linjeta™ and our ability to secure additional patents for Linjeta™ and for our other product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the degree of clinical utility of our products;
- the ability of our major suppliers, including suppliers of insulin, to produce our product or products in our final dosage form;
- our commercialization, marketing and manufacturing capabilities and strategies; and
- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or

events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report, particularly in Item 1A of this Annual Report, and in our other public filings with the Securities and Exchange Commission that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this Annual Report and the documents that we have filed as exhibits to the Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. It is routine for internal projections and expectations to change as the year, or each quarter in the year, progresses, and therefore it should be clearly understood that the internal projections and beliefs upon which we base our expectations are made as of the date of this Annual Report on Form 10-K and may change prior to the end of each quarter or the year. While we may elect to update forward-looking statements at some point in the future, we do not undertake any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise.

PART I

ITEM 1: ***BUSINESS***

Overview

We are a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. We develop our product candidates by applying our proprietary formulation technologies to existing drugs in order to improve their therapeutic profiles. Our most advanced product candidate is Linjeta™ (formerly known as VIAject®). We have formulated Linjeta™ as a rapid-acting mealtime insulin for the treatment of patients with Type 1 and Type 2 diabetes. Earlier stage product candidates include follow-on and second generation rapid-acting mealtime insulins or insulin analogs, VIAtab™, a sublingual tablet formulation of insulin, a line of basal insulins, and a stabilized formulation of glucagon.

Diabetes is a disease characterized by abnormally high levels of blood glucose and inadequate levels of insulin. Glucose is a simple sugar used by all the cells of the body to produce energy and support life. Humans need a minimum level of glucose in their blood at all times to stay alive. Insulin is a peptide hormone naturally secreted by the pancreas to regulate the body's management of glucose. When a healthy individual begins a meal, the pancreas releases a natural spike of insulin called the first-phase insulin release, which is critical to the body's overall control of glucose. Virtually all patients with diabetes lack the first-phase insulin release. All patients with Type 1 diabetes must treat themselves with mealtime insulin injections to compensate for the lack of natural pancreatic first phase insulin release. As the disease progresses, patients with Type 2 diabetes also require mealtime insulin. However, none of the currently marketed mealtime insulin products adequately mimics the first-phase insulin release. As a result, patients using insulin typically have inadequate levels of insulin in their systems at the start of a meal and too much insulin in their systems between meals. This, in turn, results in the lack of adequate glucose control associated with diabetes. The long-term adverse effects of elevated glucose levels include blindness, loss of kidney function, nerve damage and loss of sensation and poor circulation in the periphery, which in some severe cases, may lead to amputations.

Advances in insulin technology in the 1990s led to the development of new molecules, referred to as rapid-acting insulin analogs, which are similar to insulin, but are absorbed into the blood more rapidly.

Linjeta™ Development Status. Linjeta™ is our proprietary injectable formulation of recombinant human insulin designed to be absorbed into the blood faster than the currently marketed rapid-acting insulin analogs. We have completed two pivotal Phase 3 clinical trials of Linjeta™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. In both clinical trials we compared Linjeta™ to Humulin® R, a form of recombinant human insulin, to determine if Linjeta™ is not inferior to Humulin® R in the management of blood glucose levels, as measured by the mean change in patients' glycosylated hemoglobin, or HbA1c, levels from baseline. Patients in both clinical trials were treated for a period of six months. HbA1c is a measure of a patient's average blood glucose level over a period of approximately three months.

In December 2009, we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, under section 505(b)(2) of the FFDCA for approval to market Linjeta™ as a treatment for diabetes. The NDA included results from pharmacokinetic and standardized meal studies, our two pivotal six month Phase 3 clinical trials of Linjeta™ in patients with Type 1 and Type 2 diabetes, as well as results from the long-term 18 month safety extension trials for patients who completed the pivotal Phase 3 clinical trials. The NDA sought approval for a 100 IU/cc liquid formulation of Linjeta™ that we determined was bioequivalent to the two-part 25 IU/cc lyophilized powder formulation of Linjeta™ that was used in our pivotal Phase 3 clinical trials. The FDA accepted the NDA for review with a Prescription Drug User Fee Act, or PDUFA, action date for the NDA of October 30, 2010.

On November 1, 2010, we announced that the FDA issued a complete response letter requesting additional information regarding our NDA for Linjeta™. The complete response letter stated that the FDA's review cycle was complete and that the application could not be approved in its present form. The FDA requested that we conduct two new Phase 3 clinical trials using the final commercial formulation of Linjeta™,

one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes, to establish efficacy and safety as related to hypoglycemia and toleration. The FDA also requested additional data related to stability and manufacturing of our final commercial formulation of Linjeta™. We have contacted the FDA to formally request a meeting to discuss the complete response letter.

Other Corporate Developments. In October 2009, we executed a letter of intent to purchase a disposable insulin pen designed by Wockhardt, Ltd. for use with Linjeta™. As of September 30, 2010, we were operating under the same letter of intent.

In March 2010, we appointed Dr. Errol B. De Souza as our President and Chief Executive Officer and Dr. Charles Sanders as our board chairman. Dr. Solomon S. Steiner, our former Chairman, President and Chief Executive Officer, became our Chief Scientific Officer and remains a member of our board. Dr. Sanders is currently taking a leave of absence from our board of directors due to medical reasons. During Dr. Sanders' leave of absence, Dr. Brian J.G. Pereira is serving as our Lead Director.

In August 2010, we entered into definitive agreements with two institutional investors to sell 2,398,200 shares of our common stock and warrants to purchase 2,398,200 shares of our common stock, resulting in gross proceeds to us, after deducting placement agents' fees and offering expenses, of approximately $8.7 million.

In September 2010, we announced that Linjeta™ would replace VIAject® as the proposed trade name for the insulin formulation that is the subject of the complete response letter we received from the FDA.

In November 2010, we announced that we had been awarded approximately $1.2 million in research grants under the Internal Revenue Service's therapeutic discovery tax credit program. This program was created under the Patient Protection and Affordable Care Act of 2010 to provide tax credits or grants representing up to 50 percent of eligible qualified investments in therapeutic discovery projects during tax years 2009 and 2010. We applied for and will receive these funds to support our Linjeta™, VIAtab™, glucagon, extended glargine and glucose-sensing glargine insulin development projects.

Fiscal Year 2011 Strategic Focus. The complete response letter we received from the FDA with regard to Linjeta™ has caused us to limit some of our product development and research and development activities. We plan to focus our efforts over the next several months as follows:

- *Determine Whether to Advance our Current Formulation of Linjeta™ through Pivotal Phase 3 Clinical Trials.* In light of the extensive nature of the FDA's comments regarding our NDA, we do not anticipate commencing new pivotal Phase 3 clinical trials with our current formulation of Linjeta™ prior to meeting with the FDA and, separately, determining whether one of our other proprietary rapid-acting insulin or insulin analog formulations should be advanced in its place. These alternate formulations generally use the same or similar excipients as Linjeta™, but may present improvements with regard to injection site discomfort. In fiscal year 2011, we intend to conduct preclinical studies and Phase 1 clinical trials studies to determine whether one or more of our newer insulin formulations is likely to offer a combination of pharmacokinetic, stability and tolerability characteristics that is preferable to Linjeta™. Following our meeting with the FDA regarding Linjeta™, and based on our analysis of the preclinical and Phase 1 clinical data for our alternate formulations, we will determine the number, type and duration of additional trials we intend to conduct prior to initiating Phase 3 clinical trials with a proprietary rapid-acting insulin.
- *Advance Proof-of-Concept Formulations.* We intend to make limited investments in our VIAtab™, glucagon, extended glargine and glucose-sensing basal insulin development programs. Our goal is to advance proof-of-concept formulations that we can discuss with potential corporate partners. Because we are focusing on therapeutic indications in large markets, we believe that these larger companies have the marketing, sales and financial resources to maximize the commercial potential of our technologies and products.

Diabetes and the Insulin Market

Diabetes Overview

Glucose is a simple sugar used by all the cells of the body to produce energy and support life. Humans need a minimum level of glucose in their blood at all times to stay alive. The primary manner in which the body produces blood glucose is through the digestion of food. When a person is not getting this glucose from food digestion, glucose is produced from stores and released by the liver. The body's glucose levels are regulated by insulin. Insulin is a peptide hormone that is naturally secreted by the pancreas. Insulin helps glucose enter the body's cells to provide a vital source of energy.

When a healthy individual begins a meal, the pancreas releases a natural spike of insulin called the first-phase insulin release. In addition to providing sufficient insulin to process the glucose coming into the blood from digestion of the meal, the first-phase insulin release acts as a signal to the liver to stop making glucose while digestion of the meal is taking place. Because the liver is not producing glucose and there is sufficient additional insulin to process the glucose from digestion, the blood glucose levels of healthy individuals remain relatively constant and their blood glucose levels do not become too high.

Diabetes is a disease characterized by abnormally high levels of blood glucose and inadequate levels of insulin. There are two major types of diabetes — Type 1 and Type 2. In Type 1 diabetes, the body produces no insulin. In the early stages of Type 2 diabetes, although the pancreas does produce insulin, the body loses its early phase insulin response to a meal. In addition, the body's cells do not respond as well as they should to a normal amount of insulin, a condition known as insulin resistance. According to the Centers for Disease Control and Prevention, or CDC, Type 2 diabetes is the more prevalent form of the disease, affecting approximately 90% to 95% of all people diagnosed with diabetes.

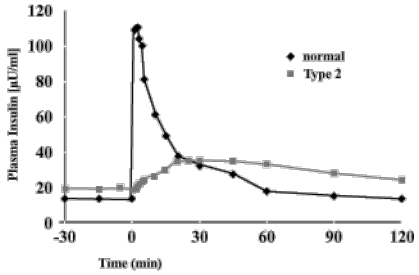
Even before any other symptoms are present, one of the first effects of Type 2 diabetes is the loss of the meal-induced first-phase insulin release. In the absence of the first-phase insulin release, the liver will not receive its signal to stop making glucose. As a result, the liver will continue to produce glucose at a time when the body begins to produce new glucose through the digestion of the meal. As a result, the blood glucose level of patients with diabetes rises too high after eating, a condition known as hyperglycemia. Hyperglycemia causes glucose to attach unnaturally to certain proteins in the blood, interfering with these proteins' ability to perform their normal function of maintaining the integrity of the small blood vessels. With hyperglycemia occurring after each meal, the tiny blood vessels eventually break down and leak. The long-term adverse effects of hyperglycemia include blindness, loss of kidney function, nerve damage and loss of sensation and poor circulation in the periphery, potentially requiring amputation of the extremities.

Between two and three hours after a meal, an untreated diabetic's blood glucose becomes so elevated that the pancreas receives a signal to secrete an inordinately large amount of insulin. In a patient with early Type 2 diabetes, the pancreas can still respond and secretes this large amount of insulin. However, this occurs at the time when digestion is almost over and blood glucose levels should begin to fall. This inordinately large amount of insulin has two detrimental effects. First, it puts an undue extreme demand on an already compromised pancreas, which may lead to its more rapid deterioration and eventually render the pancreas unable to produce insulin. Second, too much insulin after digestion leads to weight gain, which may further exacerbate the disease condition.

The figure below, which is derived from an article in the *New England Journal of Medicine,* illustrates the differences in the insulin release profiles of a healthy individual and a person in the early stages of Type 2 diabetes. In response to an intravenous glucose injection, which simulates eating a meal, the healthy individual produces the first-phase insulin release. In contrast, the patient with Type 2 diabetes lacks the first-phase insulin release and

releases the insulin more slowly and over time. As a result, in the early stages of the disease, the Type 2 patient's insulin level is too low at the initiation of a meal and too high after meal digestion.

First Phase Insulin Release



Current Treatments for Diabetes and their Limitations

Because patients with Type 1 diabetes produce no insulin, the primary treatment for Type 1 diabetes is daily intensive insulin therapy. The treatment of Type 2 diabetes typically starts with management of diet and exercise. Although helpful in the short-run, treatment through diet and exercise alone is not an effective long-term solution for the vast majority of patients with Type 2 diabetes. When diet and exercise are no longer sufficient, treatment commences with various non-insulin oral medications. These oral medications act by increasing the amount of insulin produced by the pancreas, by increasing the sensitivity of insulin-sensitive cells, by reducing the glucose output of the liver or by some combination of these mechanisms. These treatments are limited in their ability to manage the disease effectively and generally have significant side effects, such as weight gain. Because of the limitations of non-insulin treatments, many patients with Type 2 diabetes deteriorate over time and eventually require insulin therapy to support their metabolism.

Insulin therapy has been used for more than 80 years to treat diabetes. This therapy usually involves administering several injections of insulin each day. These injections consist of administering a long-acting basal injection one or two times per day and an injection of a rapid-acting insulin at mealtime. Although this treatment regimen is accepted as effective, it has limitations. First, patients generally dislike injecting themselves with insulin due to the inconvenience and pain of needles. As a result, patients tend not to comply adequately with the prescribed treatment regimens and are often inadequately medicated.

More importantly, even when properly administered, insulin injections do not replicate the natural time-action profile of insulin. In particular, the natural spike of the first-phase insulin release in a person without diabetes results in blood insulin levels rising within several minutes of the entry into the blood of glucose from a meal. By contrast, injected insulin enters the blood slowly, with peak insulin levels occurring within 80 to 100 minutes following the injection of regular human insulin.

A potential solution is the injection of insulin directly into the vein of diabetic patients immediately before eating a meal. In studies of intravenous injections of insulin, patients exhibited better control of their blood glucose for 3 to 6 hours following the meal. However, for a variety of medical reasons, intravenous injection of insulin before each meal is not a practical therapy.

One of the key improvements in insulin treatments was the introduction in the 1990s and 2000s of rapid-acting insulin analogs, such as Humalog®, NovoLog® and Apidra®. However, even with the rapid-acting insulin analogs, peak insulin levels typically occur within 50 to 70 minutes following the injection. Because the rapid-acting insulin analogs do not adequately mimic the first-phase insulin release, diabetics using insulin therapy continue to have inadequate levels of insulin present at the initiation of a meal and too much insulin

present between meals. This lag in insulin delivery can result in hyperglycemia early after meal onset. Furthermore, the excessive insulin between meals may result in an abnormally low level of blood glucose known as hypoglycemia. Hypoglycemia can result in loss of mental acuity, confusion, increased heart rate, hunger, sweating and faintness. At very low glucose levels, hypoglycemia can result in loss of consciousness, coma and even death. According to the American Diabetes Association, or ADA, patients with Type 1 diabetes have a serious hypoglycemic event approximately once per year, many of which require hospital emergency room visits.

A More Rapid-Acting Mealtime Insulin

Linjeta™ is our proprietary formulation of injectable human insulin to be taken at mealtime. Linjeta™ is designed to be absorbed into the blood faster than the currently marketed rapid-acting insulin analogs. One of the key features of our formulation of insulin is that it allows the insulin to disassociate, or separate, from the six molecule, or hexameric, form to the single molecule, or monomeric, form and inhibits re-association to the hexameric form. We believe that by favoring the monomeric form, Linjeta™ allows for more rapid delivery of insulin into the blood as the human body requires insulin to be in the form of a single molecule before it can be absorbed into the body to produce its desired biological effects. Based upon our preclinical and clinical data, we believe Linjeta™ may produce a profile of insulin levels in the blood that approximates the natural first-phase insulin release following a meal that is normally seen in persons without diabetes.

Clinical Trials of Linjeta™

Phase 1 and Phase 2 Clinical Trials. We have conducted Phase 1 and Phase 2 clinical trials comparing the performance of Linjeta™ to Humalog®, the largest selling rapid-acting insulin analog in the United States, and Humulin® R. In these trials, we observed that Linjeta™ produced a release profile into the blood that more closely approximates the natural first-phase insulin release in response to a meal that is seen in healthy individuals.

Pivotal Phase 3 Clinical Trials. We completed our two pivotal Phase 3 clinical trials of Linjeta™ in July 2008. Our pivotal Phase 3 clinical trials were open-label, parallel group, randomized trials conducted at centers in the United States, Germany and India. The trials were designed to compare the efficacy and safety of Linjeta™ to Humulin® R. One of the trials tested Linjeta™ in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. We enrolled more than 400 patients in each trial for a six month treatment period. Approximately one-half of the patients in each trial were treated with Linjeta™ and the remainder with Humulin® R. The primary objective of the trials was to determine if Linjeta™ was not inferior to Humulin® R in the management of blood glucose levels, as measured by the mean change in patients' glycosylated hemoglobin, or HbA1c, levels from baseline to the end of the trial. HbA1c levels are a measure of patients' average blood glucose levels over a period of approximately 3 months. HbA1c is the FDA's preferred endpoint for diabetes trials. Predefined secondary endpoints in the trials included rates of mild and moderate and severe hypoglycemic events, and changes in body weight.

Approximately 400 patients with Type 1 and Type 2 diabetes who completed the pivotal Phase 3 clinical trials elected to participate in a long term safety extension trial in which all patients were treated with Linjeta™ as their mealtime insulin. The last patient visit in the extension trial was in February 2010.

In September 2008, we announced results from a preliminary analysis of the data from our pivotal Phase 3 clinical trials of Linjeta™. In our Type 1 trial, we found that data from patients with Type 1 diabetes in India were anomalous when compared to data from the United States and Germany for the same trial. When HbA1c data from patients in India were included in the analysis of the Type 1 trial, change in HbA1c favored the Humulin® R treatment group. In our Type 2 trial, we found that Linjeta® was comparable to Humulin® R in terms of blood glucose control, when measured by the mean change in patients' HbA1c levels.

In December 2009, we submitted an NDA to the FDA under section 505(b)(2) of the FFDCA for clearance to market Linjeta™ as a treatment for diabetes. The NDA included results from pharmacokinetic and standardized meal studies, our pivotal six month Phase 3 clinical trials of Linjeta™ in patients with Type 1 and Type 2 diabetes, as well as interim results from the long-term 18 month safety extension trials for patients

who completed the pivotal Phase 3 clinical trials. The NDA sought approval for a 100 IU/cc liquid formulation of Linjetatm that we determined was bioequivalent to the two-part 25 IU/cc lyophilized powder formulation of Linjetatm that was used in our pivotal Phase 3 clinical trials. We believed at the time of our NDA filing that the FDA could conclude, on the basis of our pharmacokinetic and pharmacodynamic studies as well as our two pivotal Phase 3 clinical trials, that the efficacy and safety of Lintejatm were established. The FDA accepted the NDA for review with a PDUFA action date for the NDA of October 30, 2010.

Complete Response Letter. On November 1, 2010, we announced that the FDA issued a complete response letter requesting additional information regarding our NDA for Linjetatm. The complete response letter stated that the FDA's review cycle is complete and that the application cannot be approved in its present form. The complete response letter included comments related to clinical trials, statistical analysis and chemistry, manufacturing and controls. With regard to efficacy, the FDA stated that, in the Type 1 trial analysis, excluding data from India was post-hoc and therefore not sufficient for establishing conclusive evidence of efficacy. In the Type 2 trial analysis, the FDA acknowledged that non-inferiority was established in the completer population but stated that non-inferiority was not established in the intent-to-treat population because the agency did not consider a post-hoc modification of the statistical model as establishing conclusive evidence of efficacy. With regard to safety, the FDA commented that unequivocal non-inferiority needs to be achieved in order to compare the risk of hypoglycemia. The FDA requested that the company conduct two new Phase 3 clinical trials using the commercial formulation of Linjetatm, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes, to establish efficacy and safety as related to hypoglycemia and toleration. The FDA also requested additional data related to stability and manufacturing and identified resolution of manufacturing issues related to recent site inspections at third-party manufacturers, Hyaluron, Inc. and Wockhardt, Ltd. as a requisite for approval. We have contacted the FDA to formally request a meeting to discuss the complete response letter.

Tolerability. The Linjetatm formulation used in the pivotal Phase 3 clinical trials was a two vial presentation, with one vial containing lyophilized insulin and the second vial containing 10 ml of the proprietary Linjetatm diluent, which upon reconstitution yields a concentration of 25 IU/ml at a pH of 4. We have also developed two pre-mixed, liquid formulations of Linjetatm at concentrations of 100 IU/ml that we determined are bioequivalent to the 25 IU/ml, two-vial, presentation used in the pivotal Phase 3 clinical trials. One of these formulations is at a pH of 4, and the other is at a pH of 7.

In October 2009, we completed a trial studying the tolerability of the pH 7 100 IU/ml liquid formulation of Linjetatm compared to both the Linjetatm pH4 25 IU/ml two-part lyophilized formulation and to Humalog®. This was a double blind, randomized trial in which patients were injected with each of the three study drugs in triplicate, for a total of 9 doses, each given on separate days. The primary endpoint of the trial was injection site discomfort as measured on a visual analog scale. A secondary endpoint was the patient's qualitative description of severity (mild, moderate or severe). Results from the tolerability trial indicated that the liquid formulation of Linjetatm presented a statistically significant reduction in injection site discomfort when compared to the lyophilized formulation. However, some patients experienced more injection site discomfort with the liquid formulation of Linjetatm than they did with Humalog®. As measured by a visual analog scale where 0 represents no discomfort and 100 represents the worst possible discomfort, the 25 IU/ml lyophilized formulation of Linjetatm and the pH 7 100 IU/ml liquid formulation of Linjetatm received scores (arithmetic mean±SE) of 22.0 ± 2.78 and 17.3 ± 2.50 ($p = 0.041$ for difference between Linjetatm formulations), respectively, compared to a score of 5.3 ± 1.02 for Humalog®. The mean qualitative severity ratings were in the mild range or lower for all three study drugs.

In July 2010, we completed a Phase 1 single-center, double-blind, randomized crossover trial in 13 subjects with Type 1 diabetes who received a single injection of the pH 7 100 IU/ml liquid formulation of Linjetatm or one of two modified liquid formulations, each on a separate day. The purpose of the clinical trial was to compare the pharmacokinetic characteristics and toleration of Linjetatm to the two modified formulations. We found that the modified formulations, when compared to the proposed commercial formulation that is the subject of the complete response letter we received from the FDA, were associated with similar rates of absorption, lower maximal insulin concentrations and substantially improved toleration profiles. As measured by a visual analog scale described above, the modified formulations received scores (arithmetic mean±SE) of 9.0 ±2.55 and 4.0 ± 1.17 compared to a score of 20.6 ± 6.68 for the proposed commercial formulation of Linjetatm ($p = 0.112$ and $p = 0.028$ for difference between each respective modified formulation and Linjetatm). The mean

qualitative severity ratings were in the mild range for Linjetatm and were significantly improved for the two modified formulations. The modified formulations generally use the same or similar excipients as Linjetatm, while varying the ratios of salts.

Use of Linjetatm in Insulin Pumps. In September 2010, we performed a preliminary analysis of data from a double-blind, two-period crossover study comparing Linjetatm to Humalog® with regard to glucose control when administered through an insulin pump. Twenty patients with Type 1 diabetes received one of the study drugs for 72 hours, after which the patients crossed over to the other study drug. The clinical trial included in-patient and out-patient periods. In the in-patient period, blood glucose levels were measured following a standard meal challenge. In both the in-patient and out-patient periods, blood glucose levels were measured using continuous glucose monitoring devices. Our preliminary analysis of the data resulting from this clinical trial indicated that for the in-patient meal challenge, neither Linjetatm nor Humalog® were as effective in controlling peak blood glucose levels as would be expected had the study drugs been administered through standard injections. The initial peak in blood glucose levels following the meal challenge was higher for Linjetatm than for Humalog®. Also, in the period of time following the mean postprandial peak, Linjetatm was associated with higher glucose levels on average, whereas Humalog® was associated with more hypoglycemia. During the out-patient portion of the study, overall glucose control was comparable between the two study drugs. We continue to analyze the data resulting from this clinical trial and intend to present final results at an appropriate scientific forum. Additionally, we are conducting studies in an animal model of diabetes in an effort to optimize the parameters for delivery of Linjetatm through insulin pumps.

Development status. In light of the extensive nature of the FDA's comments regarding our NDA, we do not anticipate commencing new pivotal Phase 3 clinical trials with our current formulation of Linjetatm prior to meeting with the FDA and, separately, determining whether one of our other proprietary rapid-acting insulin or insulin analog formulations should be advanced in its place. These alternate formulations generally use the same or similar excipients as Linjetatm, but may present improvements with regard to injection site discomfort. In fiscal year 2011, we intend to conduct preclinical studies and Phase 1 clinical trials to determine whether one or more of our newer insulin formulations is likely to offer a combination of pharmacokinetic, stability and tolerability characteristics that is preferable to Linjetatm. Following our meeting with the FDA regarding Linjetatm and based on our analysis of the preclinical and Phase 1 clinical data for our alternate formulations, we will determine the number, type and duration of additional trials we intend to conduct prior to initiating Phase 3 clinical trials with a proprietary rapid-acting insulin.

Government Regulation

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

United States Government Regulation

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the FFDCA and other statutes and implementing regulations. Biodel intends to seek FDA approval for its product candidates in an NDA, and not under an application submitted for approval as a biologic under the Public Health Service Act. The process required by the FDA before a drug product candidate may be marketed in the United States under an NDA generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;

- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Clinical Trials. Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Each protocol is submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap, or be combined.

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase 2 clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks.
- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Clinical testing must satisfy extensive FDA regulations. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early stage clinical trials does not assure success in later stage clinical trials. The FDA, an IRB or we may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

New Drug Applications. Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market. The agency may also impose requirements that the NDA holder conduct new studies, make labeling changes, implement Risk Evaluation and Mitigation Strategies, and take other corrective measures.

Section 505(b)(2) NDAs. There are two types of NDAs: the full NDA and the Section 505(b)(2) NDA. We intend to file Section 505(b)(2) NDAs that might, if accepted by the FDA, save time and expense in the development and testing of our product candidates. A full NDA is submitted under Section 505(b)(1) of the FFDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug. A Section 505(b)(2) NDA may be submitted for a drug for which one or more of the investigations relied upon by the applicant was not conducted by or for the applicant and for which the applicant has no right of reference from the person by or for whom the investigations were conducted. A Section 505(b)(2) NDA may be submitted based in whole or in part on published literature or on the FDA's finding of safety and efficacy of one or more previously approved drugs, which are known as reference drugs. Thus, the filing of a Section 505(b)(2) NDA may result in approval of a drug based on fewer clinical or nonclinical studies conducted by the applicant than would be required under a full NDA. The number and size of studies that need to be conducted by the sponsor depends on the amount and quality of data pertaining to the reference drug that are publicly available, and on the similarity of and differences between the applicant's drug and the reference drug. In some cases, extensive, time-consuming, and costly clinical and nonclinical studies may still be required for approval of a Section 505(b)(2) NDA.

Because we are developing new formulations of previously approved chemical entities, such as insulin, our drug approval strategy is to submit Section 505(b)(2) NDAs to the FDA. We plan to pursue similar routes for submitting applications for our product candidates in foreign jurisdictions if available. The FDA may not agree that our product candidates are approvable as Section 505(b)(2) NDAs. Insulin is a small protein molecule which is known to be associated with significant intra- and inter-patient variability of absorption and resulting glucose lowering response. This makes it more difficult to demonstrate that two insulin substances are highly similar than would be the case with many small molecule drugs. The availability of the

Section 505(b)(2) NDA pathway for insulin is even more controversial than for small molecule drugs, and the FDA may not accept this pathway for our insulin drug candidates. There is no specific guidance available for insulin Section 505(b)(2) NDAs, and no insulin product has been approved under a Section 505(b)(2) NDA. If the FDA determines that Section 505(b)(2) NDAs are not appropriate and that full NDAs are required for our product candidates, the time and financial resources required to obtain FDA approval for our product candidates could substantially and materially increase, and our products might be less likely to be approved. If the FDA requires full NDAs for our product candidates, or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than our product candidates would be adversely impacted.

Patent Protections. An applicant submitting a Section 505(b)(2) NDA must certify to the FDA with respect to the patent status of the reference drug upon which the applicant relies in support of approval of its drug. With respect to every patent listed in the FDA's Orange Book, which is the FDA's list of approved drug products, as claiming the reference drug or an approved method of use of the reference drug, the Section 505(b)(2) applicant must certify that: (1) there is no patent information listed by the FDA for the reference drug; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date; (4) the listed patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the product in the Section 505(b)(2) NDA; or (5) if the patent is a use patent, that the applicant does not seek approval for a use claimed by the patent. If the applicant files a certification to the effect of clause (1), (2) or (5), FDA approval of the Section 505(b)(2) NDA may be made effective immediately upon successful FDA review of the application, in the absence of marketing exclusivity delays, which are discussed below. If the applicant files a certification to the effect of clause (3), the Section 505(b)(2) NDA approval may not be made effective until the expiration of the relevant patent and the expiration of any marketing exclusivity delays.

If the Section 505(b)(2) NDA applicant provides a certification to the effect of clause (4), referred to as a paragraph IV certification, the applicant also must send notice of the certification to the patent owner and the holder of the NDA for the reference drug. The filing of a patent infringement lawsuit within 45 days of the receipt of the notification may prevent the FDA from approving the Section 505(b)(2) NDA for 30 months from the date of the receipt of the notification unless the court determines that a longer or shorter period is appropriate because either party to the action failed to reasonably cooperate in expediting the action. However, the FDA may approve the Section 505(b)(2) NDA before the 30 months have expired if a court decides that the patent is invalid, unenforceable, or not infringed, or if a court enters a settlement order or consent decree stating the patent is invalid or not infringed.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged in court, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit. The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Moreover, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Marketing Exclusivity. Market exclusivity provisions under the FFDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a Section 505(b)(2) product from entering the market. The FFDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity generally prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active moiety during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until

7.5 years after the NCE approval date. The FFDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting a full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the preclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other types of exclusivity in the United States include orphan drug exclusivity and pediatric exclusivity. The FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Seven-year orphan drug exclusivity is available to a product that has orphan drug designation and that receives the first FDA approval for the indication for which the drug has such designation. Orphan drug exclusivity prevents approval of another application for the same drug for the same orphan indication, for a period of seven years, regardless of whether the application is a full NDA or a Section 505(b)(2) NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protection or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Section 505(b)(2) NDAs are similar to full NDAs filed under Section 505(b)(1) in that they are entitled to any of these forms of exclusivity if they meet the qualifying criteria. They also are entitled to the patent protections described above, based on patents that are listed in the FDA's Orange Book in the same manner as patents claiming drugs and uses approved for NDAs submitted as full NDAs.

Other Regulatory Requirements. Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including cGMPs. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided

over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, and disgorgement or profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Regulations Outside the United States

In addition to regulations in the United States, we will be subject to a variety of laws and regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of countries outside the United States before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary between jurisdictions.

To obtain regulatory approval of a drug under European Union regulatory systems, we may submit applications for marketing authorizations either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, new active substances indicated for the treatment of certain diseases such as AIDS, cancer, neurodegenerative disorders and diabetes, and products designated as orphan medicinal products, and optional for other new active substances and those products which constitute a significant therapeutic, scientific or technical innovation. The procedure provides for the grant of a single marketing authorization that is valid for all European Union member states, as well as for Iceland, Liechtenstein, and Norway. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to the public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

Competition

The pharmaceutical industry is characterized by intense competition and rapidly evolving technology. For several decades, scientists have attempted to improve the bioavailability of injected formulations and to devise alternative non-invasive delivery systems for the delivery of macromolecules such as insulin. If approved, our product candidates will compete against many products with similar indications.

If approved, our primary competition for Linjeta™ will be rapid-acting mealtime injectable insulins such as Humalog®, which is marketed by Eli Lilly, NovoLog®, which is marketed by Novo Nordisk, and Apidra®, which is marketed by Sanofi-Aventis.

In addition, other development stage rapid-acting insulin formulations may be approved and compete with Linjeta™. Halozyme Therapeutics, Inc. has conducted a Phase 1 and multiple Phase 2 clinical trials of

Humulin® R and Humalog® in combination with a recombinant human hyaluronidase enzyme and has reported that in each case the combination yielded pharmacokinetics and glucodynamics that better mimicked physiologic mealtime insulin release and activity than Humulin® R or Humalog® alone. Novo Nordisk has reported that they have initiated clinical development of an ultra-fast-acting insulin analogue intended to provide faster onset of action than the currently available fast-acting insulin analogs.

Several companies are also developing alternative insulin systems for diabetes, including MannKind Corporation, which has an inhalable insulin product candidate for which an NDA was submitted in early 2009 with an upcoming PDUFA date of December 29, 2010. The approval and acceptance of an inhaled insulin such as MannKind's product could reduce the overall market for injectable prandial insulin.

Treatment practices can also change with the introduction of new classes of therapy. Currently GLP-1 analogs such as exantide, marketed by Eli Lilly, and liraglutide, marketed by Novo Nordisk, are growing in usage and could delay the start of insulin usage in some patients therefore decreasing the size of the prandial insulin market.

While at this time there are no approved generic or biosimilar insulin analogs in the market in the United States or Europe, in other countries such as India there are multiple approved manufacturers of insulin analogs such has Humalog®. Both Humalog® and NovoLog® have limited remaining patent protection in the United States and Europe. Biocon, an established biosimilar manufacturer, has entered into a collaboration with Pfizer to commercialize biosimilar versions of Humalog® and NovoLog®. The possible introduction of lower priced brands or substitutable generic versions of these products could negatively impact the revenue potential of Linjetatm.

Intellectual Property and Proprietary Technology

Our technologies have been developed exclusively by our employees, without input from third parties.

On October 9, 2007 the United States Patent and Trademark Office issued U.S. Patent No. 7,279,457 encompassing Linjetatm and VIAtabtm. The patent will expire no earlier than January 2026.

On October 12, 2008 we reported that we received a notice of allowance from the European Patent Office for patent claims encompassing Linjetatm and VIAtabtm. The European Patent granted as EP 1 740 154 on June 17, 2009 and expire on March 11, 2025 in the designated countries if all annuity fees are paid.

We have a policy of filing for patent protection on all our product candidates. Our patents and patent applications consist of the following:

- one granted United States patent, three foreign patents, and several pending United States patent applications and corresponding foreign and international patent applications relating to our Linjetatm and VIAtabtm technology;
- one foreign patent and one pending foreign patent application relating to our technology for enhancing delivery of drugs in a form for absorption through the skin into the blood, a process known as transdermal drug delivery;
- one granted United States patent, one foreign patent, one pending United States patent application and corresponding foreign patent applications relating to sublingual and/or oral delivery devices that can be used to deliver the certain insulin based products; and
- two granted United States patents, several United States patent applications and a corresponding foreign and international patent applications relating to other early stage product candidates.

Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued.

The individual active and inactive ingredients in our Linjetatm and VIAtabtm product candidates have been known and used for many years and, therefore, are no longer subject to patent protection, except in proprietary combinations. Accordingly, our patent and pending applications are directed to the particular formulations of these ingredients in our products, and to their use. Although we believe our formulations and their use are

patented and provide a competitive advantage, our patents may not prevent others from marketing formulations using the same active and inactive ingredients in similar but different formulations.

We require our employees, consultants and members of our scientific advisory board to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

Manufacturing

We have previously used our laboratory in Danbury, Connecticut to meet the limited manufacturing requirements of some of our product candidates through Phase 2 clinical trials. We intend to continue to do so in the future. We intend to also manufacture our product candidates by contracting with third parties that operate manufacturing facilities in accordance with cGMP. To date, we have relied on two commercial manufacturers — Hyaluron, Inc. and Wockhardt, Ltd. — to manufacture our Linjetatm product candidate. Hyaluron, Inc. and Wockhardt, Ltd. have each recently undergone an inspection by the FDA in which deficiencies were identified and a warning letter from the FDA was issued. The FDA has required that these deficiencies be corrected prior to the approval or manufacture of Linjetatm or the manufacture of our other product formulations for use in clinical trials. At this time, the ability of, and the length of time that may be required by, Hyaluron, Inc. and Wockhardt, Ltd. to remediate the deficiencies identified by the FDA is uncertain. Failure by either Hyaluron, Inc. or Wockhardt, Ltd. to adequately and timely remediate the deficiencies identified by the FDA may delay the execution of our strategic plans, including the manufacturing of study drugs for use in clinical trials.

We have contracted with N.V. Organon (formerly known as Diosynth B.V.), a global producer of insulin, to supply us with all of the insulin that we will need for the testing and manufacturing of our product candidates. Our agreement with N.V. Organon will terminate in December 2011, and we are discussing the possibility of extending the agreement. We believe that our current supplies of insulin, together with the quantities of insulin called for under our existing supply agreement, will be sufficient to allow us to complete our current and anticipated future clinical trials of Linjetatm or alternative rapid-acting insulin formulations using regular human insulin, as well as support the commercial launch of the product if approved by the FDA. We may seek to qualify another insulin supplier to serve as additional or alternative supplier.

Sales and Marketing

We currently have no sales and marketing capabilities and no distribution capabilities. Our current strategy is to selectively enter into collaboration agreements with leading pharmaceutical or biotechnology companies for the commercialization of our product candidates.

Employees

At September 30, 2010 we had 55 full time-employees and several part-time consultants who perform services for us on a regular basis. We consider our employee relations to be good.

Additional Information

Our website is www.biodel.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnished it to, the Securities and Exchange Commission. Our reports filed with the Securities and Exchange Commission are also available at the Securities and Exchange Commission's website at www.sec.gov.

Executive Officers of the Registrant

The following table sets forth our executive officers, their respective ages and positions as of November 30, 2010:

Name	Age	Position
Dr. Errol B. De Souza	57	President and Chief Executive Officer
Dr. Solomon S. Steiner	73	Chief Scientific Officer
Gerard Michel	47	Chief Financial Officer, Vice President, Corporate Development and Treasurer
Dr. Alan Krasner	47	Chief Medical Officer
Paul Bavier	38	General Counsel and Secretary
Erik Steiner	44	Vice President, Operations

Dr. De Souza joined our management and board of directors in March 2010. Dr. De Souza has nearly two decades of experience in the biopharmaceutical industry. From March 2009 until March 2010, Dr. De Souza was a pharmaceutical and biotechnology consultant. From April 2003 to January 2009, Dr. De Souza was president and chief executive officer of Archemix Corporation, a privately-held biopharmaceutical company focused on aptamer therapeutics. From September 2002 to March 2003, he was president, chief executive officer and a director of Synaptic Pharmaceuticals Corporation, a publicly traded biopharmaceutical company that was acquired by H. Lundbeck A/S in March 2003. Dr. De Souza is a member of the board of directors of each of the following publicly traded companies: Bionomics Ltd., Palatin Technologies, Inc. and Targacept, Inc. Dr. De Souza received his B.A. (Honors) in physiology and his Ph.D. in neuroendocrinology from the University of Toronto and he received his postdoctoral fellowship in neuroscience from The Johns Hopkins University School of Medicine. We believe Dr. DeSouza's qualifications to sit on our board of directors include his extensive experience with pharmaceutical companies, and his years of experience providing services to pharmaceutical and biotechnology organizations, including evaluating business plans involving clinical trials.

Dr. Solomon S. Steiner co-founded our company and served as our Chairman, President and Chief Executive Officer since our inception in December 2003 until March 2010 when he became our Chief Scientific Officer and remained a member of our board of directors. In 1991, Dr. Steiner founded Pharmaceutical Discovery Corporation, or PDC, a biopharmaceutical corporation. Dr. Steiner served as PDC's Chief Executive Officer and Chairman of the Board of Directors from its inception until December 2001, when PDC was merged with two other companies to form MannKind Corporation. From December 2001 to February 2003, Dr. Steiner served on MannKind's Board of Directors and as a Corporate Vice President and Chief Scientific Officer. In 1985, Dr. Steiner founded and was the Chairman of the Board of Directors and President of Clinical Technologies Associates, Inc., or CTAI, now known as Emisphere Technologies, Inc. Under his leadership CTAI went public in February of 1989. Dr. Steiner is an inventor of Emisphere's oral delivery system for peptides and mucopolysaccharides. Dr. Steiner is currently an adjunct full professor at New York Medical College and research full professor of psychiatry and neurology at New York University School of Medicine. Dr. Steiner received a Ph.D. from New York University. We believe Dr. Steiner's extensive experience in the pharmaceutical, biotechnology and healthcare industries provides valuable background and insight to our board of directors.

Mr. Gerard Michel joined our company in November 2007 as Chief Financial Officer, Vice President of Corporate Development and Treasurer. From October 2003 to November 2007, Mr. Michel served as Chief Financial Officer and from April 2006 to November 2007, Vice President, Corporate Development of NPS Pharmaceuticals, a biopharmaceutical company. From June 1995 to July 2002, Mr. Michel served as a Principal of the consulting firm Booz-Allen & Hamilton. Mr. Michel received an MBA and B.S. from University of Rochester, and an M.S., in Microbology from The University of Rochester School of Medicine and Dentistry.

Dr. Alan Krasner joined our company in May 2008 as Chief Medical Officer. From 2002 to 2008, Dr. Krasner served as Director of the Department of Clinical Research Metabolic Diseases at Pfizer Global Research and Development where he was responsible for the design, execution, clinical analysis, and reporting

of multiple, global clinical trials supporting registration of late stage drug candidates. Dr. Krasner currently serves as a consulting physician at the Joslin Diabetes and Endocrinology Center of the Lawrence and Memorial Hospital in New London, Connecticut. Dr. Krasner holds a B.S. from the Medical Education Honors Program at Northwestern University and a M.D. from Northwestern University Medical School. He completed his residency at Johns Hopkins Hospital in internal medicine and subsequently received a fellowship from Johns Hopkins Hospital in endocrinology and metabolism.

Mr. Paul Bavier has served as our general counsel and secretary since December 2008. From October 2007 to December 2008, Mr. Bavier served as our deputy general counsel. From November 2004 to October 2007, Mr. Bavier served as assistant general counsel at Gerber Scientific, Inc. Mr. Bavier began his legal career as an associate in the corporate law department of Ropes & Gray in Boston. He holds a B.A. from Middlebury College and a J. D. from the University of Michigan Law School.

Mr. Erik Steiner co-founded our company and has served as our Vice President, Operations since our inception in December 2003. From February 2003 to December 2003, Mr. Steiner co-founded and served as the Vice President, Operations of Steiner Ventures. From May 1999 to February 2003, Mr. Steiner served as Head of Operations of Cabot McMullen Inc., a film and television production company. Prior thereto, Mr. Steiner served as Administrative Director and Fiscal Administrator of the New Jersey Public Interest Research Group. Mr. Steiner is Solomon Steiner's son.

ITEM 1A. *RISK FACTORS*

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception in December 2003, we have incurred significant operating losses. Our net loss was approximately $38.3 million for the year ended September 30, 2010. As of September 30, 2010, we had a deficit accumulated during the development stage of approximately $164.8 million. We have invested a significant portion of our efforts and financial resources in the development of Linjetatm. In October 2010, the FDA notified us that it would not approve our NDA for Linjetatm unless and until we conduct two new Phase 3 clinical trials, one in Type 1 diabetes and the other in Type 2 diabetes, using the final commercial formulation of Linjetatm, we address deficiencies with the chemistry, manufacturing and controls, or CMC, section of the NDA, and our primary third-party manufacturers adequately remediate facility inspection observations. In light of the extensive nature of the FDA's comments, we do not anticipate commencing new pivotal Phase 3 clinical trials with Linjetatm prior to meeting with the FDA to clarify their requests and, separately, determining whether related rapid-acting insulin or insulin analogs that we are formulating should be advanced instead. These alternate formulations generally use the same or similar excipients as the formulation of Linjetatm in our NDA, but they may present improvements with regard to injection site discomfort. After meeting with the FDA to discuss the complete response letter we received for Linjetatm, we expect to determine our preferred development, clinical and regulatory program for our rapid-acting insulin or insulin analog formulations and whether to advance our current formulation of Linjetatm in additional pivotal Phase 3 clinical trials. We expect to continue to incur significant operating losses for at least the next several years as we may:

- conduct pre-clinical studies and Phase 1 clinical trials to study formulations of Linjetatm and other related rapid-acting insulin and insulin analog formulations that that may be associated with less injection site discomfort than the formulation that is the subject of the complete response letter we received from the FDA;
- commence a stability program to determine whether any of our alternate formulations of rapid-acting insulins or insulin analogs are likely to present a commercially acceptable stability profile;
- conduct additional clinical trials of Linjetatm, including two potential pivotal Phase 3 clinical trials requested by the FDA to support approval;

- produce additional validation batches of Linjeta™ vials, cartridges, and disposable pens to support our NDA for Linjeta™;
- purchase recombinant human insulin and other materials consistent with our existing contractual obligations; and
- conduct additional clinical development of our other product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities, including successfully completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations. A decline in the market price of our common stock could also cause you to lose all or a part of your investment.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We are a development stage company with no commercial products. All of our product candidates are still being developed. All but Linjeta™ are in early stages of development, and we are in the process of determining whether to commence new pivotal Phase 3 clinical trials with our current formulation of Linjeta™ or advance one of our other proprietary rapid-acting insulin or insulin analog formulations instead. Our product candidates will require significant additional clinical development, regulatory approvals and related investment before they can be commercialized. While we have reduced expenditures on our development programs that are not related to rapid-acting mealtime insulins, we do not expect our research and development expenses to decrease as we continue our formulation work. Unless we are successful in consummating a strategic partnership to develop and commercialize Linjeta™ or an alternate rapid-acting insulin or insulin analog, we may need to raise substantial additional capital to develop and commercialize a competitive mealtime insulin product. Such financing may not be available on terms acceptable to us, or at all. If we are unable to obtain financing on favorable terms, our business, results of operations and financial condition may be materially adversely affected.

Based upon our current plans, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our anticipated operating expenses and capital expenditures at least through the second quarter of fiscal year 2012. We cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Our future capital requirements will depend on many factors, including:

- our ability to respond to the complete response letter regarding our NDA for Linjeta™ in a timely manner and the possibility that information we provide in response to the letter may not be sufficient for the approval of Linjeta™ or another rapid-acting insulin or insulin analog by the FDA;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA and the degree to which we are able to clarify with the FDA related regulatory requirements;
- our ability to conduct the additional pivotal clinical trials that the FDA requested in the complete response letter or other tests or analyses required by the FDA to secure approval to commercialize Linjeta™;
- our ability to develop and commercialize formulations of Linjeta™ or other rapid-acting insulin or insulin analog formulations that may be associated with less injection site discomfort than the formulation that is the subject of the complete response letter we received from the FDA;

- the progress, timing or success of our product candidates, particularly Linjeta™, and that of our research, development and clinical programs, including any resulting data analyses;
- the cost to develop an insulin pen for use with Linjeta™ and a formulation of Linjeta™ for use in insulin pumps;
- the costs of pre-commercialization activities, if any;
- the costs associated with qualifying and obtaining regulatory approval of suppliers of insulin and manufacturers of our product candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse market developments; and
- our ability to establish and maintain collaborations and the terms and success of the collaborations, including the timing and amount of payments that we might receive from potential strategic collaborators.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through public or private equity offerings and debt financings, strategic collaborations and licensing arrangements. If we raise additional funds by issuing additional equity securities, our stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in January 2004. Our operations to date have been limited to organizing and staffing our company, developing and securing our technology and undertaking preclinical studies and clinical trials of our product candidates. We have limited experience completing large-scale, pivotal clinical trials and we have not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We may need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to the Development and Commercialization of Our Product Candidates

We have depended heavily on the success of our most advanced product candidate, Linjeta™.

We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, Linjeta™. The FDA has concluded, however, that the results from our completed pivotal Phase 3 clinical trials of Linjeta™ are not sufficient to obtain marketing approval for Linjeta™. If we are unable, or choose not to, complete the two new pivotal Phase 3 clinical trials of Linjeta™ required by the FDA, or if we experience significant delays in doing so, our business may be materially harmed.

Our development of alternate formulations of Linjeta™ or other rapid-acting mealtime insulins or insulin analogs may not be successful; some formulations may have different regulatory requirements to obtain marketing approval from the FDA.

While we have significant experience with the technology we use to develop mealtime insulin formulations designed to be more rapid-acting than currently available products, we cannot guarantee that our program to advance alternate formulations of Linjetatm or other rapid-acting insulins or insulin analogs will be successful. Some of these formulations appear to be less stable in accelerated testing than the Linjetatm formulation submitted in our NDA, and we have clinical data suggesting improvements in injection site discomfort relative to Linjetatm only with regard to two of the alternate formulations. We may be unable to develop a new formulation that is as tolerable and stable as is minimally acceptable to us, a potential strategic partner or the FDA. Furthermore, the regulatory requirements for any alternate formulation may not meet our expectations or may be different from those applicable to the formulation of Linjetatm submitted in our NDA. For example, advancing any formulation based on an insulin analog may necessitate our conducting additional toxicology work or filing an investigational new drug application.

We may never reinitiate significant expenditures on our earlier stage product candidates.

We have suspended significant expenditures on the development of product candidates that are not related to a rapid-acting insulin or insulin analog. Until we determine our development, clinical and regulatory program for our rapid-acting insulin formulations and whether to advance our current formulation of Linjetatm in additional pivotal Phase 3 clinical trials, we cannot guarantee that we will have sufficient resources to allocate to earlier stage product candidates or that the focus of our early stage product development program will not change.

The results of clinical trials do not ensure success in future clinical trials or commercial success.

We have completed and released the results of our two pivotal Phase 3 clinical trials of Linjetatm. We have not completed the development of any products through commercialization. In October 2010, the FDA notified us that it would not approve our NDA for Linjetatm unless and until we conduct two new pivotal Phase 3 clinical trials using the final commercial formulation of Linjetatm, we address deficiencies with the CMC section of our NDA, and our primary third-party manufacturers adequately remediate facility inspection observations. The outcomes of preclinical testing and clinical trials may not be predictive of the success of later clinical trials. Furthermore, interim or preliminary results of a clinical trial do not necessarily predict final results. We cannot assure you that our additional clinical trials of Linjetatm, if any, will ultimately be successful. New information regarding the safety, efficacy and tolerability of Linjetatm may arise that may be less favorable than the data observed to date.

If we are not successful in commercializing any of our product candidates, or are significantly delayed in doing so, our business will be materially harmed. The commercial success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical development and clinical trials;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing that, with regard to Linjetatm or any rapid or long-acting insulin or insulin analog, the formulation is well-tolerated in chronic use;
- establishing commercial manufacturing capabilities through arrangements with third-party manufacturers;
- launching commercial sales of the products, whether alone or in collaboration with others;
- competition from other products; and
- continued acceptable safety and tolerability profiles of the products following approval.

If our clinical trials are delayed or do not produce positive results, we may incur additional costs and ultimately be unable to commercialize our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials of Linjeta™ or alternate rapid-acting insulin or insulin analog formulations can occur at any stage of testing. We may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we currently anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate, any of which would result in significant delays;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and
- the effects of our product candidates may not be the desired effects, may include undesirable side effects or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not be able to obtain marketing approval;
- obtain approval for indications that are not as broad as intended; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates and may harm our business and results of operations.

If our product candidates are found to cause undesirable side effects we may need to delay or abandon our development and commercialization efforts.

Any undesirable side effects that might be caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. In addition, if any of our product candidates receive marketing approval and

we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

- a change in the labeling statements or withdrawal of FDA or other regulatory approval of the product;
- a change in the way the product is administered; or
- the need to conduct additional clinical trials.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from its sale.

In our analysis of our completed pivotal Phase 3 clinical trials, we found that Linjeta™ was associated with injection site discomfort, although the prevalence of discomfort decreased during the course of the treatment. In addition, in an October 2009 tolerability trial of the liquid formulation of Linjeta™, it was determined that some patients experienced more injection site discomfort with Linjeta™ than they did with Humalog®.

The commercial success of any product candidates that we may develop, including Linjeta™, will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market, including Linjeta™, if they receive marketing approval, may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. Physicians will not recommend our product candidates until clinical data or other factors demonstrate the safety and efficacy of our product candidates as compared to other treatments. Even if the clinical safety and efficacy of our product candidates is established, physicians may elect not to recommend these product candidates for a variety of reasons including the reimbursement policies of government and third-party payors, the effectiveness of our competitors in marketing their products and, in the case of Linjeta™, the possibility that patients may experience more injection site discomfort than they experience with competing products.

The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the willingness and ability of patients and the healthcare community to adopt our products;
- the ability to manufacture our product candidates in sufficient quantities with acceptable quality and to offer our product candidates for sale at competitive prices;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our product candidates compared to those of competing products or therapies;
- the convenience and ease of administration of our product candidates relative to existing treatment methods;
- the label and promotional claims allowed by the FDA, such as, in the case of Linjeta™, claims relating to glycemic control, hypoglycemia, weight gain, injection site discomfort, expiry dating and required handling conditions;
- the pricing and reimbursement of our product candidates relative to existing treatments; and
- marketing and distribution support for our product candidates.

If we fail to enter into strategic collaborations for the commercialization of our product candidates or if our collaborations are unsuccessful, we may be required to establish our own sales, marketing, manufacturing and distribution capabilities which will be expensive, require additional capital we do not currently have, and could delay the commercialization of our product candidates and have a material and adverse effect on our business.

A broad base of physicians, including primary care physicians, internists and endocrinologists, treat patients with diabetes. A large sales force may be required to educate and support these physicians. Therefore, our current strategy for developing, manufacturing and commercializing our product candidates includes securing collaborations with leading pharmaceutical and biotechnology companies for the commercialization of our product candidates. To date, we have not entered into any collaborations with pharmaceutical or biotechnology companies. We face significant competition in seeking appropriate collaborators. In addition, collaboration agreements are complex and time-consuming to negotiate, document and implement. For all these reasons, it may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all. Even if we do enter into any such collaboration, the collaboration may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

If we fail to enter into collaborations, or if our collaborations are unsuccessful, we may be required to establish our own direct sales, marketing, manufacturing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and we have little experience in doing so. Because of our size, we would be at a disadvantage to our potential competitors to the extent they collaborate with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or provide the same degree of market research or marketing support. In addition, our competitors would have a greater ability to devote research resources toward expansion of the indications for their products. We cannot assure prospective investors that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, they may not be purchased or used and our revenues and prospects for profitability will suffer.

Our future revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the United States and in other markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable authorities. In addition, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs.

Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

We may be subject to pricing pressures and uncertainties regarding Medicare reimbursement and reform.

Reforms in Medicare added a prescription drug reimbursement benefit beginning in 2006 for all Medicare beneficiaries. Although we cannot predict the full effects on our business of the implementation of this legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers, and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to generate revenues.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently carry global liability insurance that we believe is sufficient to cover us from potential damages arising from clinical trials of Linjeta™. We also carry local insurance policies per clinical trial of our product candidates. The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. If losses from product liability claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product

liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and, if so, our business and results of operations would be harmed.

We face substantial competition in the development of our product candidates which may result in others developing or commercializing products before or more successfully than we do.

We are engaged in segments of the pharmaceutical industry that are characterized by intense competition and rapidly evolving technology. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target endocrine disorders. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. There are several approved injectable rapid-acting mealtime insulin analogs currently on the market including Humalog®, marketed by Eli Lilly and Company, NovoLog®, marketed by Novo Nordisk A/S, and Apidra®, marketed by Sanofi-Aventis. These rapid-acting insulin analogs provide improvement over regular forms of short-acting insulin, including faster subcutaneous absorption, an earlier and greater insulin peak and more rapid post-peak decrease. In addition, other development stage rapid-acting insulin formulations may be approved and compete with Linjetatm. Halozyme Therapeutics, Inc. has conducted a Phase 1 and multiple Phase 2 clinical trials of Humulin® R and Humalog® in combination with a recombinant human hyaluronidase enzyme and has reported that in each case the combination yielded pharmacokinetics and glucodynamics that better mimicked physiologic mealtime insulin release and activity than Humulin® R or Humalog® alone. Novo Nordisk has reported that they have initiated clinical development of an ultra-fast-acting insulin analogue intended to provide faster onset of action than the currently available fast-acting insulin analogs.

Several companies are also developing alternative insulin systems for diabetes, including MannKind Corporation, which has an inhalable insulin product candidate for which an NDA was submitted in early 2009 with an upcoming PDUFA date of December 29, 2010. The approval and acceptance of an inhaled insulin such as MannKind's product could reduce the overall market for injectable prandial insulin.

Treatment practices can also change with the introduction of new classes of therapy. Currently GLP-1 analogs such as exantide, marketed by Eli Lilly, and liraglutide, marketed by Novo Nordisk, are growing in usage and could delay the start of insulin usage in some patients therefore decreasing the size of the prandial insulin market.

While at this time there are no approved generic or biosimilar insulin analogs in the market in the United States or Europe, in other countries such as India there are multiple approved manufacturers of insulin analogs such has Humalog®. Both Humalog® and NovoLog® have limited remaining patent protection in the United States and Europe. Biocon, an established biosimilar manufacturer, has entered into a collaboration with Pfizer to commercialize biosimilar versions of Humalog® and NovoLog®. The possible introduction of lower priced brands or substitutable generic versions of these products could negatively impact the revenue potential of Linjetatm.

Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our potential competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize product candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- product candidates that have been approved or are in late-stage clinical development; or
- collaborative arrangements in our target markets with leading companies and research institutions.

Our product candidates may be rendered obsolete by technological change.

The rapid rate of scientific discoveries and technological changes could result in one or more of our product candidates becoming obsolete or noncompetitive. For several decades, scientists have attempted to improve the bioavailability of injected formulations and to devise alternative non-invasive delivery systems for the delivery of drugs such as insulin. Our product candidates will compete against many products with similar indications. In addition to the currently marketed rapid-acting insulin analogs, our competitors are developing insulin formulations delivered by oral pills, pulmonary devices and oral spray devices. Our future success will depend not only on our ability to develop our product candidates, but also on our ability to maintain market acceptance against emerging industry developments. We cannot assure present or prospective stockholders that we will be able to do so.

Our business activities involve the storage and use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development work and manufacturing processes involve the controlled storage and use of hazardous materials, including chemical and biological materials. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of such materials and waste products comply in all material respects with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident or failure to comply with environmental laws, we could be held liable for any damages that may result, and any such liability could fall outside the coverage or exceed the limits of our insurance. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future or pay substantial fines or penalties if we violate any of these laws or regulations. Finally, current or future environmental laws and regulations may impair our research, development or production efforts.

Risks Related to Our Dependence on Third Parties

Use of third parties to manufacture our product candidates may increase the risks that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, or that our suppliers will not be able to manufacture our products in their final dosage form. In any such case, clinical development and commercialization of our product candidates could be delayed, prevented or impaired.

We do not currently own or operate manufacturing facilities for commercial production of our product candidates. We have limited experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties. We also expect to rely upon third parties to produce materials required for the commercial production of our product candidates if we succeed in obtaining necessary regulatory approvals. We currently rely on two manufacturers, Hyaluron, Inc. and Wockhardt, Ltd., to manufacture Linjeta™, but we do not have commercial supply agreements with these third parties.

Hyaluron, Inc. and Wockhardt, Ltd. have each recently undergone an inspection by the FDA in which deficiencies were identified and a warning letter from the FDA was issued. The FDA has required that these deficiencies be corrected prior to the approval or manufacture of Linjeta™ or the manufacture of our other product formulations for use in clinical trials. At this time, the ability of, and the length of time that may be required by Hyaluron, Inc. and Wockhardt, Ltd. to remediate the deficiencies identified by the FDA is uncertain. Failure by either Hyaluron, Inc. or Wockhardt, Ltd. to adequately and timely remediate the deficiencies identified by the FDA may delay the execution of our strategic plans, including the manufacturing of study drugs for use in clinical trials.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible refusal by the third party to support our manufacturing programs, based on its own business priorities, at a time that is costly or inconvenient for us.

Our manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or other regulatory requirements or similar regulatory requirements outside the United States. Our manufacturers are subject to unannounced inspections by the FDA, state regulators and similar regulators outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If the third parties that we engage to manufacture product for our clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these trials while we identify and qualify replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If our suppliers, principally our sole insulin supplier, fail to deliver materials and provide services needed for the production of Linjeta™ or any alternative rapid-acting insulin or insulin analog in a timely and sufficient manner, or if they fail to comply with applicable regulations, clinical development or regulatory approval of our product candidates or commercialization of our products could be delayed, producing additional losses and depriving us of potential product revenue.

We need access to sufficient, reliable and affordable supplies of recombinant human insulin and other materials for which we rely on various suppliers. We also must rely on those suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with cGMP. We can make no assurances that our suppliers, particularly our insulin supplier, will comply with cGMP.

We have entered into an agreement with our existing single insulin supplier from which we obtain all of the insulin that we use for testing and manufacturing Linjeta™ or any alternative rapid-acting insulin formulation based on recombinant human insulin. Our agreement with this insulin supplier will terminate in December 2011. We are discussing the possibility of extending this supply agreement beyond 2011, depending on our strategic plans, but we cannot guarantee that this effort will be successful.

We believe that our current supplies of insulin, together with the quantities of insulin called for under our existing supply agreement, will be sufficient to allow us to complete, if we so choose, the two new pivotal Phase 3 clinical trials of Linjeta™ required by the FDA in order to receive approval to market Linjeta™. We may seek to qualify other insulin suppliers to serve as additional or alternative suppliers if we are unable or choose not to enter into a new commercial supply agreement with our existing supplier. We do not anticipate being able to qualify a new insulin supplier prior to December 2011. Even if we do qualify a new supplier in a timely manner, the cost of switching or adding additional suppliers may be significant, and we cannot assure you that we will be able to enter into a commercial supply agreement with a new supplier on favorable terms. If we are unable to procure sufficient quantities of insulin from our current or any future supplier, if supply of recombinant human insulin and other materials otherwise becomes limited, or if our suppliers do not meet relevant regulatory requirements, and if we were unable to obtain these materials in sufficient amounts, in a timely manner and at reasonable prices, we could be delayed in the manufacturing and possible commercialization of Linjeta™, which may have a material adverse effect on our business. We would incur substantial costs and manufacturing delays if our suppliers are unable to provide us with products or services approved by the FDA or other regulatory agencies.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights, our competitors may develop and market similar or identical products that may reduce demand for our products, and we may be prevented from establishing collaborative relationships on favorable terms.

The following factors are important to our success:

- receiving patent protection for our product candidates;
- maintaining our trade secrets;
- not infringing on the proprietary rights of others; and
- preventing others from infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors.

We have been granted one U.S. patent, one European patent, one Hong Kong patent, and one Australian patent. The European patent entered the national phase in all of the designated countries. In addition, we have several pending United States and corresponding foreign and international patent applications relating to our Linjetatm and VIAtabtm technology and several pending U.S. and foreign patent applications relating to our technology for enhancing delivery of drugs. These pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If patents do not issue with claims encompassing our products, our competitors may develop and market similar or identical products that compete with ours. Even if patents are issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Failure to obtain effective patent protection for our technology and products may reduce demand for our products and prevent us from establishing collaborative relationships on favorable terms.

The active and inactive ingredients in our Linjetatm and VIAtabtm product candidates have been known and used for many years and, therefore, are no longer subject to patent protection. Accordingly, our granted U.S. and foreign patents and pending patent applications are directed to the particular formulations of these ingredients in our products, and their use. Although we believe our formulations and their use are patentable and provide a competitive advantage, even if issued, our patents may not prevent others from marketing formulations using the same active and inactive ingredients in similar but different formulations.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as potential corporate partners, collaborators, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors may learn of the information in some other way. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The laws of many foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

We may become involved in lawsuits and administrative proceedings to protect, defend or enforce our patents that would be expensive and time-consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties in the United States or in foreign countries. In addition, we may be subject to certain opposition proceedings conducted in patent and trademark offices challenging the validity of our patents and may become involved in future opposition proceedings challenging the patents of others. The defense of intellectual property rights, including patent rights, through lawsuits, interference or opposition proceedings, and other legal and administrative proceedings can be costly and can divert our technical and management personnel from their normal responsibilities. Such costs increase our operating losses and reduce our resources available for development activities. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation and despite protective orders entered by the court, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could materially adversely affect our business and financial results.

Claims by other parties that we infringe or have misappropriated their proprietary technology may result in liability for damages, royalties, or other payments, or stop our development and commercialization efforts.

Competitors and other third parties may initiate patent litigation against us in the United States or in foreign countries based on existing patents or patents that may be granted in the future. Many of our competitors may have obtained patents covering products and processes generally related to our products and processes, and they may assert these patents against us. Moreover, there can be no assurance that these competitors have not sought or will not seek additional patents that may cover aspects of our technology. As a result, there is a greater likelihood of a patent dispute than would be expected if our competitors were pursuing unrelated technologies.

While we conduct patent searches to determine whether the technologies used in our products infringe patents held by third parties, numerous patent applications are currently pending and may be filed in the future for technologies generally related to our technologies, including many patent applications that remain confidential after filing. Due to these factors and the inherent uncertainty in conducting patent searches, there can be no guarantee that we will not violate third-party patent rights that we have not yet identified.

There may be U.S. and foreign patents issued to third parties that relate to aspects of our product candidates. There may also be patent applications filed by these or other parties in the United States and various foreign jurisdictions that relate to some aspects of our product candidates, which, if issued, could subject us to infringement actions. The owners or licensees of these and other patents may file one or more infringement actions against us. In addition, a competitor may claim misappropriation of a trade secret by an employee hired from that competitor. Any such infringement or misappropriation action could cause us to incur substantial costs defending the lawsuit and could distract our management from our business, even if the allegations of infringement or misappropriation are unwarranted. A need to defend multiple actions or claims could have a disproportionately greater impact. In addition, either in response to or in anticipation of any such infringement or misappropriation claim, we may enter into commercial agreements with the owners or licensees of these rights. The terms of these commercial agreements may include substantial payments, including substantial royalty payments on revenues received by us in connection with the commercialization of our products.

Payments under such agreements could increase our operating losses and reduce our resources available for development activities. Furthermore, a party making this type of claim could secure a judgment that requires us to pay substantial damages, which would increase our operating losses and reduce our resources available for development activities. A judgment could also include an injunction or other court order that could prevent us from making, using, selling, offering for sale or importing our products or prevent our customers from using our products. If a court determined or if we independently concluded that any of our products or manufacturing processes violated third-party proprietary rights, our clinical trials could be delayed and there can be no assurance that we would be able to reengineer the product or processes to avoid those rights, or to obtain a license under those rights on commercially reasonable terms, if at all.

If the FDA does not believe that our product candidates satisfy the requirements for the Section 505(b)(2) approval procedure, or if the requirements for Linjeta™ under Section 505(b)(2) are not as we expect, the approval pathway will take longer and cost more than anticipated and in either case may not be successful.

We believe Linjetatm and our other rapid-acting insulin formulations using regular human insulin qualify for approval under Section 505(b)(2) of the FFDCA. Because we are developing new formulations of previously approved chemical entities, such as insulin, this may enable us to avoid having to submit certain types of data and studies that are required in full NDAs and instead submit an NDA under Section 505(b)(2). The FDA has not published any guidance that specifically addresses an NDA for an insulin product candidate under Section 505(b)(2). No other insulin product has yet been approved pursuant to an NDA under Section 505(b)(2). If the FDA determines that NDAs under Section 505(b)(2) are not appropriate and that full NDAs are required for our product candidates, we would have to conduct additional studies, provide additional

data and information, and meet additional standards for approval. The time and financial resources required to obtain FDA approval for our product candidates could substantially and materially increase. This would require us to obtain substantially more funding than previously anticipated which could significantly dilute the ownership interests of our stockholders. Even with this investment, the prospect for FDA approval may be significantly lower. If the FDA requires full NDAs for our product candidates or requires more extensive testing and development for some other reason, our ability to compete with alternative products that arrive on the market more quickly than our product candidates would be adversely impacted.

Notwithstanding the approval of many products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its interpretation of Section 505(b)(2) which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). The pharmaceutical industry is highly competitive, and it is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Moreover, even if Linjeta™ or an alternate rapid-acting insulin or insulin analog formulation is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other state and federal regulatory authorities. These requirements include, in the case of FDA, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. In addition, if any of our product candidates are approved, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted in a misleading manner or for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other state and federal entities actively enforce the laws and regulations prohibiting misleading promotion and the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Discovery after approval of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with state or federal regulatory requirements, may result in actions such as:

- restrictions on such products' manufacturers or manufacturing processes;
- restrictions on the marketing or distribution of a product;
- requirements that we conduct new studies, make labeling changes, and implement Risk Evaluation and Mitigation Strategies;
- warning letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product embargo and/or seizure;
- injunctions; or
- imposition of civil or criminal penalties.

Changes in law, regulations, and policies legislation may preclude approval of our product under a 505(b)(2) or make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute our existing products.

On March 23, 2010, the President signed into law new legislation creating an abbreviated pathway for approval of biological products under the Public Health Service, or PHS Act, that are similar to previously approved biological products. This legislation also expanded the definition of biological product to include proteins such as insulin. The new law contains transitional provisions governing protein products such as insulin that, under certain circumstances, might permit companies to seek approval for their insulin products as biologics under the PHS Act and might require that Biodel's product be approved under the PHS Act rather than in a 505(b)(2) NDA. We would be unlikely to pursue approval of our insulin product candidates if we were required to seek approval under the PHS Act rather than in a 505(b)(2) NDA.

In addition, the federal and state regulations, policies or guidance may change and new may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations implemented or modified, or what the impact of such changes, if any, may be.

Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products abroad.

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The regulatory approval processes outside the United States may include all of the risks associated with obtaining FDA approval, as well as additional risks. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Reports of side effects or safety concerns in related technology fields or in other companies' clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates.

At present, there are a number of clinical trials being conducted by us and by other pharmaceutical companies involving insulin or insulin delivery systems. The major safety concern with patients taking insulin is the occurrence of hypoglycemic events. If we discover that our product is associated with a significantly increased frequency of hypoglycemic or other adverse events, or if other pharmaceutical companies announce that they observed frequent or significant adverse events in their trials involving insulin or insulin delivery systems, we could encounter delays in the commencement or completion of our clinical trials or difficulties in obtaining the approval of our product candidates. In addition, the public perception of our products might be adversely affected, which could harm our business and results of operations, even if the concern relates to another company's product.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Errol B. De Souza, President and Chief Executive Officer, Gerard Michel, our Chief Financial Officer and Dr. Alan Krasner, our Chief Medical Officer. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experiences required to develop, gain regulatory approval of and commercialize our product candidates successfully. We generally do not maintain key person life insurance to cover the loss of any of our employees.

Recruiting and retaining qualified scientific personnel, clinical personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from other companies, universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We may expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

If our development and commercialization plans for any of our product candidates are successful, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of manufacturing, clinical trials management, and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of

our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

Among others, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan or "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price has been and may continue to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Our outstanding warrants may be exercised in the future, which would increase the number of shares in the public market and result in dilution to our stockholders.

In August 2010 we sold to two institutional investors 2,398,200 shares of our common stock and warrants to purchase 2,398,200 shares of our common stock, resulting in gross proceeds to us, before deducting placement agents' fees and offering expenses, of approximately $8.7 million. The warrants to purchase 2,398,200 shares of our common stock had an initial exercise price of $4.716, subject to re-pricing following our receipt of the complete response letter for Linjeta™. On December 1, 2010, the exercise price of the warrants was re-set to become $1.56 per share. These warrants will expire on December 1, 2011.

We have never paid any cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on our capital stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 30, 2010, we had approximately 26,433,982 million shares of common stock outstanding. Of these, approximately 9 million shares are able to be sold in accordance with the SEC's Rule 144 and the remainder are generally freely tradable without restriction under securities laws.

We incur substantial costs as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 as well as other federal and state laws. These requirements may place a strain on our people, systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, significant resources and management oversight will be required. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not applicable.

ITEM 2. *PROPERTIES*

We lease approximately 29,300 square feet of office space and laboratory facilities in Danbury, Connecticut from Mulvaney Properties LLC. Our corporate headquarters are located at 100 Saw Mill Road, Danbury, Connecticut, in approximately 19,500 square feet of rentable office space. The lease for this office space expires July 31, 2014, subject to our right to renew the lease under the same terms and conditions for an additional seven year term. Our laboratory facility is located at 6 and 8 Christopher Columbus Avenue, Danbury, Connecticut, in approximately 7,200 and 2,600 square feet of rentable laboratory and office space. The leases for our facilities at 6 and 8 Christopher Columbus expire in January 2013. We expect to renew these leases before they expire. Our

laboratory facility is fully equipped to perform our current drug delivery and related research and development activities, as well as to manufacture on a limited basis our own product line in accordance with cGMP.

Mulvaney Properties LLC is controlled by a non-affiliated stockholder of ours.

ITEM 3. ***LEGAL PROCEEDINGS***

We currently are not involved in any legal proceedings.

ITEM 4. ***REMOVED AND RESERVED***

PART II-OTHER INFORMATION

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Market Information

Since May 11, 2007, our common stock has traded on the NASDAQ Global Market under the symbol "BIOD."

The following table sets forth the high and low sale prices per share for our common stock for each of the quarters in the period beginning October 1, 2009 through September 30, 2010, as reported on the NASDAQ Global Market:

Quarter Ended	High	Low
December 31, 2008	$4.99	$1.62
March 31, 2009	$6.00	$3.29
June 30, 2009	$6.02	$3.64
September 30, 2009	$5.48	$4.46
December 31, 2009	$5.39	$3.29
March 31, 2010	$5.30	$3.22
June 30, 2010	$6.25	$3.74
September 30, 2010	$6.08	$3.25

The closing price of our common stock, as reported by the NASDAQ Global Market, was $1.80 on December 9, 2010.

Holders

As of November 30, 2010, the number of holders of record of our common stock was 46.

Dividends

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. Payment of future dividends, if any, will be at the discretion of our board of directors.

Equity Compensation Plan Information

Information relating to compensation plans under which our equity securities are authorized for issuance is set forth under "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for our 2011 Annual Meeting of Stockholders.

Issuer Purchases of Equity Securities

We did not make any purchases of our shares of common stock in the fourth quarter of fiscal 2010, nor did any affiliated purchaser or anyone acting on behalf of us or an affiliated purchaser.

ITEM 6. ***SELECTED FINANCIAL DATA***

You should read the following selected financial data together with our financial statements and the related notes which are included elsewhere in this Annual Report and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report. We have derived the statement of operations data set forth below for the three-year period ended September 30, 2010 and the balance sheet data as of September 30, 2009 and 2010 set forth below from our audited financial statements which are included in this Annual Report. We have derived the statement of operations data set forth below for the years ended September 30, 2006, and 2007 and the balance sheet data as of September 30, 2006, 2007 and 2008 set forth below from our audited financial statements, which are not included in this Annual Report. Our audited financial statements include, in the opinion of our management, all adjustments, consisting of only normal recurring accruals, necessary for a fair presentation of those statements. Historical results for any prior or interim period are not necessarily indicative of results to be expected in any future period or for a full fiscal year.

	Year Ended September 30,				
	2006	2007	2008	2009	2010
	(In thousands, except share and per share amounts)				
Statement of operations data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	5,987	15,939	32,554	32,325	26,177
General and administrative	1,548	8,386	14,800	10,994	10,980
Total operating expenses	7,535	24,325	47,354	43,319	37,157
Other (income) and expense:					
Interest and other income	(182)	(1,902)	(3,010)	(386)	(17)
Interest expense	78	—	—	—	—
Adjustment to fair value of common stock warrant liability	—	—	—	—	1,254
Loss on settlement of debt	627	—	—	—	—
Loss before tax provision (benefit)	(8,058)	(22,423)	(44,344)	(42,933)	(38,394)
Tax provision (benefit)	10	125	(983)	337	(104)
Net loss	(8,068)	(22,548)	(43,361)	(43,270)	(38,290)
Charge for accretion of beneficial conversion rights	(603)	—	—	—	—
Deemed dividend — warrants	—	(4,457)	—	—	—
Net loss applicable to common stockholders	$ (8,671)	$ (27,005)	$ (43,361)	$ (43,270)	$ (38,290)
Net loss per share — basic and diluted	$ (1.05)	$ (1.76)	$ (1.94)	$ (1.82)	$ (1.58)
Weighted average shares outstanding — basic and diluted	8,252,113	15,354,898	22,390,434	23,746,598	24,161,866

	As of September 30,				
	2006	2007	2008	2009	2010
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents, and marketable securities	$ 17,539	$ 80,022	$ 90,283	$ 54,640	$ 28,923
Working capital (deficit)	(15,307)	75,244	84,377	46,787	25,178
Total assets	18,659	82,506	97,511	59,625	32,616
Deficit accumulated during the development stage	(12,828)	(39,833)	(83,194)	(126,464)	(164,754)
Total stockholders' equity	16,348	77,223	88,487	50,538	24,060

ITEM 7 ***MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Form 10-K. Some of the information in this discussion and analysis or set forth elsewhere in this Form 10-K, including our plans and strategies for our business, includes forward-looking statements which involve risks and uncertainties. Please review the "Forward-Looking Statements" and the "Risk Factors" sections of this Form 10-K for a discussion of important factors that could cause actual results to materially differ from those anticipated or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. We develop our product candidates by applying our proprietary formulation technologies to existing drugs in order to improve their therapeutic profiles. Our most advanced product candidate is Linjeta™ (formerly known as VIAject®). We have formulated Linjeta™ as a rapid-acting mealtime insulin for the treatment of patients with Type 1 and Type 2 diabetes. Earlier stage product candidates include follow-on and second generation rapid-acting mealtime insulins or insulin analogs, VIAtab™, a sublingual tablet formulation of insulin, a line of basal insulins, and a stabilized formulation of glucagon.

Linjeta™ is our proprietary injectable formulation of recombinant human insulin designed to be absorbed into the blood faster than the currently marketed rapid-acting insulin analogs. We have recently completed two pivotal Phase 3 clinical trials of Linjeta™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. In both clinical trials we compared Linjeta™ to Humulin® R, a form of recombinant human insulin. Based upon our preclinical and clinical data, we believe Linjeta™ may produce a profile of insulin levels in the blood that approximates the natural first-phase insulin release following a meal that is normally seen in persons without diabetes following a meal.

In November 2010, we announced that the FDA issued a complete response letter requesting additional information regarding our NDA for Linjeta™. The complete response letter stated that the FDA's review cycle was complete and that the application could not be approved in its present form. The FDA requested that we conduct two new Phase 3 clinical trials using the final commercial formulation of Linjeta™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes, to establish efficacy and safety as related to hypoglycemia and toleration. The FDA also requested additional data related to stability and manufacturing of our final commercial formulation of Linjeta™. In addition, the FDA indentified resolution of manufacturing issues related to recent site inspections at Hyaluron, Inc. and Wockhardt, Ltd. as a requisite for approval. We have contacted the FDA to formally request a meeting to discuss the complete response letter.

We are a development stage company. We were incorporated in December 2003 and commenced active operations in January 2004. To date, we have generated no revenues and have incurred significant losses. We have financed our operations and internal growth through our initial public offering in May 2007, a follow-on offering in February 2008, a registered direct offering in August 2010 and, prior to these public offerings, private placements of convertible preferred stock and other securities. We have devoted substantially all of our efforts to research and development activities, including clinical trials. Our net loss was $38.3 million for the year ended September 30, 2010. As of September 30, 2010, we had a deficit accumulated during the development stage of $164.8 million. The deficit accumulated during the development stage is attributable primarily to our research and development activities and non-cash charges for (1) accretion of beneficial conversion rights and (2) deemed dividend-warrants and share-based compensation. Research and development and general and administrative expenses, as a percentage of net loss applicable to common stockholders, represent approximately 71% and 29%, respectively, of the expenses that we have incurred since our inception. We expect to continue to generate significant losses as we continue to develop our product candidates.

To date, we have not generated revenues and we expect to incur operating losses as we continue our efforts to seek FDA approval of Linjeta™ or advance follow-on and second generation rapid-acting mealtime insulins or insulin analogs. As of September 30, 2010, we had approximately $28.9 million in cash, cash equivalents and marketable securities compared to $54.6 million in cash and cash equivalents as of September 30, 2009. We believe that our existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to fund our anticipated operating expenses and capital expenditures at least through the first quarter of fiscal year 2012. If the August 2010 warrants are exercised, we anticipate the cash runway to extend at least through the second quarter of fiscal year 2012.

We believe that future cash expenditures will be partially offset by raising additional capital from the capital markets, registered direct deals, proceeds derived from collaborations, including, but not limited to, upfront fees, research and development funding, milestone payments and royalties. We can give no assurances that such funding will, in fact, be realized in the time frames we expect, or at all. We may be required to secure alternative financing arrangements and/or defer or limit some or all of our research, development and/or clinical projects.

Financial Operations Overview

Revenues

To date, we have generated no revenues. We do not expect to begin generating any revenues unless any of our product candidates receive marketing approval or if we receive payments in connection with strategic collaborations that we may enter into for the commercialization of our product candidates.

Research and Development Expenses

Research and development expenses consist of the cost associated with our basic research activities, as well as the costs associated with our drug development efforts, conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of:

- external research and development expenses incurred under agreements with third-party contract research organizations and investigative sites, third-party manufacturing organizations and consultants;
- employee-related expenses, which include salaries and benefits for the personnel involved in our preclinical and clinical drug development and manufacturing activities; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment and laboratory and other supplies.

While we have reduced expenditures on our earlier stage product candidates, we expect to continue to incur operating losses for the next several years as we:

- conduct preclinical studies and Phase 1 clinical trials to determine whether one or more of our newer insulin formulations is likely to offer a combination of pharmacokinetic, stability and tolerability characteristics that is preferable to Linjeta™;
- determine our preferred development, clinical and regulatory program for a proprietary rapid-acting insulin or insulin analog formulation following our meeting with the FDA regarding Linjeta™, and based on our analysis of the preclinical and Phase 1 clinical data for our alternate insulin formulations;
- conduct preclinical studies with earlier stage product candidates and make limited investments in order to advance proof-of-concept formulations; and
- purchase recombinant human insulin and other materials as required under existing contractual commitments.

We have used our employee and infrastructure resources across multiple research projects and our drug development program for Linjeta™. To date, we have not tracked expenses related to our product development

activities on a project or program basis. Accordingly, we cannot reasonably estimate the amount of research and development expenses that we incurred with respect to each of our clinical and preclinical product candidates. However, substantially all of our research and development expenses incurred to date are attributable to our Linjeta™ program.

The following table illustrates, for each period presented, our research and development costs by nature of the cost.

	Year Ended September 30,			December 3, 2003 (Inception) to September 30, 2010
	2008	2009	2010	
		(In thousands)		
Research and development expenses:				
Preclinical expenses	$ 4,230	$ 2,709	$ 2,746	$ 15,000
Manufacturing expenses	6,728	11,674	8,894	30,955
Clinical/regulatory expenses	21,596	17,942	14,537	70,273
Total	$32,554	$32,325	$26,177	$ 116,228

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- our ability to respond to the complete response letter regarding our NDA for Linjeta™ in a timely manner and the possibility that information we provide in response to the letter may not be sufficient for the approval of Linjeta™ or another rapid-acting insulin or insulin analog by the FDA;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA and the degree to which we are able to clarify with the FDA related regulatory requirements;
- our ability to conduct the additional pivotal clinical trials the FDA requested in the complete response letter or other tests or analyses required by the FDA to secure approval to commercialize Linjeta™;
- our ability to develop and commercialize formulations of Linjeta™ or other rapid-acting insulin or insulin analog formulations that may be associated with less injection site discomfort than the formulation that is the subject of the complete response letter we received from the FDA;
- the progress, timing or success of our product candidates, particularly Linjeta™, and that of our research, development and clinical programs, including any resulting data analyses;
- the cost to develop an insulin pen for use with Linjeta™ and a formulation of Linjeta™ for use in insulin pumps;
- the costs of pre-commercialization activities, if any;
- the costs associated with qualifying and obtaining regulatory approval of suppliers of insulin and manufacturers of our product candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse market developments; and
- our ability to establish and maintain collaborations and the terms and success of the collaborations, including the timing and amount of payments that we might receive from potential strategic collaborators.

A change in the outcome of any of these variables with respect to the development of Linjetatm or our other product candidates could mean a significant change in the costs and timing associated with product development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for personnel, including share-based compensation expenses, in our executive, legal, accounting, finance and information technology functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, travel expenses, costs associated with industry conventions and professional fees, such as legal and accounting fees and consulting costs.

We anticipate that our general and administrative expenses will change as we focus our efforts on preclinical and Phase 1 studies. Over the longer term, however, these expenses could increase as we approach the commercial launch of Linjetatm or our other product candidates.

Restricted Cash

Restricted cash as of September 30, 2010 consisted of $150 thousand held in a money market account with a bank to secure a credit card purchasing agreement utilized to facilitate employee travel and certain ordinary purchases. The restricted cash balance as of September 30, 2009 was $0.

Marketable Securities

In accordance with Accounting Standard Codification (ASC) Topic 320, Investments in Debt and Equity Securities issued by the Financial Accounting Standard Board ("FASB") in May 1993, our marketable securities were classified as available-for-sale. In accordance with that standard, these securities are reported at market value with unrealized gains and losses shown as a component of accumulated other comprehensive income (loss). We regularly evaluate the performance of these investments individually for impairment, taking into consideration the investment, volatility and current returns. If a determination is made that a decline in fair value is other-than-temporary, the related securities are written down to their estimated fair value. As of September 30, 2009 and 2010, the Company had $0 and $6.0 of million marketable securities investments, respectively.

Pre-Launch Inventory

Inventory costs associated with products that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then costs associated with pre-launch inventory that has not yet received regulatory approval are expensed as research and development expense during the period the costs are incurred. For the year ended September 30, 2010, we expensed $4.5 million of costs associated with the purchase of recombinant human insulin, as research and development expense after it passed quality control inspection and transfer of title occurred. In November 2010, we announced that the FDA has issued a complete response letter requesting additional information regarding the company's NDA for Linjetatm. The complete response letter stated that the FDA's review cycle was complete and that the application could not be approved in its present form. At this time, the Company will continue to expense pre-launch inventory as research and development. The pre-launch inventory treatment will be reevaluated if we complete Phase 3 clinical trials of Linjetatm or an alternate product candidate for which the inventory is applicable and file a related NDA or NDA supplement for review by the FDA.

Warrant Liability

On August 24, 2010, we entered into definitive agreements to sell to two institutional investors 2,398,200 shares of our common stock and warrants to purchase an additional 2,398,200 shares of our common stock with an initial exercise price of $4.716 per share. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share. These warrants are measured at fair value using

an accepted valuation model which takes in account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock, the risk-free interest rate for the term of the warrant and the probability of a change of control. The liability is revalued at each reporting period and changes in fair value are recognized currently in the statements of operations under the caption "Adjustment to fair value of common stock warrant liability." These warrants will expire on December 1, 2011, one year and 21 trading days after receiving the complete response letter from the FDA.

Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in equity for unrealized holding gains (losses) on marketable securities during the period. For the years ended September 30, 2008, 2009 and 2010, the Company had $(43,423), $(43,208) and $(38,289) of comprehensive loss.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents and marketable securities, resulting primarily from the $134.3 million in net proceeds received from our initial public offering in May 2007, follow-on offering in February 2008, and registered direct offering in August 2010. In November 2007, our board of directors approved investment policy guidelines, the primary objectives of which are the preservation of capital, the maintenance of liquidity and maintenance of appropriate fiduciary control — subject to our business objectives and tax situation.

Due to the uncertainty in the credit and financial markets, along with receiving a complete response letter from the FDA, we have maintained our investment strategy of primarily investing in certain marketable securities, which consist primarily of short-to-intermediate-term debt securities issued by the U.S. government, Treasury securities and U.S. government agencies. The focus on preserving cash and investing in stable securities generated lower returns during the year ended September 30, 2010. We intend to maintain this conservative strategy until the credit and financial markets improve and become more stable.

Exercise of Warrants

In March 2007, we offered the holders of warrants to purchase an aggregate of 149,125 shares of our Series B convertible preferred stock and an aggregate of 3,417,255 shares of our common stock with an exercise price of $5.56 per share the opportunity to exercise such warrants at an exercise price of $3.67, representing a 34% discount in the exercise price. Such holders exercised all of such warrants on a combination of cashless and cash exercise basis. We issued an aggregate of 2,636,907 shares of common stock and received aggregate cash proceeds of approximately $0.4 million in connection with such exercises.

As a result of the discounted exercise price, in the fiscal quarter ended March 31, 2007, we recorded a deemed dividend charge of approximately $4.5 million for the warrants that were so exercised.

As of September 30, 2010, we had the following warrants outstanding: (i) warrants to purchase 118,815 shares of our common stock with an exercise price of $1.41 and (ii) warrants to purchase 2,398,200 share of our common stock with an initial exercise price of $4.716 per share. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share. These warrants will expire on December 1, 2011, one year and 21 trading days following our receipt of the FDA's complete response letter for Linjeta™.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements that have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting

periods. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing at the end of this Form 10-K, we believe that the following accounting policies, which we have discussed with our audit committee, are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Preclinical Study and Clinical Trial Accruals

In preparing our financial statements, we must estimate accrued expenses pursuant to contracts with multiple research institutions, clinical research organizations and contract manufacturers that conduct and manage preclinical studies, clinical trials and manufacture product for these trials on our behalf. This process involves communicating with relevant personnel to identify services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for services when we have not yet been invoiced for or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. The financial terms of these agreements vary and may result in uneven payment flows. To date, we have not adjusted our estimates at any balance sheet date in any material amount. Examples of preclinical study, clinical trial and manufacturing expenses include the following:

- fees paid to contract research organizations in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- professional service fees.

Share-Based Compensation

In March 2010, our shareholders approved a new 2010 Stock Incentive Plan, or the 2010 Plan. Up to 5,400,000 shares of our common stock may be issued pursuant to awards granted under the 2010 Plan, plus shares of common stock underlying already outstanding awards under our prior plans. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.6 shares for each one share of common stock. We have not made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by our stockholders. We will continue to use the Black-Scholes pricing model to assist in the calculation of fair value. The expected life for these grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110. The simplified method was chosen due to our limited history. Until we have adequate history, we will continue to utilize the simplified method.

We recognize compensation costs related to share-based transactions, including employee stock options, in the financial statements based on fair value. The fair value of the stock underlying the options is a significant factor in determining credits or charges to operations appropriate for the share-based payments to both employees and non-employees.

We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants to employees, members of our board of directors and non-employees. The fair value of these stock option grants is estimated as of their date of grant using the Black-Scholes valuation model.

Because we lack sufficient company-specific historical and implied volatility information, we based our estimate of expected volatility on the median historical volatility of a group of publicly-traded companies that we believe are comparable to us based on the criteria set forth in Accounting Standards Codification (ASC) Topic 718-10-55-37(c) and SAB Topic 14.D, particularly line of business, stage of development, size and financial leverage. We will continue to consistently apply this process using the same companies or, if those companies become no longer comparable, other appropriately comparable companies until a sufficient amount of historical information regarding the volatility of our share price becomes available. However, we will regularly review these comparable companies, and may substitute more appropriate companies if facts and circumstances warrant a change. We use the average of (1) the weighted average vesting period and (2) the contractual life of the option, seven or eight years, as the estimated term of the option. The risk free rate of interest for periods within the contractual life of the stock option is based on the yield of a U.S. Treasury strip on the date the award is granted with a maturity equal to the expected term of the award. We estimate forfeitures based on actual forfeitures during our limited history. Additionally, we have assumed that dividends will not be paid.

For options granted to non-employees and non-directors, primarily consultants serving on our Scientific Advisory Board, we measure fair value of the equity instruments utilizing the Black-Scholes valuation model, if that value is more reliably measurable than the fair value of the consideration or service received. The fair value of these equity investments are periodically revalued as the options vest and are recognized as expense over the related period of service or the vesting period, whichever is longer. As of September 30, 2010, we issued to these non-employees options to purchase an aggregate of 377,111 shares of our common stock. Because we must revalue these options for accounting purposes each reporting period, the amount of the share-based compensation expense related to these non-employee options will increase or decrease, based on changes in the price of our common stock. For the years ended September 30, 2010, 2009 and 2008, the share-based compensation expense (income) related to these options was ($0.01) million, $0.1 million, and $0.2 million, respectively.

For the year ended September 30, 2010, the share-based compensation expense was $5.6 million, of which $2.0 million is reflected in research and development expenses and $3.6 million is reflected in general and administrative expenses. For the year ended September 30, 2009, the share-based compensation expense was $5.1 million, of which $1.7 million is reflected in research and development expenses and $3.4 million is reflected in general and administrative expenses. For the year ended September 30, 2008, the share-based compensation expense was $6.7 million, of which $1.6 million is reflected in research and development expenses and $5.1 million is reflected in general and administrative expenses.

Income Taxes

As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax expense together with assessing temporary differences resulting from differing treatments of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities.

At September 30, 2010, we recorded a 100% valuation allowance against our net deferred tax asset of approximately $50.0 million, as our management believes it is uncertain that it will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net deferred tax asset, an adjustment to the deferred tax valuation allowance would increase net income in the period in which we make such a determination.

As of September 30, 2010, we had net operating loss carryforwards of approximately $114.7 million for U.S. federal and $132.1 million for state tax purposes. These loss carryforwards expire between 2024 and 2030. To the extent these net operating loss carryforwards are available, we intend to use them to reduce the corporate income tax liability associated with our operations. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. We have performed a preliminary Section 382 analysis in connection with the registered direct offering that we

completed in August 2010. The sale of common stock in this offering created an additional ownership change. It was determined that we had an ownership change under Section 382. We believe that approximately $18.2 million of the $132.9 million federal losses will expire unused due to Section 382 limitations. The maximum annual limitation under Section 382 is approximately $9.4 million for the first five (5) years and then decreases to $4.3 million for the remaining fifteen (15) years. The limitation could be further restricted if ownership changes occur in future years. To the extent our use of net operating loss carryforwards is limited, future income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards, which could result in decreased net income.

We also have federal and state research and development credit carryovers of approximately $2.8 million, which expire commencing in fiscal 2025.

Results of Operations

Year Ended September 30, 2010 Compared to Year Ended September 30, 2009

Revenue. We did not recognize any revenue during the years ended September 30, 2010 or 2009.

Research and Development Expenses.

	Year Ended September 30,		Decrease	
	2009	2010	$	%
	In thousands, except per share amounts			
Research and Development	$32,325	$26,177	$6,148	19.0%
Percentage of net loss	74.7%	68.4%		

Research and development expenses were $26.2 million for the year ended September 30, 2010, a decrease of $6.1 million or 19.2%, from $32.3 million for the year ended September 30, 2009. This decrease was primarily attributable to reductions of $6.4 million in clinical expenses and $3.6 million in manufacturing and device development expenses. The savings in clinical expenses are directly related to conducting fewer studies during the fiscal year ended September 30, 2010. For example, our 18 month safety extension trials for patients who completed the pivotal Phase 3 clinical trials of Linjeta™ ended in February 2010. The savings in manufacturing and device development are the result of purchasing a reduced quantity of recombinant human insulin in the twelve months ended September 30, 2010 of $4.5 million, as compared to the $6.5 million of purchases made in the twelve months ended September 30, 2009. The decreases in clinical and manufacturing expenses were offset by increases of $1.9 million in regulatory expense attributable to professional and consulting fees associated with filing our NDA in December 2009 and our 120 day safety update in April 2010, $0.9 million in personnel and share-based compensation expenses, $0.4 million in expenses related to further develop our earlier staged products, and $0.7 million in professional fees, storage and other expenses. Research and development expenses for the year ended September 30, 2010 include $2.0 million in share-based compensation expense related to options granted to employees. Because we must revalue options granted to non-employees for accounting purposes each reporting period, the amount of the share-based compensation income for the year ended September 30, 2010 was $2 thousand.

We anticipate that our research and development expenses will decrease as we plan to conduct preclinical studies and Phase 1 clinical trials to study Linjeta™ follow-on and second generation rapid-acting mealtime insulins or insulin analogs in order to determine our preferred development, clinical and regulatory program for our rapid-acting insulin formulations. Over the longer term, however, we anticipate these expenses will increase as we advance a preferred formulation toward pivotal Phase 3 clinical trials.

General and Administrative Expenses.

	Year Ended September 30,		Decrease	
	2009	2010	$	%
	In thousands, except per share amounts			
General and Administrative	$ 10,994	$ 10,980	$ 14	0.1%
Percentage of net loss	25.5%	28.7%		

General and administrative expenses were $11.0 million for the year ended September 30, 2010, a decrease of $14 thousand, or 0.1%, from $11.0 million for the year ended September 30, 2009. This decrease is attributable to a decrease in personnel and employee share-based compensation expenses of $1.0 million offset by an increase of $0.5 million in professional fees, $0.4 million in non-employee director share-based compensation expense and other expenses of $0.1 million. General and administrative expenses for the year ended September 30, 2010 include $3.6 million in stock-based compensation expense related to options granted to employees and non-employee directors. Because we must revalue options granted to non-employees for accounting purposes each reporting period, the amount of the stock-based compensation income for the year ended September 30, 2010 was $5 thousand.

We expect our general and administrative expenses to decrease over the next twelve months as we focus our efforts to conduct preclinical and Phase 1 clinical trials to study Linjeta™ follow-on and second generation rapid-acting mealtime insulins or insulin analogs. Over the longer term, however, we anticipate these expenses will increase as we advance a preferred formulation toward pivotal Phase 3 clinical trials.

Interest and Other Income.

	Year Ended September 30,		Decrease	
	2009	2010	$	%
	In thousands, except per share amounts			
Interest and Other Income	$ 386	$ 17	$ 369	95.6%
Percentage of net loss	0.9%	0.04%		

Interest and other income decreased to $0.02 million for the year ended September 30, 2010 from $0.4 million for the year ended September 30, 2009. The decrease was due to a lower cash balance and shifting our investments primarily into treasury securities. The focus on preserving cash and investing in stable securities generated lower returns during the year ended September 30, 2010.

Interest Expense. For the years ended September 30, 2010 and 2009, we had no interest expense.

Adjustments to Fair Value of Common Stock Warrant Liability.

	Year Ended September 30,		Increase	
	2009	2010	$	%
	In thousands, except per share amounts			
Adjustments to fair value of common stock warrant liability	$ —	$ 1,254	$ 1,254	100%
Percentage of net loss	—%	3.3%		

Adjustments to fair value of common stock warrant liability increased to $1.3 million for the year ended September 30, 2010 from $0 for the year ended September 30, 2009. The September 30, 2010 charge represents an increase in fair value of our warrant liability determined by the Monte Carlo simulation method. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of our and our peer group's future expected stock prices and minimizes standard error. These warrants will be revalued each reporting period.

Net Loss and Net Loss per Share.

	Year Ended September 30,		Decrease	
	2009	2010	$	%
	In thousands, except per share amounts			
Net loss	$ (43,270)	$ (38,290)	$4,980	11.5%
Net loss per share	$ (1.82)	$ (1.58)		

Net loss was $38.3 million, or $(1.58) per share, for the year ended September 30, 2010 compared to $43.3 million, or $(1.82) per share, for the year ended September 30, 2009. The decrease in net loss was primarily due to reduced clinical and manufacturing expenses as noted above. We expect our losses to continue as we plan to conduct preclinical and Phase 1 clinical trials of several rapid-acting insulin and insulin analog formulations prior to advancing a preferred rapid-acting formulation by conducting Phase 2 or Phase 3 clinical trials.

Year Ended September 30, 2009 Compared to Year Ended September 30, 2008

Revenue. We did not recognize any revenue during the years ended September 30, 2009 or 2008.

Research and Development Expenses.

	Year Ended September 30,		Decrease	
	2008	2009	$	%
	In thousands, except per share amounts			
Research and Development	$ 32,554	$ 32,325	$ 229	0.7%
Percentage of net loss	75.1%	74.7%		

Research and development expenses were $32.3 million for the year ended September 30, 2009, a decrease of $0.2 million, or 0.7%, from $32.6 million for the year ended September 30, 2008. This decrease was primarily attributable to a $5.8 million decrease in research and development costs related to our pivotal Phase 3 clinical trials for Linjeta™ and a decrease of $1.5 million in the costs of manufacturing clinical supplies. These decreases were offset by an increase of $5.8 million for the purchase of recombinant human insulin during the fiscal year in order to build commercial supply as per existing contractual commitments and an increase of $0.9 million in professional fees for the preparation of the filing of our planned NDA. Research and development expenses for the year ended September 30, 2009 include $1.6 million in share-based compensation expense related to options granted to employees and $0.1 million in share-based compensation expense related to options granted to non-employees.

General and Administrative Expenses.

	Year Ended September 30,		Decrease	
	2008	2009	$	%
	In thousands, except per share amounts			
General and Administrative	$14,800	$10,994	$3,806	25.7%
Percentage of net loss	33.1%	25.5%		

General and administrative expenses were $11.0 million for the year ended September 30, 2009, a decrease of $3.8 million, or 25.7%, from $14.8 million for the year ended September 30, 2008. This decrease is attributable to the following items: a decrease of $1.6 million in share-based compensation charges for the non-employee directors due to a change in vesting policy from immediate vesting to vesting pro rata over one year; a decrease of $0.6 million in professional fees, a decrease of $0.5 million in personnel expenses and a

decrease of $0.6 million in travel expenses were due to a one-time event that occurred in 2008. General and administrative expenses for the year ended September 30, 2009 include $3.4 million in share-based compensation expense related to options granted to employees. Because we must revalue options granted to non-employees for accounting purposes each reporting period, the amount of the share-based compensation income for the year ended September 30, 2009 was $13 thousand.

Interest and Other Income.

	Year Ended September 30,		Decrease	
	2008	2009	$	%
	In thousands, except per share amounts			
Interest and Other Income	$ 3,010	$ 386	$ 2,624	87.2%
Percentage of net loss	6.8%	0.9%		

Interest and other income decreased to $0.4 million for the year ended September 30, 2009 from $3.0 million for the year ended September 30, 2008. The decrease was due to lower cash balance and shifting our investments primarily into treasury securities. The focus on preserving cash and investing in stable securities generated lower returns during the year ended September 30, 2009.

Interest Expense. For the years ended September 30, 2009 and 2008, we had no interest expense.

Net Loss and Net Loss per Share.

	Year Ended September 30,		Decrease	
	2008	2009	$	%
	In thousands, except per share amounts			
Net loss	$ (43,361)	$ (43,270)	$ 91	0.2%
Net loss per share	$ (1.94)	$ (1.82)		

Net loss was $43.3 million, or $(1.82) per share, for the year ended September 30, 2009 compared to $43.4 million, or $(1.94) per share, for the year ended September 30, 2008. The decrease in net loss was primarily attributable to the decreased expenses described above.

Liquidity and Capital Resources

Sources of Liquidity and Cash Flows

As a result of our significant research and development expenditures and the lack of any approved products or other sources of revenue, we have not been profitable and have generated significant operating losses since we were incorporated in 2003. We initially funded our research and development operations through proceeds from our Series A convertible preferred stock financing in 2005 and our mezzanine and Series B convertible preferred stock financings in 2006. Through December 31, 2006, we had received aggregate gross proceeds of $26.6 million from these sales. We received an aggregate of $134.3 million from our initial public offering in May 2007, our follow-on offering in February 2008 and our registered direct offering in August 2010.

At September 30, 2010, we had cash, cash equivalents, and marketable securities, totaling approximately $28.9 million. We have invested our excess funds primarily in managed money funds with one major financial institution. All highly liquid investments with an original maturity of less than three months at the date of purchase are categorized as cash equivalents. We plan to continue to invest our cash and cash equivalents in accordance with our approved investment policy guidelines, which set forth our policy to hold investment securities to maturity.

Net cash used in operating activities was $34.4 million for the year ended September 30, 2010, $35.3 million for the year ended September 30, 2009 and $34.9 million for the year ended September 30,

2008. Net cash used in operating activities for the year ended September 30, 2010 primarily reflects the net loss for the period, offset in part by share-based compensation, depreciation and amortization expenses, adjustment to fair value of common stock warrant liability, decrease in income tax receivable, income tax payable and accrued expenses and an increase in accounts payable. Net cash used in operations for the years ended September 30, 2009 and 2008 primarily reflects the net loss for the period, offset in part by depreciation and amortization, share-based compensation and changes in income tax receivable, prepaid expenses, accrued expenses, accounts payable and income tax payable.

Net cash provided by (used in) investing activities was ($6.3) million for the year ended September 30, 2010, $25.0 million for the year ended September 30, 2009 and ($28.4) million for the year ended September 30, 2008. Net cash used in investing activities for the year ended September 30, 2010 primarily reflects purchase of marketable securities and the purchase of property and equipment. Net cash provided by investing activities for the year ended September 30, 2009 primarily reflects the sale of marketable securities offset by the purchase of property and equipment. Net cash used in investing activities for the year ended September 30, 2008 primarily reflects the purchases of marketable securities, property and equipment and leasehold improvement costs.

Net cash provided by financing activities was $9.0 million for the year ended September 30, 2010, $0.2 million for the year ended September 30, 2009 and $48.0 million for the year ended September 30, 2008. Net cash provided by financing activities for the year ended September 30, 2010 primarily reflects the proceeds from the sale of our securities in our registered direct offering in August 2010 and through our employee stock purchase plan. Net cash provided by financing activities in 2009 primarily reflects proceeds from sale of stock through our employee stock purchase plan. Net cash provided by financing activities in 2008 primarily reflects proceeds from our follow-on public offering.

In July 2008, we entered into a supply agreement with N.V. Organon, which will terminate in December 2011, to purchase specified minimum quantities of recombinant human insulin. Our minimum purchase requirements for the next five consecutive quarters could total as much as $6.7 million, depending on our regulatory plans for Linjeta™.

On August 24, 2010, we sold to two institutional investors an aggregate of 2,398,200 units that were immediately separated and we issued 2,398,200 shares of our common stock and warrants to purchase an additional 2,398,200 shares of our common stock at an exercise price of $4.716. The financing resulted in gross proceeds of $9.4 million. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share.

On February 12, 2008, we completed a follow-on public offering of 3,260,000 shares of our common stock at a price to the public of $15.50 per share and received net proceeds from this offering, after deducting after deducting underwriting discounts and commissions and offering expenses, of $46.8 million. Certain of our stockholders sold 550,000 shares in the offering. We did not receive any proceeds from the sale of shares from the selling stockholders.

Funding Requirements

We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses and capital expenditures at least through the first quarter of fiscal year 2012. If the August 2010 warrants are exercised, we anticipate the cash runway to extend at least through the second quarter of fiscal year 2012. We have based this estimate upon assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect. Our existing capital resources are not sufficient to complete our clinical development program for Linjeta™. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and to the extent that we may or may not enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current anticipated clinical trials.

Our future capital requirements will depend on many factors, including:

- our ability to respond to the complete response letter regarding our NDA for Linjeta™ in a timely manner and the possibility that information we provide in response to the letter may not be sufficient for the approval of Linjeta™ or another rapid-acting insulin or insulin analog by the FDA;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA and the degree to which we are able to clarify with the FDA related regulatory requirements;
- our ability to conduct the additional pivotal clinical trials the FDA requested in the complete response letter or other tests or analyses required by the FDA to secure approval to commercialize Linjeta™;
- our ability to develop and commercialize formulations of Linjeta™ or other rapid-acting insulin or insulin analog formulations that may be associated with less injection site discomfort than the formulation that is the subject of the complete response letter we received from the FDA;
- the progress, timing or success of our product candidates, particularly Linjeta™, and that of our research, development and clinical programs, including any resulting data analyses;
- the cost to develop an insulin pen for use with Linjeta™ and a formulation of Linjeta™ for use in insulin pumps;
- the costs of pre-commercialization activities, if any;
- the costs associated with qualifying and obtaining regulatory approval of suppliers of insulin and manufacturers of our product candidates;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse market developments; and
- our ability to establish and maintain collaborations and the terms and success of the collaborations, including the timing and amount of payments that we might receive from potential strategic collaborators; and
- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

We do not anticipate generating product revenue for the next few years. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several years. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We do not currently have any commitments for future external funding.

Management may seek to meet all or some of our operating cash flow requirements through financing activities, such as private placements of our common stock, preferred stock offerings and offerings of debt and convertible debt instruments as well as through merger or acquisition opportunities. In January 2010, we filed a shelf registration statement (File No. 333-153167) with the Securities and Exchange Commission pursuant to which we registered an indeterminate number of shares of common stock, preferred stock, debt securities and an indeterminate number of warrants and units with an aggregate initial offering price of up to $100,000,000.

On August 24, 2010, we sold to two institutional investors an aggregate of 2,398,200 units that were immediately separated and we issued 2,398,200 shares of our common stock and warrants to purchase an additional 2,398,200 shares of our common stock at an initial exercise price of $4.716. The financing resulted in gross proceeds of $9.4 million. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share.

We may receive additional proceeds from the exercise of warrants in connection with the securities purchase agreement and related documents we entered into in August 2010. The exercise will be dependent

upon whether the market price or our common stock exceeds the current exercise price of $1.56 per share of common stock and the investors choose to exercise.

Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to reduce general and administrative expenses and delay, reduce the scope of or eliminate some or all of our research and development programs, which could possibly include a reduction in personnel. We would also reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently or enter into corporate collaborations at a later stage of development. In addition, any future equity funding will dilute the ownership of our equity investors.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Contractual Obligations

The following table summarizes our significant contractual obligations and commercial commitments as of September 30, 2010 (in thousands):

	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Operating lease obligations	$2,347	$ 635	$ 1,712	$ —	$ —
Purchase commitments	6,740	4,155	2,585	—	—
Total fixed contractual obligations	$9,087	$ 4,790	$ 4,297	$ —	$ —

Adopted Accounting Pronouncements

Subsequent Events

In February 2010, we adopted the updated authoritative guidance regarding the reporting of subsequent events, removing the requirement for an issuer to disclose a date through which subsequent events have been evaluated. The guidance was effective upon issuance in February 2010 and was adopted as of our Report on Form-10-Q for the three months ended March, 31, 2010 as filed with the SEC on May 7, 2010. The adoption of this guidance did not have a material impact on our financial statements.

Fair Value Measurement

Effective October 1, 2009, we adopted the provisions of ASU 2009-5 Fair Value and Disclosures (Topic 820) Measuring Liabilities at Fair Value ("ASU 2009-5"). ASU 2009-5 provides amendments to Subtopic 820-10, Fair Value Measurements and Disclosures-Overall, for the fair value measurement of liabilities. ASU 2009-5 clarifies that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value. The adoption of this accounting pronouncement did not have a material effect on our financial statements.

Participating Securities

In June 2008 the FASB issued ASC 260-10-55 Earnings Per Share — Overall (formerly Financial Statement Position Emerging Issues Task Force 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities) ("ASC 260-10-55"). ASC 260-10-55 provides that securities and unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. ASC 260-10-55 is effective for fiscal years beginning after December 15, 2008, and interim periods within those years. Upon adoption, a company is required to

retrospectively adjust its earnings per share data (including any amounts related to interim periods, summaries of earnings and selected financial data) to conform to the provisions of ASC 260-10-55.

Warrant Liability — Given that the warrant holders will participate fully on any dividends or dividend equivalents, we determined that the warrants are participating securities and therefore are subject to ASC 260-10-55. These securities were excluded from the EPS calculation since their inclusion would be anti-dilutive.

Share-based Compensation — Given that the holders of Restricted Stock Unit awards ("RSUs") will only receive dividends or dividend equivalents on RSUs that have vested prior to the Company declaring dividends as well as forfeiting their rights to receive dividends or dividend equivalents on any unvested portion, we determined that the RSUs are non-participating securities and therefore are not subject to ASC 260-10-55.

Recent Accounting Pronouncements

In January 2010, the FASB issued authoritative guidance that requires new disclosures and clarifies certain existing disclosure requirements about fair value measurements. The new guidance requires a reporting entity to disclose significant transfers in and out of Level 1 and Level 2 fair value measurements, to describe the reasons for the transfers and to present separately information about purchases, sales, issuances and settlements for fair value measurements using significant unobservable inputs. The guidance is effective on a prospective basis for periods beginning after December 15, 2010. We anticipate that the adoption of this guidance will not have a material impact on our financial statements in future periods.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, as permitted by the terms of our investment policy guidelines. Currently, our investments are primarily limited to highly liquid money market investments. A portion of our investments may be subject to interest rate risk and could fall in value if interest rates were to increase. The effective duration of our portfolio is currently less than one year, which we believe limits interest rate and credit risk. We do not hedge interest rate exposure.

Pursuant to our supply agreement with N.V. Organon, our purchases of insulin are denominated in Euros. Most of our other transactions are denominated in United States dollars and do not present a material exposure to fluctuations in currency exchange rates.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

Refer to page F-1.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES*

Not applicable.

ITEM 9A. *CONTROLS AND PROCEDURES*

Management's Evaluation of Disclosure Controls and Procedures

We are required to maintain disclosure controls and procedures designed to ensure that material information related to us is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or

submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2010 and, based on this evaluation, our chief executive officer and chief financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of September 30, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of September 30, 2010, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accountants have issued an audit report on our assessment of our internal control over financial reporting. This report appears below.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We have audited Biodel Inc.'s (a development stage company) internal control over financial reporting as of September 30, 2010, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Biodel Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying

"Item 9A, Controls and Procedures, Management's Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Biodel Inc. maintained, in all material respects, effective internal control over financial reporting as of September 30, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Biodel Inc. as of September 30, 2010 and 2009, and the related statements of operations, stockholders' equity, cash flows and comprehensive loss for each of the three years in the period ended September 30, 2010 and for the period from December 3, 2003 (inception) to September 30, 2010 and our report dated December 14, 2010 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

New York, New York
December 14, 2010

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file a definitive proxy statement within 120 days after the end of our fiscal year for our 2010 annual meeting of stockholders, or proxy statement, and the information included in the proxy statement is incorporated herein by reference.

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Certain information required by this Item is contained under the heading "Executive Officers of the Registrant" in Part I of this Annual Report on Form 10-K. Other information required by this Item will appear under the headings "Election of Directors", "Section 16(a) Beneficial Ownership Reporting Compliance" and "Corporate Governance" in our proxy statement, which sections are incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics, which also applies to our directors and all of our officers and employees, can be found on our website, which is located at www.biodel.com. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the NASDAQ Global Market by filing such amendment or waiver with the Securities and Exchange Commission and by posting it on our website.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this Item will appear under the heading "Executive Compensation" including "Compensation Discussion and Analysis", "Director Compensation", "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" in our proxy statement, which sections are incorporated herein by reference.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

The information required by this Item will appear under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans" in our proxy statement, which sections are incorporated herein by reference.

ITEM 13. *CERTAIN RELATIONSHIP AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this Item will appear under the headings "Certain Relationships and Related Transactions" and "Corporate Governance" in our proxy statement, which sections are incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this Item will appear under the heading "Auditors' Fees" in our proxy statement, which section is incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

(1) Financial Statements: See Index to Financial Statements and Schedules.

(2) Financial Statement Schedules: Not applicable.

(3) Exhibits: The Exhibit Index annexed to this report is incorporated by reference.

SIGNATURES

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

BIODEL INC.

By: /s/ Errol De Souza
Dr. Errol De Souza
President and Chief Executive Officer
Date: December 14, 2010

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

Signature	Title	Date
/s/ Errol De Souza Errol De Souza	President and Chief Executive Officer (Principal Executive Officer), Director	December 14, 2010
/s/ Gerard Michel Gerard Michel	Chief Financial Officer, Vice President, Corporate Development and Treasurer (Principal Financial and Accounting Officer)	December 14, 2010
/s/ Donald Casey Donald Casey	Director	December 14, 2010
/s/ Barry Ginsberg Barry Ginsberg	Director	December 14, 2010
/s/ Ira W. Lieberman Ira W. Lieberman	Director	December 14, 2010
/s/ Daniel Lorber Daniel Lorber	Director	December 14, 2010
/s/ Brian J.G. Pereira Brian J.G. Pereira	Director	December 14, 2010
/s/ Solomon S. Steiner Solomon S. Steiner	Director	December 14, 2010
/s/ Arthur Urciuoli Arthur Urciuoli	Director	December 14, 2010

Exhibits Index

Exhibit Number	Description of Document
3.1	Registrant's Second Amended and Restated Certificate of Incorporation (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
3.2	Registrant's Amended and Restated Bylaws (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.1	Specimen Common Stock Certificate (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.2	Form of Warrant issued to Scott Weisman and McGinn Smith Holdings LLC to Purchase Shares of Series A convertible preferred stock (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.3	Form of Warrant to Purchase Shares of Common stock (Incorporated by reference to exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 25, 2010).
4.4	Form of Subscription and Rights Agreement by and among the Registrant and the holders of the Series A convertible preferred stock (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.5	Amended and Restated Registration Rights Agreement, dated September 19, 2006, by and among the Registrant and other parties named therein (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.1	2010 Stock Incentive Plan (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.2	2010 Incentive Stock Option Agreement (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.3	2010 Non Statutory Stock Option Agreement (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.4	2010 Restricted Stock Unit Agreement (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.5	Form of Indemnity Agreement entered into between the Registrant and its directors and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.6	Amended and Restated 2004 Stock Incentive Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.7	2005 Employee Stock Purchase Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.8	2005 Non-Employee Directors' Stock Option Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.9	Employment Agreement, dated March 26, 2010, between the Registrant and Solomon S. Steiner (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 1, 2010).
10.10	Employment Agreement, dated March 26, 2010, between the Registrant and Errol B. De Souza (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 1, 2010).
10.11	Letter agreement, dated October 1, 2010, between the Registrant. and Errol B. De Souza (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 6, 2010).
10.12	Amended and Restated Consulting Agreement entered into on November 13, 2007, effective June 5, 2007, between the Registrant and Dr. Andreas Pfützner (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 14, 2007).
10.13†	Manufacturing Agreement, dated December 20, 2005 between the Registrant and Cardinal Health — PTS, LLC (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.14	Change of Control Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).

Exhibit Number	Description of Document
10.15	Executive Severance Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.16	Lease Agreement, dated February 2, 2004, between the Registrant and Mulvaney Properties, LLC and amendment thereto dated September 29, 2006 (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.17	Commercial Lease, dated July 23, 2007, by and between the Registrant and Mulvaney Properties LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.18	Lease Amendment, dated October 1, 2007, between the Registrant and Mulvaney Properties LLC (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 4, 2007).
10.19	Amendment to Lease Agreement, dated February 2, 2004, as amended, by and between the Registrant and Mulvaney Properties LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.20	Offer Letter, dated November 12, 2007, by and between the Registrant and Gerard J. Michel. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 14, 2007).
10.21	Form of Incentive Stock Option Agreement for 2004 Amended and Restated Stock Incentive Plan. (Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).
10.22	Form of Option Agreement for 2005 Non-Employee Directors' Stock Option Plan. (Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).
10.23	Base salaries of Executive Officers of the Registrant.
10.24	Summary of the Registrant's Non-Employee Director Compensation.
10.25†	Supply Agreement, dated July 7, 2008, between the Registrant and N.V. Organon (Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2008).
10.26*	Letter Agreement, dated November 12, 2009, between the Registrant and N.V. Organon, amending the Supply Agreement, dated July 7, 2008, between the parties. (Incorporated by reference to Registrant's Annual Report on Form 10-K filed on December 14, 2009).
21.1	Subsidiaries of the Registrant.
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
24.1	Powers of Attorney (included on signature page).
31.01	Chief Executive Officer — Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.02	Chief Financial Officer — Certification pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.01	Chief Executive Officer and Chief Financial Officer — Certification pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Confidential treatment granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

BIODEL INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We have audited the accompanying balance sheets of Biodel Inc. (a development stage company) as of September 30, 2010 and 2009 and the related statements of operations, stockholders' equity, cash flows and comprehensive loss for each of the three years in the period ended September 30, 2010 and for the period from December 3, 2003 (inception) to September 30, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Biodel Inc. at September 30, 2010 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2010**,** and for the period from December 3, 2003 (inception) to September 30, 2010, in conformity with accounting principles generally accepted in the United States.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Biodel Inc.'s internal control over financial reporting as of September 30, 2010, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated December 14, 2010 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

New York, New York
December 14, 2010

Biodel Inc.
(A Development Stage Company)

Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2009	September 30, 2010
ASSETS		
Current:		
Cash and cash equivalents	$ 54,640	$ 22,922
Restricted cash	—	150
Marketable securities, available for sale	—	6,001
Taxes receivable	752	116
Other receivable	—	11
Prepaid and other assets	482	365
Total current assets	55,874	29,565
Property and equipment, net	3,695	2,998
Intellectual property, net	56	53
Total assets	$ 59,625	$ 32,616
Current:		
Accounts payable	$ 1,007	$ 1,989
Accrued expenses:		
Clinical trial expenses	5,647	1,362
Payroll and related	1,117	357
Accounting and legal fees	325	300
Severance	183	—
Other	643	334
Income taxes payable	165	45
Total current liabilities	9,087	4,387
Common stock warrant liability	—	4,169
Commitments		
Stockholders' equity:		
Preferred stock, $.01 par value; 50,000,000 shares authorized, none outstanding	—	—
Common stock, $.01 par value; 100,000,000 shares authorized; 23,803,672 and 26,399,764 issued and outstanding	238	264
Additional paid-in capital	176,764	188,549
Accumulated other comprehensive loss	—	1
Deficit accumulated during the development stage	(126,464)	(164,754)
Total stockholders' equity	50,538	24,060
Total liabilities and stockholders' equity	$ 59,625	$ 32,616

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

Statements of Operations
(In thousands, except share and per share amounts)

	Year Ended September 30,			December 3, 2003 (Inception) to September 30, 2010
	2008	2009	2010	
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	32,554	32,325	26,177	116,228
General and administrative	14,800	10,994	10,980	47,625
Total operating expenses	47,354	43,319	37,157	163,853
Other (income) and expense:				
Interest and other income	(3,010)	(386)	(17)	(5,506)
Interest expense	—	—	—	78
Adjustments to fair value of common stock warrant liability	—	—	1,254	1,254
Loss on settlement of debt	—	—	—	627
Loss before tax provision (benefit)	(44,344)	(42,933)	(38,394)	(160,306)
Tax provision (benefit)	(983)	337	(104)	(612)
Net loss	(43,361)	(43,270)	(38,290)	(159,694)
Charge for accretion of beneficial conversion rights	—	—	—	(603)
Deemed dividend — warrants	—	—	—	(4,457)
Net loss applicable to common stockholders	$ (43,361)	$ (43,270)	$ (38,290)	$ (164,754)
Net loss per share — basic and diluted	$ (1.94)	$ (1.82)	$ (1.58)	
Weighted average shares outstanding — basic and diluted	22,390,434	23,746,598	24,161,866	

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

Statements of Stockholders' Equity
(In thousands, except share and per share amounts)

	Common Stock $01 Par Value		Series A Preferred stock $.01 Par Value		Series B Preferred stock $.01 Par Value		Additional Paid in Capital	Accumulated Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Shares issued to employees	732,504	$ 7	—	$ —	—	$ —	$ (7)	$	$ —	$ —
January 2004 Proceeds from sale of common stock	4,581,240	46	—	—	—	—	1,308		—	1,354
Net loss	—	—	—	—	—	—	—		(774)	(774)
Balance, September 30, 2004	5,313,744	53	—	—	—	—	1,301	—	(774)	580
Additional stockholder contributions	—	—	—	—	—	—	514		—	514
Share-based compensation	—	—	—	—	—	—	353		—	353
Shares issued to employees and directors for services	42,656	1	—	—	—	—	60		—	61
July 2005 Private placement — Sale of Series A preferred stock, net of issuance costs of $379	—	—	569,000	6	—	—	2,460		—	2,466
Founder's compensation contributed to capital	—	—	—	—	—	—	63		—	63
Net loss	—	—	—	—	—	—	—	—	(3,383)	(3,383)
Balance, September 30, 2005	5,356,400	54	569,000	6	—	—	4,751	—	(4,157)	654
Share-based compensation	—	—	—	—	—	—	1,132		—	1,132
July 2006 Private placement — Sale of Series B preferred stock, net of issuance costs of $1,795	—	—	—	—	5,380,711	54	19,351		—	19,405
July 2006 — Series B preferred stock units issued July 2006 to settle debt	—	—	—	—	817,468	8	3,194		—	3,202
Shares issued to employees and directors for services	4,030	—	—	—	—	—	23		—	23
Accretion of fair value of beneficial conversion charge	—	—	—	—	—	—	603		(603)	—
Net loss	—	—	—	—	—	—	—	—	(8,068)	(8,068)
Balance, September 30, 2006	5,360,430	54	569,000	6	6,198,179	62	29,054	—	(12,828)	16,348
May 2007 Proceeds from sale of common stock	5,750,000	58	—	—	—	—	78,697		—	78,755
Conversion of preferred stock on May 16, 2007	6,407,008	64	(569,000)	(6)	(6,198,179)	(62)	4		—	—
Share-based compensation	—	—	—	—	—	—	4,224		—	4,224
Shares issued to employees, non-employees and directors for services	2,949	—	—	—	—	—	16		—	16
Stock options exercised	3,542	—	—	—	—	—	5		—	5
March 2007 Warrants exercised	2,636,907	26	—	—	—	—	397		—	423
Deemed dividend — warrants	—	—	—	—	—	—	4,457		(4,457)	—
Net loss	—	—	—	—	—	—	—		(22,548)	(22,548)
Balance, September 30, 2007	20,160,836	202	—	—	—	—	116,854	—	(39,833)	77,223
Proceeds from sale of common stock	3,260,000	32	—	—	—	—	46,785		—	46,817
Issuance of restricted stock	9,714	—	—	—	—	—	172		—	172
Share-based compensation	—	—	—	—	—	—	6,503		—	6,503
Stock options exercised	174,410	1	—	—	—	—	901		—	902
Warrants exercised	79,210	1	—	—	—	—	111		—	112
Net unrealized (loss) on Marketable Securities	—	—	—	—	—	—	—	(62)	—	(62)
Proceeds from sale of stock — ESPP	14,388	1	—	—	—	—	180		—	181
Net loss	—	—	—	—	—	—	—		(43,361)	(43,361)
Balance, September 30, 2008	23,698,558	$ 237	—	$ —	—	$ —	$ 171,506	$ (62)	$ (83,194)	$ 88,487
Balance, September 30, 2008	23,698,558	$ 237	—	$ —	—	$ —	$ 171,506	$ (62)	$ (83,194)	$ 88,487
Share-based compensation							5,064			5,064
Stock options exercised	17,661	—	—	—	—	—	25	—	—	25
Net unrealized gain on Marketable Securities	—	—	—	—	—	—	—	62	—	62
Proceeds from sale of stock — ESPP	87,453	1	—	—	—	—	169	—	—	170
Net loss									(43,270)	(43,270)
Balance, September 30, 2009	23,803,672	$ 238	—	$ —	—	$ —	$ 176,764	$ —	$ (126,464)	$ 50,538
Registered direct offering	2,398,200	24	—	—	—	—	8,688	—	—	8,712
Initial value of warrants issued in a registered direct offering	—	—	—	—	—	—	(2,915)	—	—	(2,915)
Share-based compensation	—	—	—	—	—	—	5,621	—	—	5,621
Stock options exercised	32,320	—	—	—	—	—	68	—	—	68
Net unrealized gain on Marketable Securities	—	—	—	—	—	—		1	—	1
Proceeds from sale of stock — ESPP	165,572	2	—	—	—	—	323	—	—	325
Net loss	—	—	—	—	—	—	—	—	(38,290)	(38,290)
Balance, September 30, 2010	26,399,764	$ 264	—	$ —	—	$ —	$ 188,549	$ 1	$ (164,754)	$ 24,060

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

Statements of Comprehensive Loss
(In thousands)

	Year Ended September 30,		
	2008	2009	2010
Net loss	$(43,361)	$(43,270)	$(38,290)
Unrealized holding gains (losses) arising during the period	(62)	62	1
Comprehensive loss	$(43,423)	$(43,208)	$(38,289)

Biodel Inc.
(A Development Stage Company)

Statements of Cash Flows
(In thousands, except share and per share amounts)

	Year Ended September 30,			December 3, 2003 (Inception) to September 30,
	2008	2009	2010	2010
Cash flows from operating activities:				
Net loss	$ (43,361)	$(43,270)	$(38,290)	$ (159,694)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	567	877	991	3,140
Founder's compensation contributed to capital	—	—	—	271
Share-based compensation for employees and directors	6,434	4,970	5,628	20,832
Share-based compensation for non-employees	241	94	(7)	2,318
Loss on settlement of debt	—	—	—	627
Write-off of capitalized patent expense	208	—	—	208
Write-off of loan to related party	—	—	—	41
Adjustment to fair value of common stock warrant liability	—	—	1,254	1,254
(Increase) decrease in:				
Prepaid expenses and other assets	(745)	768	117	(365)
Income taxes receivable	(1,988)	1,236	636	(116)
Other receivable	—	—	(11)	(11)
Increase (decrease) in:				
Accounts payable	(1,374)	194	982	1,989
Income tax payable	917	(847)	(120)	45
Accrued expenses and other liabilities	4,198	715	(5,561)	2,572
Total adjustments	8,458	8,007	3,909	32,805
Net cash used in operating activities	(34,903)	(35,263)	(34,381)	(126,889)
Cash flows from investing activities:				
Purchase of property and equipment	(2,769)	(637)	(292)	(6,101)
Purchase of marketable securities	(25,614)	—	(6,000)	(31,614)
Sale of marketable securities	—	25,614	—	25,614
Capitalized intellectual properties	(17)	—	—	(298)
Loan to related party	—	—	—	(41)
Net cash provided by (used in) investing activities	(28,400)	24,977	(6,292)	(12,440)
Cash flows from financing activities:				
Restricted cash	—	—	(150)	(150)
Options exercised	902	25	68	1,000
Warrants exercised	112	—	—	535
Deferred public offering costs	—	—	—	(1,458)
Stockholder contribution	—	—	—	1,660
Net proceeds from sale of Series A preferred stock	—	—	—	2,466
Net proceeds from employee stock purchase plan	181	170	325	676
Net proceeds from sale of common stock	46,817	—	8,712	135,742
Proceeds from bridge financing	—	—	—	2,575
Net proceeds from sale of Series B preferred stock	—	—	—	19,205
Net cash provided by financing activities	48,012	194	8,955	162,251
Net increase (decrease) in cash and cash equivalents	(15,291)	(10,091)	(31,718)	22,922
Cash and cash equivalents, beginning of period	80,022	64,731	54,640	—
Cash and cash equivalents, end of period	$ 64,731	$ 54,640	$ 22,922	$ 22,922
Cash paid for interest and income taxes was:				
Interest	$ —	$ —	$ —	$ 9
Income taxes	88	111	60	306
Non-cash financing and investing activities:				
Warrants issued in connection with registered direct offering	$ —	$ —	$ 2,915	$ 2,915
Settlement of debt with Series B preferred stock	—	—	—	3,202
Accrued expenses settled with Series B preferred stock	—	—	—	150
Deemed dividend — warrants	—	—	—	4,457
Accretion of fair value of beneficial charge on preferred stock	—	—	—	603
Conversion of convertible preferred stock to common stock	—	—	—	68

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

Notes to Financial Statement
(In thousands, except share and per share amounts)

1. Business and Basis of Presentation

Business

Biodel Inc. ("Biodel" or the "Company", and formerly Global Positioning Group Ltd.) is a development stage specialty pharmaceutical company located in Danbury, Connecticut. The Company was incorporated in the State of Delaware on December 3, 2003 and commenced operations in January 2004. The Company is focused on the development and commercialization of innovative treatments for diabetes. The Company develops product candidates by applying its proprietary formulation technologies to existing drugs in order to improve their therapeutic profiles. The Company's most advanced product is Linjeta™ (formerly known as VIAject®). The Company has formulated Linjeta™ as a rapid-acting mealtime insulin for the treatment of patients with Type 1 and Type 2 diabetes. Earlier stage product candidates include follow-on and second generation rapid-acting mealtime insulin or insulin analogs, VIAtab™, a sublingual tablet formulation of insulin, a line of basal insulins and a stabilized formulation of glucagon.

Basis of Presentation

The Company is in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning and raising capital.

On April 12, 2007, the Company effected a 0.7085 for one (0.7085:1) reverse stock split (see Note 13). All references in these financial statements and accompanying notes to units of common stock or per share amounts are reflective of the reverse split for all periods reported.

2. Summary of Significant Accounting Policies

Research and Development Costs

The Company is in the business of research and development and, therefore, research and development costs include, but are not limited to, salaries and benefits, lab supplies, preclinical fees, clinical trial and related clinical manufacturing costs, allocated overhead costs and professional service providers. Research and development costs are expensed when incurred. Research and development costs aggregated $32,554, $32,325, and $26,177 for the years ended September 30, 2008, 2009 and 2010, respectively.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions including, but not limited to, accruals, income taxes payable, and deferred tax assets. Actual results may differ from those estimates.

Cash and Cash Equivalents

The Company considers currency on hand, demand deposits and all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash and cash equivalents. At September 30, 2010, cash and cash equivalents of $22,922 are primarily held in a U.S. treasury denominated money market account.

Biodel Inc.
(A Development Stage Company)

Notes to Financial Statement — (Continued)
(In thousands, except share and per share amounts)

Restricted Cash

Restricted cash as of September 30, 2010 consisted of a $150 money market account held with a bank to secure a credit card purchasing agreement utilized to facilitate employee travel and certain ordinary purchases. The restricted balance as of September 30, 2009 was $0.

Marketable securities

The Company's marketable securities were classified as available-for-sale and were reported at market value with unrealized gains and losses shown as a component of accumulated other comprehensive income (loss). The Company regularly evaluates the performance of these investments individually for impairment, taking into consideration the investment, volatility and current returns. If a determination is made that a decline in fair value is other-than-temporary, the related investments are written down to its estimated fair value. At September 30, 2009 and 2010, marketable securities total $0 and $6,001, respectively. Due to the short-term need for funds and uncertainty in the credit and financial markets, the Company modified its investment strategy and primarily invested in money market accounts comprised of treasury securities.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, accounts payable, and accrued expenses approximate their fair values due to their short term maturities.

Pre-Launch Inventory

Inventory costs associated with products that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then costs associated with pre-launch inventory that has not yet received regulatory approval are expensed as research and development expense during the period the costs are incurred. For the year ended September 30, 2010, the Company expensed $4.5 million of costs associated with the purchase of recombinant human insulin, as research and development expense after it passed quality control inspection by the Company and transfer of title occurred. In November 2010, the Company announced that the U.S. Food and Drug Administration ("FDA") issued a complete response letter requesting additional information regarding its New Drug Application ("NDA") for Linjeta™. The complete response letter stated that the FDA's review cycle was complete and that the application could not be approved in its present form. At this time, the Company will continue to expense pre-launch inventory as research and development. The pre-launch inventory treatment will be reevaluated if the Company completes Phase 3 clinical trials of Linjeta™ or if an alternate product candidate for which the inventory is applicable and files a related NDA or NDA supplement for review by the FDA (see Note 8)

Intellectual Property

Intangible assets consist primarily of capitalized costs associated with Linjeta™ patents and the purchase of two domain addresses. They are amortized using the straight-line method over twenty years. If the Company determines that a patent will not result in future revenues, the cost related to such patent will be expensed in full on the date of that determination. Intellectual property amortization expense for the years ended September 30, 2008, 2009 and 2010 was $13, $3 and $3, respectively.

Biodel Inc.
(A Development Stage Company)

Notes to Financial Statement — (Continued)
(In thousands, except share and per share amounts)

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation or amortization. Major improvements are capitalized, while maintenance and repairs are expensed in the period the cost is incurred. Property and equipment are depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are amortized using the straight-line method over their estimated useful lives, or the remaining term of the lease, whichever is shorter. When assets are retired or otherwise disposed of, the assets and related accumulated depreciation are removed from the accounts and resulting gains or losses are included in other income (expense) in the statement of operations. Estimated useful lives for each asset category are as follows: Furniture and fixtures — 7 years, Leasehold improvements — estimated useful life or remaining term of lease, whichever is shorter, Laboratory equipment — 7 years, Manufacturing equipment — 5 years, Device development— 5 years, Facility equipment— 3 years and 7 years, Computer equipment — 5 years and Computer software — 3 years.

Impairment of Long-Lived Assets

Whenever events or changes in circumstances indicate that the carrying amounts of a long-lived asset may not be recoverable, the Company reviews these assets for impairment and determines whether adjustments are needed to carrying values. There were no adjustments to the carrying value of long-lived assets at September 30, 2009 and 2010.

Warrant Liability

The Company applies the provisions of FSP 150-5, Issuers Accounting under FASB Statement No. 150 for Freestanding Warrants and other Similar Instruments on Shares that are Redeemable or ASC 480 Distinguishing Liabilities from Equities ("ASC 480"). Pursuant to FASB SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity, a freestanding financial instrument (other than outstanding share) that, at inception, embodies an obligation to repurchase the issuer's shares and "requires or may require" the obligation to be settled by transferring assets, qualifies as a liability (if the obligation is conditional, the number of conditions is irrelevant). The Company issued warrants in August 2010 and recorded an amount of $2,915 for the initial fair value of the warrant liability. As of September 30, 2010, the Company recorded a charge of $1,254 to reflect the increase in the estimated fair value of the warrants determined by the Monte Carlo simulation method. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of future expected stock prices of the Company and its peer group and minimizes standard error. These warrants will be revalued each reporting period and any increase or decrease will be recorded to the statement of operations under the caption of "Adjustment to fair value of common stock warrant liability." (See Note 10).

Comprehensive Income (Loss)

Comprehensive Loss is comprised of net loss and changes in equity for unrealized holding gains (losses) on marketable securities during the period. For the years ended September 30, 2008, 2009 and 2010, the Company had $(43,423), $(43,208) and $(38,289) of comprehensive loss.

Income Taxes

The Company uses the asset and liability method of accounting for deferred income taxes. The provision for income taxes includes income taxes currently payable and those deferred as a result of temporary differences between the financial statement and tax bases of assets and liabilities. A valuation allowance is

provided to reduce deferred tax assets to the amount of future tax benefit when it is more likely than not that some portion of the deferred tax assets will not be realized. Projected future taxable income and ongoing tax planning strategies are considered and evaluated when assessing the need for a valuation allowance. Any increase or decrease in a valuation allowance could have a material adverse or beneficial impact on the Company's income tax provision and net income or loss in the period which the determination is made.

The Company adopted the provisions of Accounting Standards Codification (ASC) Topic 740, Income Taxes, with respect to uncertain tax positions (substantially incorporating the Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes, or FIN 48) effective October 1, 2007. These provisions clarify the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. Recognition thresholds and measurement attributes were prescribed for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Guidance was also provided on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. The adoption had no resulting effect on the Company's financial statements. See Note 9 for additional information.

Concentration of Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes that its investment policy guideline for its excess cash maintains safety and liquidity through its policies on credit requirements, diversification and investment maturity.

The Company has experienced significant operating losses since inception. At September 30, 2010, the Company had a deficit accumulated during the development stage of $164,754. The Company has generated no revenue to date. The Company has funded its operations to date principally from the sale of securities. The Company expects to incur substantial additional operating losses for the next several years and will need to obtain additional financing in order to complete the clinical development of Linjeta™ or another rapid-acting insulin or insulin analog, launch and commercialize the product if it receives regulatory approval, and continue research and development programs. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

The Company is currently developing its first product candidates and has no products that have received regulatory approval. Any products developed by the Company will require approval from the U.S. Food and Drug Administration ("FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's products will receive the necessary approvals. If the Company is denied such approvals or such approvals are delayed, it would have a material adverse effect on the Company's future operating results.

To achieve profitable operations, the Company must successfully develop, test, manufacture and market products, as well as secure the necessary regulatory approvals. There can be no assurance that any such products can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed. These factors would have a material adverse effect on the Company's future financial results.

Share-Based Compensation

In March 2010, the shareholders of the Company approved a new 2010 Stock Incentive Plan (the "2010 Plan"). Up to 5,400,000 shares of the Company's common stock may be issued pursuant to awards granted

(In thousands, except share and per share amounts)

under the 2010 Plan, plus shares of common stock underlying already outstanding awards under the Company's prior plans. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.6 shares for each one share of common stock. The Company has not made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by the Company's stockholders. The Company will continue to use the Black-Scholes pricing model to assist in the calculation of fair value. The expected life for grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110. The simplified method was chosen due to limited Company history. Until the Company has adequate history, it will continue to utilize the simplified method.

The Company recognizes share-based compensation arising from compensatory share-based transactions using the fair value at the grant date of the award. Determining the fair value of share-based awards at the grant date requires judgment. The Company uses an option-pricing model (the Black-Scholes valuation model) to assist in the calculation of fair value. Due to its limited history, the Company uses the "calculated value method" which relies on comparable company historical volatility and uses the average of (1) the weighted average vesting period and (2) the contractual life of the option, or seven or eight years, as the estimated term of the option. The Company bases its estimates of expected volatility on the median historical volatility of a group of publicly traded companies that it believes are comparable to the Company based on the line of business, stage of development, size and financial leverage.

The risk-free rate of interest for periods within the contractual life of the stock option award is based on the yield of U.S. Treasury strips on the date the award is granted with a maturity equal to the expected term of the award. The Company estimates forfeitures based on actual forfeitures during its limited history. Additionally, the Company has assumed that dividends will not be paid.

For stock options granted to non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes valuation model, if that value is more reliably measurable than the fair value of the consideration or service received. The fair value of these instruments is periodically revalued as the options vest, and is recognized as expense over the related period of service or vesting period, whichever is longer. The total cost expensed for options granted to non-employees for the years ended September 30, 2008, 2009 and 2010 was $241, $94, and $(7) respectively.

The Company expenses ratably over the vesting period the cost of the stock options granted to employees and directors. The total compensation cost for the years ended September 30, 2008, 2009 and 2010 was $6,434, $4,970, and $5,628 respectively. At September 30, 2010, the total compensation cost related to non-vested options not yet recognized was $7,585, which will be recognized over the next three years assuming the employees complete their service period for vesting of the options. The Black-Scholes valuation model assumptions are as follows and were determined as discussed above:

	Year Ended September 30,		
	2008	2009	2010
Expected life (in years)	5.25	5.25	2.72 - 5.25
Expected volatility	57 - 60%	59 - 68%	64 - 77%
Expected dividend yield	0%	0%	0%
Risk-free interest rate	2.36% - 4.42%	1.00% - 3.19%	0.77 - 2.69%
Weighted-average grant date fair value	$ 13.92	$ 2.69	$ 4.09

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Subsequent Events

In February 2010, the Company adopted the updated authoritative guidance regarding the reporting of subsequent events, removing the requirement for an issuer to disclose a date through which subsequent events have been evaluated. The guidance was effective upon issuance in February 2010 and was adopted as of the Company's Report on Form 10-Q for the three months ended March, 31, 2010 as filed with the SEC on May 7, 2010. The adoption of this guidance did not have a material impact on the Company's financial statements.

Fair Value Measurement

Effective October 1, 2009, the Company adopted the provisions of ASU 2009-5 Fair Value and Disclosures (Topic 820) Measuring Liabilities at Fair Value ("ASU 2009-5"). ASU 2009-5 provides amendments to Subtopic 820-10, Fair Value Measurements and Disclosures-Overall, for the fair value measurement of liabilities. ASU 2009-5 clarifies that in circumstances in which a quoted price in an active market for the identical liability is not available; a reporting entity is required to measure fair value. The adoption of this accounting pronouncement did not have a material effect on the Company's financial statements.

Participating Securities

In June 2008 the Financial Accounting Standards Board ("FASB") issued ASC 260-10-55 Earnings Per Share — Overall (formerly Financial Statement Position Emerging Issues Task Force 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities) ("ASC 260-10-55"). ASC 260-10-55 provides that securities and unvested share-based payment awards that contain non-forfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method.

Warrant Liability — Given that the warrant holders will participate fully on any dividends or dividend equivalents, the Company determined that the warrants are participating securities and therefore are subject to ASC 260-10-55. These securities were excluded from the per share calculation for the year ended September 30, 2010 since their inclusion would be anti-dilutive.

Share-based Compensation — Given that the holders of Restricted Stock Unit awards ("RSUs") will only receive dividends or dividend equivalents on RSUs that have vested prior to the Company declaring dividends as well as forfeiting their rights to receive dividends or dividend equivalents on any unvested portion, the Company determined that the RSUs are non-participating securities and therefore are not subject to ASC 260-10-55.

Codification Standard

During the fourth quarter of 2009, the Company adopted the FASB Accounting Standards Update ("ASU") No. 2009-01, "Amendments based on Statement of Financial Accounting Standards No. 168 — The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" (the "Codification"). The Codification became the single source of authoritative GAAP in the United States, and other than rules and interpretive releases issued by the United States Securities and Exchange Commission. The Codification reorganized GAAP into a topical format that eliminates the previous GAAP hierarchy and instead established two levels of guidance — authoritative and non-authoritative. All non-grandfathered, non-Securities and Exchange Commission accounting literature that was not included in the Codification became non-authoritative. The adoption of the Codification did not change previous GAAP, but rather simplified user access to all authoritative literature related to a particular accounting topic in one place. Accordingly, the adoption had no impact on the Company's consolidated financial position and results of

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operations. All prior references to previous GAAP in the Company's consolidated financial statements were updated for the new references under the Codification.

Recent Accounting Pronouncements

In January 2010, the FASB issued authoritative guidance that requires new disclosures and clarifies certain existing disclosure requirements about fair value measurements. The new guidance requires a reporting entity to disclose significant transfers in and out of Level 1 and Level 2 fair value measurements, to describe the reasons for the transfers and to present separately information about purchases, sales, issuances and settlements for fair value measurements using significant unobservable inputs. The guidance is effective on a prospective basis for periods beginning after December 15, 2010. The Company anticipates that the adoption of this guidance will not have a material impact on its financial statements in future periods.

3. Marketable Securities

The Company classifies marketable securities as available — for- sale. The Company determines the appropriate classification of debt and equity securities at the time of purchase and re-evaluates such designation as of each balance sheet date.

The Company invests in certain marketable securities, which consist primarily of short-to-intermediate-term debt securities issued by the U.S. government, U.S. government agencies and municipalities and investment grade corporate securities. The Company only invests in marketable securities with active secondary or resale markets to ensure portfolio liquidity and the ability to readily convert investments into cash to fund current operations, or satisfy other cash requirements as needed. Due to the nature of the Company as a development stage company and its funding needs at times being uncertain, the Company has classified all marketable securities as available-for-sale. The unrealized gains and losses on these securities are included in accumulated other comprehensive income as a separate component of stockholders' equity. The specific-identification method is used to determine the cost of a security sold or the amount reclassified from accumulated other comprehensive income into earnings.

Marketable securities classified as available for sale are measured at fair value based on quoted market prices. The amortized cost, gross unrealized gains and losses and fair value of investment securities at September 30, 2010 are summarized below. As of September 30, 2009, the Company had no marketable security investments.

	September 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short term marketable securities				
US government agency securities	$ 6,000	$ 1	$ —	$6,001
Total	$ 6,000	$ 1	$ —	$6,001

4. Fair Value Measurement

ASC Topic 820 ("ASC 820", originally issued as SFAS No. 157, Fair Value Measurements) applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, ASC 820 does not require any new fair value measurements. The fair value framework requires the

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categorization of assets and liabilities into three levels based upon the assumptions (inputs) used to price the assets or liabilities. The three levels of inputs used are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

As of September 30, 2010, the Company had assets and liabilities that fell under the scope of ASC 820. The fair values of the marketable securities were based on quoted market prices. The fair value of the warrant liability was determined by the Monte Carlo simulation method. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of future expected stock prices of the Company and its peer group and minimizes standard error. Accordingly, the Company's fair value measurements of the Company's marketable securities are classified as a Level 1 input and the warrant liability as a Level 3 input.

The fair value of the Company's financial assets and liabilities carried at fair value and measured on a recurring basis are as follows:

Description	Fair Value at September 30, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Market Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 22,922	$ 22,922	$ —	$ —
Restricted cash	150	150	—	—
Marketable securities:				
US government agency securities (short-term securities)	6,001	6,001	—	—
Subtotal	29,073	29,073	—	—
Liabilities:				
Common stock warrant liability	(4,169)	—	—	(4,169)
Subtotal	(4,169)	—	—	(4,169)
Total	$ 24,904	$ 29,073	$ —	$ (4,169)

As of September 30, 2010, the Company classifies all the marketable securities with original maturities of three months or less at the date of purchase as cash equivalents.

5. Net Loss per Share

Net loss per share information is determined using the two-class method, which includes the weighted-average number of common shares outstanding during the period and other securities that participate in dividends ("participating securities"). The Company considers the outstanding warrants participating securities

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because they include rights to participate in dividends with the common stock on a one for one basis. In applying the two-class method, earnings are allocated to both common stock shares and warrants based on their respective weighted-average shares outstanding for the period. Since losses are not allocated to the participating securities, the two-class method results in the same loss per common share calculated using the basic method for the periods presented in these financial statements.

Basic and diluted net loss per share has been calculated by dividing net loss by the weighted average number of common shares outstanding during the period. All potentially dilutive common shares have been excluded from the calculation of weighted average common shares outstanding since their inclusion would be anti-dilutive.

The amount of options and warrants excluded are as follows:

	Year Ended September 30,		
	2008	2009	2010
Common shares underlying warrants for Series A Preferred Stock	118,815	118,815	118,815
Common shares underlying warrants issued in registered direct offering	—	—	2,398,200
Stock options	3,135,390	3,407,633	4,635,532

6. Property and Equipment

Property and equipment consists of the following:

	September 30,	
	2009	2010
Furniture and fixtures	$ 318	$ 324
Leasehold improvements	1,549	1,549
Construction-in-progress	15	63
Laboratory equipment	1,612	1,756
Manufacturing equipment	529	587
Facility equipment	50	65
Computer equipment and other	1,270	1,291
Sub-Total	5,343	5,635
Less: Accumulated depreciation and amortization	1,648	2,637
Total	$3,695	$2,998

Depreciation expense for the years ended September 30, 2008, 2009 and 2010 was $554, $874 and $989, respectively.

7. Related Party Transactions

The following is a description of material transactions, other than compensation arrangements, since the Company's incorporation on December 3, 2003 to which the Company has been a party and in which any of its directors, executive officers or persons who it knows held more than five percent of any class of capital stock, including their immediate family members who had or will have a direct or indirect material interest. The Company believes that the terms obtained or consideration paid or received, as applicable, in connection

with the transactions described below were comparable to terms available or the amounts that would have been paid or received, as applicable, in arm's-length transactions.

Consulting and Clinical Research Services

Dr. Andreas Pfützner served as the Company's Chief Medical Officer in Europe until December 2008. During the fiscal year ended September 30, 2008, we paid Dr. Pfützner $386 in connection with his services in this capacity. Dr. Pfützner continues to perform consulting services for us from time to time, and during the fiscal years ended September 30, 2009 and 2010, we paid Dr. Pfützner $150 and $50, respectively, in consulting fees. During the fiscal years ended September 30, 2008, 2009 and 2010, we paid approximately $2,710, $1,419 and $867, respectively, in clinical related costs to the Institute for Clinical Research and Development in Mainz, Germany, where Dr. Pfützner serves as its managing director. Dr. Pfützner is majority owner of the institute together with his spouse. In July 2007, Steiner Ventures, LLC loaned Dr. Pfützner approximately $200. As of September 30, 2010, the remaining balance on the loan was approximately $89. Our Chief Scientific Officer, Dr. Solomon Steiner, is the sole managing member of Steiner Ventures, LLC. Dr. Steiner and his spouse jointly own 54% of Steiner Ventures, LLC, with the balance split equally among their four adult children, including Erik Steiner. Erik Steiner is our Vice President, Operations.

Issuance of Series A Convertible Preferred Stock

Between March and July 2005, the Company issued and sold an aggregate of 35,000 shares of its Series A convertible preferred stock (see Note 9) to two executive officers and one director.

McGinnSmith & Company, Inc. ("MSI") served as placement agent in connection with the offering of the Series A convertible preferred stock pursuant to a letter agreement (the "Letter Agreement"), for which MSI received $280 (excluding $15 reimbursement for expenses) and warrants to purchase 55,900 shares of Series A convertible preferred stock at $5.00 per share. The fair value of the warrants was $121 and was computed using the Black-Scholes valuation model using the following assumptions: term of 7 years; volatility rate of 90%; risk free rate of 3.65% and a dividend yield of 0.0%, which was treated as cost of raising capital. A member of the Board of Directors of the Company was a managing director of MSI until May 2007.

In July 2005, Steiner Ventures LLC, ("SV"), an entity controlled by Dr. Solomon S. Steiner, Chief Scientific Officer, entered into a subscription agreement with the Company to purchase 60,000 shares of the Series A convertible preferred stock at a price of $5.00 per share which could be accepted by the Company at any time until July 2006. At a meeting of the Board of Directors held on October 24, 2005, the Board of Directors approved, with the agreement of SV, the amendment of that subscription agreement into a subscription to purchase 12 Units in the Bridge Financing for $300. The Company accepted this subscription and SV purchased the Units.

Since all securities contemplated to be issued pursuant to the SV subscription agreement were to be issued at fair value, no value was ascribed to the subscription agreement or amendment.

Bridge Financing

Between February and May 2006, the Company completed a Bridge Financing (see Note 11). Four executive officers and one director purchased an aggregate of 23 units, or $575, as part of the financing. These units were subsequently settled with 182,540 shares of Series B convertible preferred stock and warrants to purchase 98,275 shares of common stock.

In connection with the sales of units in the Bridge Financing, the Company paid MSI an aggregate commission of $70 and issued to MSI additional warrants to purchase 22,222 shares of Series B convertible

preferred stock and a warrant to purchase 11,963 shares of common stock. The fair value of the warrants was $22 as computed using the Black-Scholes valuation model using the following assumptions: term of 3.5 years; volatility rate of 50%; risk free rate of 5.05% and a dividend yield of 0.0%.

Issuance of Series B Convertible Preferred Stock

On July 19, 2006, the Company issued and sold 38,071 shares of Series B convertible preferred stock (see Note 11) and a warrant to purchase 20,496 shares of common stock to its Chief Executive Officer in exchange for a $150 bonus that was earned by him during the calendar year ended December 31, 2005 but voluntarily deferred. At September 30, 2005, the Company accrued $113 of the bonus and the balance of $37 was expensed in fiscal 2006. The full amount of the accrued bonus was exchanged for Series B convertible preferred stock on July 19, 2006.

In connection with the issuance of the Series B convertible preferred stock, the Company retained MSI to serve as placement agent pursuant to an amendment to the Letter Agreement. MSI was paid (a) an aggregate commission of $350 from the sale of the Series B convertible preferred stock, (b) a warrant to purchase 126,903 shares of Series B convertible preferred stock and (c) a warrant to purchase 68,322 shares of common stock. On July 19, 2006, the Company also sold and issued to a director 12,690 shares of Series B convertible preferred stock and a warrant to purchase 6,832 shares of common stock. At the completion of the Series B preferred stock financing, the lead investor remitted the monies for its investment in the Series B Round net of offering-related expenses incurred by the investor group for which the Company was responsible. Total offering expenses were approximately $2,000, of which $1,470 was commissions for the placement of the offering. A director of the Company had arranged to pay for an investment in the Series B preferred stock financing (the "Investment") utilizing a portion of commissions due. Since the monies due for the commission were not received by the Company, the purchase price of the Investment could not be deducted from the monies received. The fair values of the warrants for common stock were $126 and $13 and were computed using the Black-Scholes valuation model using the following assumptions: term of 3.5 years; volatility rate of 50%; risk free rate of 5.05% and a dividend yield of 0.0%. The fair value of the warrants for preferred stock was $167 and was computed using the Black-Scholes valuation model using the following assumptions: term of 3.5 years; volatility rate of 50%; risk free rate of 4.70% and a dividend yield of 0.0%. These amounts were treated as cost of raising capital.

Deferred Compensation

On December 15, 2005, the Board of Directors authorized a bonus to be paid to SV, if the Chairman and Chief Executive Officer directed the completion of a successful financing in excess of $10,000. Pursuant to that board resolution, the Company owed SV $250 because of the issuance of the Series B convertible preferred stock during the year ended September 30, 2006 but payment was deferred by Dr. Steiner. The Company recorded compensation expense for this bonus and had reflected the balance as due to related party at September 30, 2006. The balance was paid in July 2007.

Separately, Dr. Steiner voluntarily deferred his calendar year compensation of $250. The Company recorded compensation expense for this salary and had reflected the balance as deferred compensation at September 30, 2006. The balance was paid in July 2007.

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8. Commitments

Chief Executive Officer Employment Agreement

On March 30, 2010, the Company announced the appointment of Errol B. De Souza, Ph.D., as the Company's President, Chief Executive Officer and a Director. In connection with his appointment, Dr. De Souza signed an employment agreement, dated March 26, 2010, setting forth the terms of his employment. The agreement provides for an initial term of employment for the period from March 29, 2010 to March 28, 2014 and it continues for successive one-year terms unless the agreement is terminated by either party on 120 days prior written notice in accordance with the terms of the agreement. The agreement provides for an annual salary of $450 and eligibility for a target bonus of 50% of the annual salary. In addition, Dr. De Souza was granted options to purchase 700,000 shares of the Company's common stock pursuant to the Company's 2010 Plan. These options will vest over a four-year period, with 25% vesting on the first anniversary of the grant date and the rest vesting in equal monthly amounts over the next three years. The Company will pay Dr. De Souza reasonable and documented temporary housing and related expenses of up to $5 per month for a period of up to 18 months following the date of the agreement.

The Company may terminate the agreement with or without cause. Dr. De Souza will not be entitled to severance benefits if the Company terminates his employment for cause, or if he terminates his employment without good reason, as defined in the agreement. If the Company terminates Dr. De Souza's employment without cause, or he terminates his employment with the Company for good reason, he is entitled to:

- two times his then current salary, plus two times his target annual bonus for the fiscal year in which he is terminated, plus the pro rata amount of his target annual bonus for the fiscal year in which he is terminated;
- COBRA benefits until the earlier of the end of the 24th month after the date his employment with the Company ends or the date his COBRA coverage expires;
- 24 months of acceleration of his outstanding equity compensation awards; and
- full vesting of his outstanding equity compensation awards, if the Company terminates his employment without cause, or he resigns within 12 months following a change in control, as defined in the agreement.

Chief Scientific Officer Employment Agreement

On March 30, 2010, the Company announced the appointment of Dr. Solomon S. Steiner, the Company's former Chairman, President and Chief Executive Officer, as the Company's Chief Scientific Officer and a Director. In connection with his appointment, Dr. Steiner signed an employment agreement, dated March 26, 2010, setting forth the terms of his employment. The agreement provides for at-will employment, meaning that the Company or Dr. Steiner can terminate his employment at any time, for any or no reason, subject to the terms of the agreement. The agreement provides for an annual salary of $400 and eligibility for a target bonus of 50% of the annual salary.

The Company may terminate the agreement with or without cause. Dr. Steiner will not be entitled to severance benefits if the Company terminates his employment for cause, as defined in the agreement. If the Company terminates Dr. Steiner's employment without cause or he resigns for any reason, he is entitled to:

- two times his then current salary, plus two times his target annual bonus for the fiscal year in which he is terminated, plus the pro rata amount of his target annual bonus for the fiscal year in which he is terminated;

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- COBRA benefits until the earlier of the end of the 24th month after the date his employment with the Company ends or the date his COBRA coverage expires;
- 24 months of acceleration of his outstanding equity compensation awards; and
- full vesting of his outstanding equity compensation awards, if the Company terminates his employment without cause, or he resigns within 12 months following a change in control, as defined in the agreement.

Leases

As of September 30, 2010, the Company leased three facilities in Danbury, Connecticut with Mulvaney Properties, LLC, which is controlled by a non-affiliated stockholder of the Company.

The Company entered into its first lease for laboratory space in February 2004, which was renewed in January 2010 for an additional three years. The lease will expire in January 2013. This lease provides for annual basic lease payments of $65, plus operating expenses.

In July 2007, the Company entered into a second lease for its corporate office, which was subsequently amended in October 2007. The October 2007 amendment increased the term from five years to seven years beginning on August 1, 2007 and ending on July 31, 2014. The renewal option was also amended from a five year to a seven year term. This lease provides for annual basic lease payments of $357, plus operating expenses.

In December 2008, the Company entered into a third lease agreement for additional office space adjacent to its laboratory space, which was renewed in January 2010 for an additional three years. The Company has agreed to use the leased premises only for offices, laboratories, research, development and light manufacturing. This lease provides for annual basic lease payments of $29, plus operating expenses.

Lease expense for the years ended September 2008, 2009, and 2010 was $383, $591, and $624, respectively.

Minimum lease payments under these agreements as of September 30, 2010, as well as equipment leases subsequently entered into, are as follows:

Years Ending September 30,	
2011	635
2012	662
2013	588
2014	462
Total	$2,347

Purchase Commitments

The Company contracted with N.V. Organon, a global producer of insulin, to supply the Company with all of the insulin that the Company will need for testing and manufacturing of the Company's product candidates. As subsequently amended in November 2009, the agreement with N.V. Organon will terminate in December 2011. As of September 30, 2010, the Company had purchase commitments of approximately $6,740 associated with the signing of a renewed contract with N.V. Organon.

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Years Ending September 30,	
2011	$4,155
2012	2,585
Total	$6,740

9. Income Taxes

Effective October 1, 2007, the Company adopted the provisions of FIN 48, which was incorporated into the Codification within ASC Topic 740, Income Taxes, with respect to uncertain tax positions. The Company did not recognize any increase or decrease in the liability for unrecognized tax benefits related to tax positions taken in prior periods as a result of the adoption, therefore, there was no corresponding adjustment to retained earnings.

The Company did not have any liabilities for unrecognized tax positions as of October 1, 2007 (adoption date). During the year ended September 30, 2009, the Company performed a review on the research and development activities that occurred in the state of Connecticut that support the Connecticut research and development credits and refunds. The results of that study decreased income tax receivable and the corresponding reserve relating to an anticipated tax refund from the state of Connecticut for research and development activities. For the year-ended September 30, 2010, this resulted in a 1% decrease to the Company's effective tax rate. The reserve does not include interest or penalties based on the nature of the liability. The Company plans to treat any future interest or penalties as operating expense.

The following table summarized the activity related to the Company's liabilities for uncertain tax positions:

	Year Ended September 30,		
	2008	2009	2010
Balance, beginning of year	$ 75	$ 988	$ 188
Increase related to current year tax position	913	6	5
Increase related to prior year's tax position	—	107	
Decrease related to prior year's tax position	—	(913)	(107)
Balance, at end of year	$988	$ 188	$ 86

The Company files U.S. federal and state tax returns and has determined that its major tax jurisdictions are the United States and Connecticut. The tax years through 2010 remain open due to net operating loss carryovers and are subject to examination by the appropriate governmental agencies in the United States and Connecticut.

The provision (benefit) for income taxes is as follows:

	Year Ended September 30,		
	2008	2009	2010
Current expense			
Federal	$ —	$ —	$ —
State	(983)	337	(104)
Actual tax provision (benefit)	$(983)	$337	$(104)

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As of September 30, 2010, the Company had net operating loss carryforwards of approximately $114,800 (net of Section 382 limitation discussed below) for U.S. federal tax purposes and $132,200 for state tax purposes. These loss carryforwards expire between 2024 and 2030. To the extent these net operating loss carryforwards are available, the Company intends to use them to reduce the corporate income tax liability associated with its operations. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. The Company performed a preliminary Section 382 analysis in connection with the registered direct offering that it completed in August 2010. The sale of common stock in the August 24, 2010 offering (Note 10) created an ownership change under Section 382. The Company believes that approximately $18,300 of the $133,100 federal losses (prior to the Section 382 limitation) will expire unused due to Section 382 limitations. The maximum annual limitation under Section 382 is approximately $9,400 for the first five (5) years and then decreases to $4,300 for the remaining fifteen (15) years. The limitation could be further restricted if ownership changes occur in future years. To the extent the Company's use of net operating loss carryforwards is limited, future income could be subject to corporate income tax earlier than it would if the Company was able to use net operating loss carryforwards, which could result in decreased net income.

The Company also has federal and state research and development credit carryovers of approximately $2,800, which expire commencing in fiscal 2025.

The major components of deferred tax assets and valuation allowances and deferred tax liabilities at September 30, 2009 and 2010 are as follows:

	September 30,	
	2009	2010
Deferred Tax Assets		
Net operating losses	$ 39,959	$ 46,917
Research and development credits	2,149	2,800
Depreciation of fixed assets	284	166
Other	802	176
Total deferred tax asset	43,195	50,059
Valuation Allowance	(43,195)	(50,059)
Net Deferred Tax Assets	$ —	$ —

The Company files its tax returns on a fiscal year basis. For the years ended September 30, 2008, 2009 and 2010, the Company paid only state taxes.

As the Company has not yet achieved profitable operations, management does not believe that it is more likely than not that the tax benefits as of September 30, 2010 will be realized and therefore has recorded a valuation allowance against its deferred tax assets.

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The following reconciles the amount of tax expense at the federal statutory rate to the tax provision (benefit) in operations:

	Year Ended September 30,		
	2008	2009	2010
Federal statutory rate	34.00%	34.00%	34.00%
Federal taxes at statutory rate	$ (15,077)	$ (14,597)	$ (13,054)
Tax expense on permanent differences	2,293	1,741	2,296
Tax benefit on research and business credits	(325)	(325)	(425)
State taxes, net of federal tax effect	61	43	23
State benefit, net operating loss	(2,784)	(1,249)	(2,990)
Valuation allowance increase	14,972	14,432	14,156
Connecticut research and development refund	(1,988)	(40)	(30)
Reserve for uncertain tax positions	913	6	4
Other	952	326	84
Actual tax provision (benefits)	$ (983)	$ 337	$ (104)

10. August 2010 Financing

On August 24, 2010, the Company sold to two institutional investors an aggregate of 2,398,200 units, with each unit consisting of (i) one share of common stock and (ii) one warrant to purchase one share of common stock, for a purchase price of $3.93 per unit. These units were not issued nor certificated. The shares and warrants were immediately separated and the Company issued 2,398,200 shares of its common stock and warrants to purchase an additional 2,398,200 shares of the Company's common stock at an initial exercise price of $4.716 per share, subject to re-pricing following the Company's receipt of the complete response letter for Linjeta™. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share as per the terms of the warrant and agreement. These warrants will expire on December 1, 2011, one year and 21 trading days following the Company's receipt of the FDA's complete response letter for Linjeta™. This financing resulted in gross proceeds of $9,400.

The warrants are exercisable at any time on or after the date of issuance and expire on November 30, 2011. Pursuant to the terms of the warrants, the exercise price per share for the warrants is $1.56, which is equal to the dollar volume weighted-average price of the Company's common stock for the ten trading days immediately preceding December 1, 2010. Additionally, until expiration, the exercise price shall be adjusted from time to time. If and whenever the Company issues or sells, or is deemed to issue or sell, any shares of common stock less than a price equal to the exercise price in effect immediately prior to such issue or sale or deemed issuance or sale, then immediately after such dilutive issuance, the exercise price then in effect shall be reduced to an amount equal to the new issuance price. There will be no adjustment to the number of warrants acquirable upon exercise of the warrants in connection with an adjustment to the exercise price.

In the event that the Company enters into a merger or change of control transaction, the holders of the warrants will be entitled to receive consideration as if they had exercised the warrant immediately prior to such transaction, or they may require the Company to purchase the warrant at the Black-Scholes value of the warrant on the date of such transaction. As per the warrants, the holders have up to 30 days following any such transaction to exercise this clause.

The Company's warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other Expense ("Adjustments to fair value of common stock warrant

(In thousands, except share and per share amounts)

liability"), until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument. The fair value of the warrant liability is determined at each reporting period by utilizing the Monte Carlo simulation model that takes into account estimated probabilities of possible outcomes provided by the Company. At the date of the transaction, the fair value of the warrant liability was $2,915 utilizing the Monte Carlo simulation method. The Monte Carlo simulation is a generally accepted statistical technique used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of future expected stock prices of the Company and its peer group and minimizes standard error.

At September 30, 2010, the fair value of the warrant liability determined utilizing the Monte Carlo simulation method was approximately $4,169. The increase in the fair value of the warrants from August 24, 2010 to September 30, 2010 mainly reflects the increase in the value of the Company's common stock price subsequent to the August 24, 2010 issuance of the warrants.

During the year ended September 30, 2010, the Company recorded a charge of $1,254 to Adjustment to fair value of common stock warrant liability, within Other income (expense), to reflect the increase in the valuation of the warrants.

The following summarizes the changes in value of the warrant liability from the date of issuance through September 30, 2010:

Balance at September 30, 2009	$ —
Initial fair value	2,915
Increase in fair value	1,254
Balance at September 30, 2010	$4,169

Fair Value Assumptions Used in Accounting for Warrant Liability

The Company has determined its warrant liability to be a Level 3 fair value measurement and used the Monte Carlo simulation approach to calculate the fair value for the fiscal year ended September 30, 2010.

At these measurement dates, the Company estimates the fair value of these securities using the Monte Carlo simulation approach, using critical assumptions provided by management reflecting conditions at the valuation dates.

Fair values at measurement dates during the fiscal year ended September 30, 2010 were estimated using the following assumptions:

	September 30, 2010
Risk-free interest rate	.25%
Expected remaining term	1.17 years
Expected volatility	100%
Dividend yield	0%

Risk-Free Interest Rate. This is the United States Treasury rate for the measurement date having a term equal to the expected remaining term of the warrant. An increase in the risk-free interest rate will increase the fair value and the associated derivative liability.

Expected Remaining Term. This is the period of time over which the warrant is expected to remain outstanding and is based on management's estimate, taking into consideration the remaining contractual life,

and historical experience. An increase in the expected remaining term will increase the fair value and the associated derivative liability.

Expected Volatility. This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. Since the Company's stock has not been traded for as long as the expected remaining term of the warrants, the Company uses a weighted-average of the historic volatility of four comparable companies over the retrospective period corresponding to the expected remaining term of the warrants on the measurement date. Extra weighting is attached to those companies most similar in terms of size and business activity. An increase in the expected volatility will increase the fair value and the associated derivative liability.

Dividend Yield. The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease the fair value and the associated derivative liability.

Change of Control. The Monte Carlo simulation incorporates the probability that the Company effects a change of control. The Company estimated a 15% probability for a change of control.

Participating Securities

If at any time the Company grants, issues or sells securities or other property to holders of any class of common stock the holders of the warrants are entitled to also acquire those same securities as if they held the number of shares of common stock acquirable upon complete exercise of the warrants.

As such, given that the warrant holders will participate fully on any dividends or dividend equivalents, the Company determined that the warrants are participating securities and therefore are subject to ASC 260-10-55 earnings per share. These securities were excluded from the year ended September 30, 2010 earnings per share calculation since their inclusion would be anti-dilutive.

11. Stockholders' Equity

Common Stock

The Company's authorized common stock consists of 100,000,000 shares of a single class of common stock, having a par value of $0.01 per share. The holders of the common stock are entitled to one vote for each share and have no cumulative voting rights or preemptive rights.

As of September 30, 2010, the Company had warrants outstanding to purchase an aggregate of 118,815 shares of its common stock with an exercise price of $1.41 per share and 2,398,200 shares of its common stock with an initial exercise price of $4.716 per share subject to re-pricing. Subsequently, on December 1, 2010, the exercise price of the warrants was re-set to $1.56 per share, as per the terms of the warrants.

On February 12, 2008, the Company completed a follow-on public offering of 3,260,000 shares of its common stock at a price to the public of $15.50 per share. The Company received net proceeds from this offering, after deducting underwriting discounts and commissions and expenses, of $46,817. Certain of the Company's stockholders sold 550,000 shares in the offering. The Company did not receive any proceeds from the sale of shares from the selling stockholders.

On May 16, 2007, the Company completed an initial public offering of 5,750,000 shares of its common stock at a price to the public of $15.00 per share. The offering resulted in gross proceeds of $86,300. The Company received net proceeds from the offering of approximately $78,800 after deducting underwriting

discounts and commissions and additional offering expenses. The completion of the initial public offering resulted in the conversion of the Company's Series A and B convertible preferred stock. A total of 6,407,008 shares of common stock were issued upon the conversion of the preferred stock.

Preferred Stock

The Company is authorized to issue up to 50,000,000 shares of preferred stock, having a par value of $0.01 per share. The Company's preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by the Company's Board of Directors, without further action by stockholders, and may include voting rights (including the right to vote as a series on particular matters), preferences as to dividends and liquidation and conversion, redemption rights and sinking fund provisions. The issuance of preferred stock could reduce the rights, including voting rights, of the holders of common stock and, therefore, could reduce the value of the common stock. In particular, specific rights granted to holders of preferred stock could be used to restrict the Company's ability to merge with or sell the Company's assets to a third party, thereby preserving control of the Company by existing management.

Series A Convertible Preferred Stock

The Company authorized 1,050,000 shares of Series A convertible preferred stock with certain rights and privileges, of which 569,000 and 0 shares were issued and outstanding as of September 30, 2006 and 2007, respectively. In July 2005, the Company completed a private placement of 569,000 shares of its Series A convertible preferred stock and received proceeds of $2,845. Fees incurred as part of the private placement totaled $379.

In connection with the Series A convertible preferred stock issuance, the Company entered into a registration rights agreement with the purchasers of its stock, which provided, among other things, for liquidated damages if the Company were initially unable to register and obtain an effective registration of the securities within the allotted time. The stockholders could not demand registration until one hundred and eighty (180) days after the Company had effected a qualified initial public offering. The penalties were (i) one and three quarters (1 3/4%) percent of the aggregate number of shares of underlying common stock for each month, or part thereof, after a ninety (90) day period that a registration statement was not filed with the SEC or (ii) one (1%) percent of the aggregate number of shares of underlying common stock for each month if the forgoing filed registration statement was not declared effective by the SEC within one hundred and twenty (120) days.

Each share of Series A convertible preferred stock was automatically convertible into a number of shares of common stock equal to the quotient of $3.54 divided by $1.00 immediately subsequent to the date of the initial public offering.

As part of the compensation agreement, the placement agent received 279,500 Series A Warrants. Each warrant consists of the right to purchase one share of fully paid and non-assessable common stock for a period of seven years which expires on July 12, 2012. The exercise price of each warrant is $1.00 per share. The exercise price may be paid in cash or by tendering common stock. The warrants are transferable and provide for anti-dilution protection. The Company evaluated the warrants to ascertain if they should be recorded as equity instruments, or if they contained features which require them to be recorded as derivative liabilities, and concluded they should be classified as equity instruments on the balance sheet.

As a result of the conversion option, the Company considered the features contained in the Series A convertible preferred stock to ascertain whether the shares contained a beneficial conversion feature. The

Company determined that the issuance of the Series A convertible preferred stock did not result in a beneficial conversion feature.

Series B Convertible Preferred Stock

The Company authorized 6,500,000 shares of Series B convertible preferred stock ("Series B Preferred Stock") of which 6,198,179 and 0 shares were issued and outstanding as of September 30, 2006 and 2007, respectively. In July 2006, the Company completed a private placement of 5,380,711 shares of its Series B preferred stock and received gross proceeds of $21,200 as part of the private placement, fees incurred totaled $1,795. Additionally in July 2006, 817,468 shares of Series B preferred stock and 440,105 common stock warrants were issued to repay the Company's Bridge Financing units.

Each share of Series B convertible preferred stock was automatically convertible into a number of shares of common stock equal to the quotient of $3.94 divided by $1.00 immediately subsequent to the date of the initial public offering.

As part of the compensation agreement relating to the Series B Preferred Stock transaction, the placement agent received 126,903 Agent Series B Preferred Warrants and 68,322 common stock warrants. Each such warrant consisted of the right to purchase one share of Series B Preferred Stock for a period of seven years which expires on July 19, 2013. The exercise price of each warrant was $5.56 per share. The exercise price was payable in cash or by tendering common stock. In the event the Company issued common stock or rights to purchase common stock below the then conversion price, then the price per share at which the Series B preferred stock was to be converted would be reduced to the weighted average of the existing conversion price per share and the price per share of the newly-issued stock or rights.

Also, as part of the compensation agreement relating to the bridge financing transaction, the placement agent received an aggregate of 22,222 Series B Preferred warrants and 11,963 common stock warrants. Each warrant consisted of the right to purchase one share of fully paid and non-assessable common stock for a period of seven years which expires on July 19, 2012. The exercise price of each warrant was $5.56 per share. The exercise price was payable in cash or by tendering common stock. In the event the Company issued common stock or rights to purchase common stock below the then conversion price, then the price per share at which the Series B preferred stock was to be converted would be reduced to the weighted average of the existing conversion price per share and the price per share of the newly-issued stock or rights.

The Company evaluated all the warrants to ascertain if they should be recorded as equity instruments, or if they contained features which require them to be recorded as derivative liabilities and concluded they should be classified as equity on the balance sheet.

As a result of the conversion option, the Company considered the features contained in the Series B convertible preferred stock to ascertain whether the shares contained a beneficial conversion feature and determined that the issuance of the Series B convertible preferred stock resulted in a beneficial conversion feature in the amount of $603.

The completion of the Company's initial public offering in May 2007 resulted in the conversion of 6,407,008 shares of the Company's Series A and B convertible preferred stock.

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Notes to Financial Statement — (Continued)
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Shares Reserved for Future Issuance

As of September 30, 2010, the Company reserved shares of common stock for future issuance as follows:

2010 stock incentive plan	8,807,633
2005 employee stock purchase plan	1,600,000
Exercise of warrants issued to placement agent	118,815
Exercise of warrants issued in connection with August 2010 registered direct offering	2,398,200
Total	12,924,648

2010 Stock Incentive Plan

In March 2010, the shareholders of the Company approved the 2010 Stock Incentive Plan (2010 Plan). Up to 5,400,000 shares of the Company's common stock may be issued pursuant to awards granted under the 2010 Plan, plus shares of common stock underlying already outstanding awards under the Company's prior plans. As of September 30, 2010, the Company had 3,407,633 shares of common stock subject to outstanding awards. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.6 shares for each one share of common stock. The Company has not made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by the Company's stockholders. The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan.

2004 Stock Incentive Plan

The Company established the 2004 Stock Incentive Plan on October 1, 2004 (the "Plan") and as amended in March 2007. The Plan provides for the granting of shares of common stock or securities convertible into or exercisable for shares of common stock, including stock options ("Incentive Stock Options") to directors, employees, consultants and advisors of or to the Company. Incentive Stock Options can be awarded only to persons who are employees of the Company at the time of the grant. Stock options are exercisable at the conclusion of the vesting period. Employees can exercise their vested shares up to 90 days after termination of services. No awards may be granted under the Plan after the effective date of the 2010 Plan.

The Plan is be administered by either the Board of Directors of the Company or a Committee thereof, which determines the terms and conditions of the awards granted under the Plan, including the recipient of the award, the nature of the award, the exercise price of the award, the number of shares subject to the award and the exercisability thereof.

Non-employee directors are not entitled to receive awards other than the non-qualified stock options the plan directs be issued to non-employee directors.

2005 Employee Stock Purchase Plan

The Company's 2005 Employee Stock Purchase Plan, or the Purchase Plan, was adopted by its Board of Directors and approved by its stockholders on March 20, 2007. The Purchase Plan became effective upon the closing of the Company's initial public offering. The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code.

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Notes to Financial Statement — (Continued)
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Under the Purchase Plan, eligible employees may contribute up to 15% of their eligible earnings for the period of that offering withheld for the purchase of common stock under the Purchase Plan. The employee's purchase price is equal to the lower of: 85% of the fair market value per share on the start date of the offering period in which the employee is enrolled or 85% of the fair market value per share on the semi-annual purchase date. The Purchase Plan imposes a limitation upon a participant's right to acquire common stock if immediately after the purchase, the employee would own 5% or more of the total combined voting power or value of the Company's common stock or of any of its affiliates not eligible to participate in the Purchase Plan. The Purchase Plan provides for an automatic rollover when the purchase price for a new offering period is lower than previously established purchase price(s). The Purchase Plan also provides for a one-time election that allows an employee the opportunity to enroll into a new offering period when the new offering is higher than their current offering price. This election must be made within 30 days from the start of a new offering period. Offering periods are twenty-seven months in length. The compensation cost in connection with the plan for the years ended September 30, 2008, 2009 and 2010 was $48, $233 and $454, respectively.

An aggregate of 1,600,000 shares of common stock are reserved for issuance pursuant to purchase rights to be granted to the Company's eligible employees under the Purchase Plan. The Purchase Plan shares are replenished annually on the first day of each fiscal year by virtue of an evergreen provision. The provision allows for share replenishment equal to the lesser of 1% of the total number of shares outstanding on that date or 100,000 shares. As of September 30, 2010, a total of 1,332,588 shares were reserved and available for issuance under this plan. As of September 30, 2010, the Company issued 267,412 shares under the Purchase Plan.

2005 Non-Employee Directors' Stock Option Plan

The Company's 2005 Non-Employee Directors' Stock Option Plan, or the Directors' Plan, was adopted by its Board of Directors and approved by its stockholders on March 20, 2007. The Directors' Plan became effective upon the closing of the Company's initial public offering. An aggregate of 500,000 shares of common stock are reserved for issuance under the Directors' Plan. Upon the effective date of the registration statement in connection with the Company's initial public offering, each of its non-employee directors automatically received an initial option to purchase 25,000 shares of common stock. Each non-employee director who is first elected or appointed to the Company's Board of Directors after the closing of the Company's initial public offering will receive an initial option to purchase 25,000 shares of common stock on the date of his or her election or appointment. In addition, each non-employee director receives an option to purchase 20,000 shares of common stock on an annual basis. Effective March 3, 2009, these shares vest pro rata over one year. However, in the event a non-employee director has not served since the date of the preceding annual meeting of stockholders, that director will receive an annual grant that has been reduced pro rata for each full quarter prior to the date of grant during which such person did not serve as a non-employee director.

The fair value per share is being recognized as compensation expense over the applicable vesting period. The fair value per share for awards granted as of December 31, 2008 through September 30, 2010 was calculated using the Black-Scholes valuation model.

The fair value of the common stock for the grants from December 23, 2004 through November 1, 2006 was determined using a retrospective valuation. The fair value of the common stock for the grants during December 2006 and subsequently was determined contemporaneously with the grants.

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Notes to Financial Statement — (Continued)
(In thousands, except share and per share amounts)

The following table summarizes the stock option activity through September 30, 2010:

Options	Number	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balance, September 30, 2004	—	$ —	—
Granted	385,432	1.41	$ 1,499
Outstanding balance, September 30, 2005	385,432	1.41	$ 1,499
Granted	461,602	5.65	55
Forfeited, expired	60,222	3.40	144
Outstanding balance, September 30, 2006	786,812	3.23	$ 1,330
Granted	955,842	13.96	—
Exercised	3,542	1.41	$ 14
Forfeited, expired	53,138	5.65	—
Outstanding balance, September 30, 2007	1,685,974	6.80	$ 1,316
Granted	1,727,397	16.88	—
Exercised	174,410	5.18	33
Forfeited, expired	103,571	11.04	—
Outstanding balance, September 30, 2008	3,135,390	$ 13.92	$ 1,283
Granted	611,500	2.69	$ 1,570
Exercised	17,661	1.41	$ 69
Forfeited, expired	321,596	13.88	—
Outstanding balance, September 30, 2009	3,407,633	$ 11.81	$ 2,784
Granted	1,314,100	4.09	1,564
Exercised	32,321	2.11	103
Forfeited, expired	53,880	13.04	—
Outstanding balance, September 30, 2010	4,635,532	9.68	4,245
Exercisable shares, September 30, 2010	2,285,867	$ 11.22	$ 1,457

Restricted Stock Units

In the quarter ended December 31, 2009, the Company granted restricted stock units to executive officers and employees pursuant to the 2004 Stock Incentive Plan. There is no direct cost to the recipients of the restricted stock units, except for any applicable taxes. Each restricted stock unit represents one share of common stock and vests annually over four years. Each year following the annual vesting date, between January 1 and March 15, the Company will issue common stock for each vested restricted stock unit. During the vesting period, the restricted stock units cannot be transferred and the grantee has no voting rights. If the Company declares a dividend, restricted stock unit recipients will receive payment based upon the percentage of RSUs that have vested prior to the date of declaration. The costs of the awards, determined as the fair value of the shares on the grant date, is expensed ratably over the vesting period.

Based on historical experience of option cancellations, the Company has estimated an annualized forfeiture rate of 9% for employee RSUs. Forfeiture rates will be adjusted over the requisite service period when actual forfeitures differ, or are expected to differ, from the estimate.

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Notes to Financial Statement — (Continued)
(In thousands, except share and per share amounts)

The share-based compensation expense associated with the restricted stock units has been recorded in the statement of operations and in additional paid-in-capital on the balance sheets is as follows:

Options	Number	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
RSUs			
Granted	250,000	$ 3.95	—
Vested	—		—
Forfeited, expired	980	3.95	—
Outstanding and unvested balance, September 30, 2010	249,020	3.95	1,319,806

At September 30, 2010, there was $779 of total unrecognized share-based compensation expense related to restricted stock unit awards granted under the 2004 Stock Incentive Plan. This expense is expected to be recognized over the remaining vesting periods up to three years.

12. Employee Benefit Plan

Effective January 1, 2006, the Company established a 401(k) plan covering substantially all employees. Employees may contribute up to 100% of their salary per year (subject to maximum limit prescribed by federal tax law). The Company may elect to make a discretionary contribution or match a discretionary percentage of employee contributions. As of September 30, 2010, the Company had not elected to make any contributions to the plan.

13. Reverse Split

On April 12, 2007, the Company completed a 0.7085 for one (0.7085:1) reverse stock split ("Reverse Split") rounding all fractional shares down to the next full share. Stockholders received cash in lieu of fractional shares. After the Reverse Split, there were 8,003,828 shares of common stock outstanding. The Reverse Split did not reduce the number of authorized shares of common stock, alter the par value or modify the voting rights or other terms thereof. As a result of the Reverse Split, the conversion prices and/or the numbers of shares issuable upon the exercise of any outstanding options and warrants to purchase common stock were proportionally adjusted pursuant to the respective anti-dilution terms of the 2004 Stock Incentive Plan and the respective warrant agreements. All references in these financial statements and accompanying notes to units of common stock or per share amounts are reflective of the Reverse Split for all periods reported.

14. Summary Selected Quarterly Financial Data (Unaudited)

The following table sets forth certain unaudited consolidated quarterly statement of operations data for the eight quarters ended September 30, 2010. This information is unaudited, but in the opinion of management, it has been prepared substantially on the same basis as the audited consolidated financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts

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stated below to state fairly the unaudited consolidated quarterly results of operations. The results of operations for any quarter are not necessarily indicative of the results of operations for any future period.

Quarter Ended
(in thousands, except share and per share amounts)

	December 31, 2009	March 31, 2010	June 30, 2010	September 30, 2010
Revenue	$ —	$ —	$ —	$ —
Net loss	$ (11,148)	$ (10,409)	$ (8,629)	$ (8,104)
Basic and diluted net loss per common share	$ (0.47)	$ (0.44)	$ (0.36)	$ (0.31)
Weighted average common shares basic and diluted	23,848,855	23,885,856	23,944,386	24,961,083

Quarter Ended
(in thousands, except share and per share amounts)

	December 31, 2008	March 31, 2009	June 30, 2009	September 30, 2009
Revenue	$ —	$ —	$ —	$ —
Net loss	$ (10,024)	$ (11,629)	$ (11,148)	$ (10,469)
Basic and diluted net loss per common share	$ (0.42)	$ (0.49)	$ (0.47)	$ (0.44)
Weighted average common shares basic and diluted	23,706,148	23,717,800	23,759,675	23,802,286

15. Subsequent Event

On October 1, 2010, the Company amended the Chief Executive Officer's employment agreement, dated March 26, 2010, whereby the cash portion of Dr. De Souza's base salary earned between October 1, 2010 and September 30, 2011 was reduced by $50 and RSUs were granted. The RSUs were granted under the Company's 2010 Stock Incentive Plan and will vest in equal installments on each of December 31, 2010, March 31, 2011, June 30, 2011, and September 30, 2011. The number of RSUs was determined by dividing $50 by the fair value of the Company's closing stock price on October 2, 2010, which equaled 9,843 RSUs. The shares of common stock represented by the RSUs will be distributed on (and not before) September 30, 2011, absent an intervening Reorganization Event or Change in Control Event (each as defined in the 2010 Plan) that causes an earlier distribution.

On October 1, 2010, the Company also reduced cash expenditures by modifying the board of directors compensation effective October 1, 2010 through September 30, 2010. Previously, the Company had paid its chairman and/or lead director $60 in cash annually and each of its other non-employee directors $30 in cash annually. For the fiscal year ending September 30, 2011, the Company's Chairman and/or lead director will receive $40 in cash as compensation for serving as a director for the fiscal year ending September 30, 2011 and the remaining $20 in the form of restricted stock units. Each other non-employee director will receive $20 in cash as compensation for serving as a director for the fiscal year ending September 30, 2011 and the remaining $10 in the form of restricted stock units. The Company granted the restricted stock units to its directors on October 1, 2010 (the "Director RSUs") under the 2010 plan and the Director RSUs will vest in

equal installments on each of December 31, 2010, March 31, 2011, June 30, 2011 and September 30, 2011. The shares of common stock represented by the Director RSUs will be distributed on (and not before) September 30, 2011, absent an intervening Reorganization Event or Change in Control Event (each as defined in the 2010 Plan) that causes an earlier distribution.

In October, 2010, the Company received a complete response letter from the FDA requesting additional information regarding the Company's NDA for Linjeta™, including data from two new Phase 3 clinical trials using the final commercial formulation of Linjeta™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes.

The complete response letter stated that the FDA's review cycle is complete and that the application cannot be approved in its present form. We have contacted the FDA to formally request a meeting to discuss the complete response letter.

The complete response letter included comments related to clinical trials, statistical analysis and chemistry, manufacturing and controls.

In November 2010, the Company announced that it has been awarded approximately $1.2 million in research grants under the Internal Revenue Service's therapeutic discovery tax credit program. This program was created under the Patient Protection and Affordable Care Act of 2010 to provide tax credits or grants representing up to 50 percent of eligible qualified investments in therapeutic discovery projects during tax years 2009 and 2010. The Company applied for and is receiving these funds to support the company's Linjeta™, VIAtab™, glucagon, extended glargine and glucose-sensing glargine insulin development programs.

On December 1, 2010, the exercise price on the warrants issued in the August 24, 2010 financing was re-set to $1.56 per share as per the terms of the warrants.

Exhibit 10.23

BASE SALARIES OF NAMED EXECUTIVE OFFICERS OF THE REGISTRANT

The following are the base salaries (on an annual basis) of the named executive officers of the Company:

Name and Title	Base Salary(1)
Errol De Souza President and Chief Executive Officer	$ 450,000
Solomon S. Steiner Chief Scientific Officer	$ 400,000
Gerard J. Michel Chief Financial Officer, Vice President Corporate Development and Treasurer	$ 317,000
Alan Krasnser Chief Medical Officer	$ 312,000
Paul Bavier General Counsel and Secretary	$ 210,000

(1) Base salaries effective March 31, 2010 for CEO and CSO, and December 1, 2009 for other named executive officers.

Exhibit 10.24

SUMMARY OF THE REGISTRANT'S NON-EMPLOYEE DIRECTOR COMPENSATION

Except as set forth below with regard to the fiscal year 2011 amendment to director compensation, the Company pays each of its non-employee directors $30,000 annually or $60,000 annually to its lead director and/or Chairman. In addition, non-employee directors receive the following committee-related fees annually: (1) $7,500 for participating on the Audit Committee or $15,000 for chairing the committee; (2) $5,000 for participating on the Compensation Committee or $15,000 for chairing the committee; and (3) $2,500 for participating on the Nominating and Governance Committee or $5,000 for chairing the committee.

For the fiscal year ending September 30, 2011, the Company's Chairman and/or lead director will receive, in lieu of the standard director compensation, $40,000 in cash as compensation for serving as a director for the fiscal year ending September 30, 2011 and the remaining $20,000 in the form of restricted stock units. Additionally, each other non-employee director will receive $20,000 in cash as compensation for serving as a director for the fiscal year ending September 30, 2011 and the remaining $10,000 in the form of restricted stock units. The Company granted the restricted stock units to its directors on October 1, 2010 (the "Director RSUs") under the Company's 2010 Stock Incentive Plan and the Director RSUs will vest in equal installments on each of December 31, 2010, March 31, 2011, June 30, 2011 and September 30, 2011. The number of RSUs was determined by dividing the amount the director's cash compensation was reduced ($20,000 or $10,000, as the case may be) by the fair value of the Company's closing stock price on October 2, 2010. The shares of common stock represented by the Director RSUs will be distributed on (and not before) September 30, 2011, absent an intervening Reorganization Event or Change in Control Event (each as defined in the Company's 2010 Stock Incentive Plan) that causes an earlier distribution.

Upon appointment, non-employee directors receive a one-time grant of an option to purchase 25,000 shares of common stock. These options vest pro rata over one year. Annually, non-employee directors receive an option to purchase 20,000 shares of common stock, which also vest pro rata over one year. The exercise price of these options is the fair market value on the date of grant. Each such option expires seven years after the date of grant under the Company's 2010 Stock Incentive Plan.

The Company reimburses its non-employee directors for reasonable expenses incurred in connection with attending board and committee meetings.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

None.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (File No. 333-153167) and the Registration Statements on Form S-8 (File Nos. 333-144407 and 333-168903) of our reports dated December 14, 2010, relating to the financial statements and effectiveness of Biodel Inc.'s internal control over financial reporting which appear in the Company's Form 10-K for the year ended September 30, 2010.

/s/ BDO USA, LLP

New York, New York
December 14, 2010

Exhibit 31.01

CERTIFICATION

I, Errol De Souza, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biodel Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Errol De Souza
Errol De Souza
President and Chief
Executive Officer

Date: December 14, 2010

Exhibit 31.02

CERTIFICATION

I, Gerard Michel, certify that:

1) I have reviewed this Annual Report on Form 10-K of Biodel Inc.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Gerard Michel
Gerard Michel
Chief Financial Officer, Vice President,
Corporate Development and Treasurer

Date: December 14, 2010

Exhibit 32.01

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Biodel Inc. (the ''Company") for the year ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Errol De Souza, President and Chief Executive Officer of the Company and Gerard Michel, Chief Financial Officer, Vice President Corporate Development and Treasurer of the Company, each hereby certifies that: (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Errol De Souza
Errol De Souza,
President and
Chief Executive Officer

Dated: December 14, 2010

/s/ Gerard Michel
Gerard Michel
Chief Financial Officer,
Vice President, Corporate
Development and Treasurer

Date: December 14, 2010