BIODEL

LETTER TO SHAREHOLDERS

Fiscal year 2007 was a landmark year for Biodel. We broadened our access to funding by successfully transitioning to a publicly traded company on the NASDAQ. Our initial public offering on May 11, 2007 raised approximately $86 million that will fund further development of our product candidates, including the completion of Phase III trials and an NDA submission for our lead product candidate, VIAject™.

2007 was a year marked by significant clinical progress for our lead product candidate VIAject™. We released substantial clinical data replicating VIAject™'s rapid absorption profile which we believe will translate into real clinical benefits over standard meal time insulins for patients with Type 1 and Type 2 diabetes.

At the 2007 European Association for the Study of Diabetes Meeting (EASD), we presented data from VIAject™'s Phase II meal study that demonstrated statistically significant and clinically relevant improved glycemic control compared to Humulin® R (regular recombinant human insulin) and Humalog® (lispro), the best selling meal time insulin in the United States. VIAject™ demonstrated increased glycemic control as well as fewer hypoglycemic events.

A further analysis from the Phase II meal study, presented at the 2007 Diabetes Technology Meeting, compared VIAject™ directly with Humalog® in patients who regularly used Humalog® as their meal time insulin. The data demonstrated that VIAject™ provided better post-meal blood glucose control with less hyperglycemia in the first three hours after the meal and less risk of hypoglycemia in the next five hours as compared to Humalog®. The data from the meal study reinforce our hypothesis that VIAject™ could be safer than the currently marketed meal time insulins.

In 2007 we continued to make real progress in moving VIAject™ to market. We expanded enrollment of both our Phase III clinical trials into Europe and Asia, which enabled us to achieve full enrollment in December of 2007. At the American Diabetes Association (ADA) Annual Meeting this past June, we announced interim results for VIAject™ from these open label trials. Patients using VIAject™ had fewer hypoglycemic events and experienced weight loss, while control patients on Humulin® R gained weight. Patients receiving VIAject™ were able to reduce their dose of meal time insulin compared to control patients receiving Humulin® R. All of these differences were statistically significant.

Biodel currently retains full rights to its product portfolio, which includes the VIAject™ suite of product candidates, VIAtab™ (in Phase I clinical development), VIAmass™ and VIAcal™.

This year, the United States Patent and Trademark Office granted Biodel a patent for our lead products VIAject™ and VIAtab™. This patent will expire no earlier than January 2026. We have filed additional patents on our technology which as of yet have not issued.

In short, 2007 was a year of accomplishment. Through the dedication of our employees and the continued support of our shareholders we anticipate continued success in creating value through the discovery and development of innovative therapies.

Thank you, our valued shareholder, for your continued support, trust and confidence as we move into another year of exciting developments at Biodel.

Solomon S. Steiner, Ph.D.
Chairman, President and Chief Executive Officer

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

Form 10-K

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

(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, 2007

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**	**06810**
(Address of Principal Executive Offices)	*(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 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12 b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☑

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

The aggregate market value of the common stock of the registrant held by nonaffiliates as of November 30, 2007, was $167.5 million based on the price at which the common stock was last sold on the NASDAQ Global Market.

The number of shares outstanding of the registrant's common stock, as of November 30, 2007 was 20,160,836.

Portions of the registrant's definitive Proxy Statement, or the 2008 Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2007, for its 2008 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report. With the exception of the portions of the 2008 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

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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. 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 secure U.S. Food and Drug Administration approval for our product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act;
- our ability to market, commercialize and achieve market acceptance for product candidates developed using our VIAdel™ technology;
- the progress or success of our research, development and clinical programs, the initiation and completion of our clinical trials, the timing of the interim analyses and the timing or success of our product candidates, particularly VIAject™ and VIAtab™;
- our ability to secure additional patents for VIAject™ and our other product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our estimates for future performance;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations that we enter, or our ability to commercialize our product candidates ourselves;
- the rate and degree of market acceptance and 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 strategy; and
- our estimates regarding 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 endocrine disorders such as diabetes and osteoporosis, which may be safer, more effective and convenient. We develop our product candidates by applying our proprietary formulation technologies to existing drugs in order to improve their therapeutic results. Our initial development efforts are focused on peptide hormones. We have two insulin product candidates currently in clinical trials for the treatment of diabetes. Additionally, we have two preclinical product candidates for the treatment of osteoporosis, one with parathyroid hormone 1-34 and the other with salmon calcitonin. Our most advanced product candidate is VIAject™, a proprietary injectable formulation of recombinant human insulin designed to be absorbed into the blood faster than currently marketed rapid-acting insulin products. We believe VIAject™ can improve the management of blood glucose levels in patients with diabetes by more closely mimicking the natural first-phase insulin release that healthy individuals experience at meal-time. We are currently conducting two pivotal Phase III clinical trials of VIAject™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. We expect to complete these two trials and intend to submit a new drug application, or NDA, under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FFDCA, to the U.S. Food and Drug Administration, or the FDA, by the end of 2008.

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 meal-time insulin injections. As the disease progresses, patients with Type 2 diabetes also require meal-time insulin. However, none of the currently marketed meal-time 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 this lack of adequate glucose control 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. These rapid-acting insulin analogs had sales in excess of $2.6 billion in 2006 according to IMS Health, a leading provider of pharmaceutical market data.

We have conducted Phase I and Phase II clinical trials comparing the performance of VIAject™ to Humalog®, the largest selling rapid-acting insulin analog in the United States, and Humulin® R, a form of recombinant human insulin. In these trials, we observed that VIAject™ produced a release profile into the blood that more closely approximates the natural first-phase insulin release seen in healthy individuals following a meal. In September 2006, we initiated two pivotal Phase III clinical trials for VIAject™, which will treat 400 patients with Type 1 diabetes and 400 patients with Type 2 diabetes over a six-month period. In September 2007, we announced that we expanded our two Phase III clinical trials into Germany and patient treatment has begun. In December 2007, we announced that we also expanded our two Phase III clinical trials into Asia and patient treatment has begun.

In addition to VIAject™, we are developing VIAtab™, a sublingual, or below the tongue, tablet formulation of insulin. We are currently in the Phase I stage of clinical testing of VIAtab™ in patients with Type 1 diabetes. We believe that VIAtab™ has the potential to rapidly deliver insulin, while sparing patients from the unpleasant aspects of injection therapy. We are developing VIAtab™ as a potential treatment for

patients with Type 2 diabetes who are in the early stages of their disease. In addition to our clinical-stage insulin programs, our preclinical product candidates for the treatment of osteoporosis are VIAmass™ and VIAcal™. VIAmass™ is a sublingual rapid-acting formulation of parathyroid hormone 1-34, or PTH 1-34. VIAcal™ is a sublingual rapid-acting formulation of salmon calcitonin.

Development of a full line of VIAject™ insulin products has progressed more rapidly than we originally anticipated. We believe that focusing our resources on the later-stage VIAject™ program provides our best opportunity to maximize stockholder value. Given the priority being placed on the development of our VIAject™ product line, we now expect to submit investigational new drug applications, or INDs, for VIAcal™ and VIAmass™ no earlier than late in 2008.

We have developed all of our product candidates utilizing our proprietary VIAdel™ technology which allows us to study the interaction between peptide hormones and small molecules. We use our technology to reformulate existing peptide drugs with small molecule ingredients that are generally regarded as safe by the FDA so as to improve their therapeutic effect by entering the blood rapidly and in greater quantities. We believe that this approach to drug development will allow us to utilize Section 505(b)(2) of the FFDCA for FDA approval of our product candidates. Section 505(b)(2) provides for a type of NDA that allows expedited development of new formulations of chemical entities and biological compounds that have already undergone extensive clinical trials and been approved by the FDA. Both the time and cost of development of a new product can be substantially less under a Section 505(b)(2) NDA than under a full NDA.

Our Strategy

Our goal is to build a leading specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for endocrine disorders, which may be safer, more effective and convenient. To achieve our goal, we are pursuing the following strategies:

- *Obtain Regulatory Approval for VIAject™.* Our current focus is to complete the clinical development of VIAject™ and seek regulatory approval for this product candidate in the major world markets starting with the United States. If our current Phase III trials for VIAject™ are successful, we expect to submit our NDA to the FDA by the end of 2008.
- *Commercialize our Product Candidates Through Strategic Collaborations.* Our product candidates target large primary care markets. To maximize the commercial potential of our product candidates, we intend to:
  - *Self-fund Clinical Trial Programs.* We intend to fund our clinical trial programs into late stage or through completion of clinical development by ourselves. By retaining the rights to our product candidates through most or all of the clinical development process, we believe that we will be able to secure more favorable economic terms when we do seek a commercialization partner.
  - *Partner Late-stage Programs with Major Pharmaceutical Companies.* We intend to selectively enter into strategic arrangements with leading pharmaceutical or biotechnology companies for the commercialization of our product candidates late in or upon completion of clinical development. 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 products.
  - *Retain Co-commercialization Rights.* In entering into collaborative relationships, our goal will be to retain co-promotion or co-commercialization rights in the United States and potentially other markets. This will allow us to begin to develop our own specialized sales and marketing organization.
- *Employ our Proprietary VIAdel™ Technology to Reformulate Approved Peptide Hormone Drugs that Address Large Markets.* Our VIAdel™ technology consists of techniques that we have developed to study the interaction between peptide hormones and small molecules. We use these techniques to reformulate existing peptide drugs with small molecule ingredients so as to improve their therapeutic effect and their method of administration. To date, we have developed all of our product candidates utilizing our proprietary VIAdel™ technology. We are focused on diabetes and osteoporosis, both of

which represent large markets with significant unmet medical needs. We intend to continue to employ our proprietary VIAdel™ technology to develop additional peptide hormone product candidates that address large markets.

- *Focus on the Section 505(b)(2) Regulatory Approval Pathway.* Using our VIAdel™ technology, we seek to reformulate existing drugs with ingredients that are generally regarded as safe by the FDA. We believe that this approach to drug development will allow us to use the abbreviated development pathway of Section 505(b)(2) of the FFDCA, which can result in substantially less time and cost in bringing a new drug to market. We intend to continue to focus our efforts on reformulating new product candidates for which we will be able to seek regulatory approval pursuant to Section 505(b)(2) NDAs.

- *Aggressively Continue the Development of our Pipeline of Product Candidates.* The VIAject™ formulation and presentation that we are using in our ongoing Phase III clinical trials is a two vial package, with one vial containing lyophilized insulin and the second vial containing 10cc of the proprietary VIAject™ diluents. We are currently developing a liquid, premixed formulation in a variety of presentations including vials and cartridges for use in pen injectors. Like Humalog®, Novolog® and Apidra®, the liquid presentations of VIAject™ are stable when refrigerated. Based on studies we have performed, we anticipate that the same formulation of VIAject™ will be stable when frozen, as well, unlike currently available insulins. We are developing the lyophilized vial and all of the liquid presentations in both the 25 IU/cc and 100 IU/cc concentrations. Accordingly, we filed a new IND for VIAject™ frozen insulin and amended our current IND to include the two part 100 IU/cc insulin concentration. In addition to our Phase III clinical trials for VIAject™, we have reached Phase I clinical development of VIAtab™, our sublingual insulin product candidate. We are also conducting preclinical studies on VIAmass™ and VIAcal™, our osteoporosis product candidates. Given the priority being placed on the development of our VIAject™ product line, we now expect to submit INDs and commence Phase I clinical trials for these preclinical product candidates no earlier than late in 2008.

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, either the body does not produce the insulin at the right time or the body's cells ignore the 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.

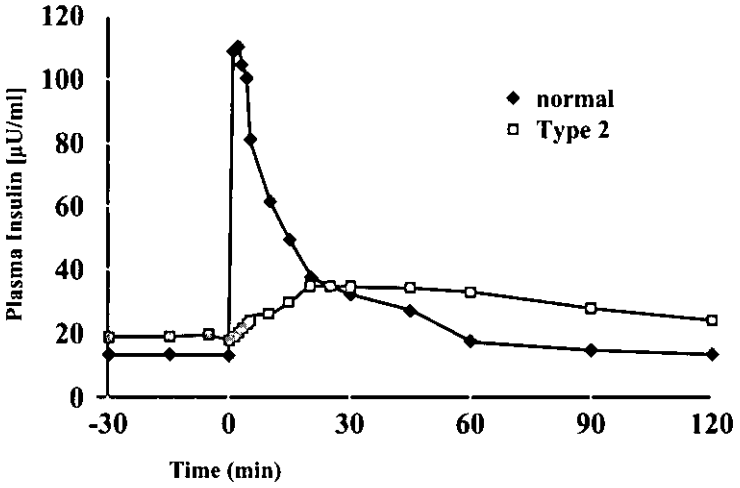
Even before any other symptoms are present, one of the first effects of Type 2 diabetes is the loss of the meal-induced first-phase insulin release. In the absence of the first-phase insulin release, the liver will not

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 goes too high after eating, a condition known as hyperglycemia. Hyperglycemia causes glucose to attach unnaturally to certain proteins in the blood, interfering with the 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 Type 2 diabetic 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 diabetic'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 and hypertension. 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 fast acting insulin at meal-time. 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 improperly 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 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, insulin-using diabetic patients have on average 1.3 serious hypoglycemic events per year, many of which events require hospital emergency room visits by the patients.

Market Opportunity

The World Health Organization estimates that more than 180 million people worldwide have diabetes and that this number is likely to more than double by 2030. The CDC estimates that approximately 20.8 million people in the United States, or 7.0% of the overall population, suffer from diabetes, with 1.5 million new cases diagnosed in 2005. Diabetes is currently the sixth leading cause of death by disease and is the leading cause of new cases of kidney disease and non-traumatic lower limb amputations and blindness among young adults.

Despite the limitations of currently available insulin therapies, the ADA estimates that approximately $12 billion was spent on insulin and related delivery supplies in 2002. The rapid-acting insulin analogs have come to dominate the market for meal-time insulin. According to IMS Health, sales of rapid-acting insulin analogs were in excess of $2.6 billion in 2006.

Because the time-course of insulin delivery to the blood plays such an important role in overall glucose control, we believe that there is significant market potential for insulin products that reach the blood more rapidly than the insulin analogs. In addition, because of the pain and inconvenience of insulin injection, we believe that there is significant market potential for rapid-acting insulin products that are delivered by means other than injection.

The Biodel Solution

Our two most advanced clinical programs are VIAject™, an injectable formulation of insulin, and VIAtab™, a sublingual formulation of insulin. We believe these product candidates may change the way Type 1 and Type 2 diabetic patients are treated by improving the efficacy, safety and ease-of-use of insulin. Based upon our preclinical and clinical data, if approved, VIAject™ may be the first commercially available drug to produce a profile of insulin levels in the blood that approximates the natural first-phase insulin release normally seen in persons without diabetes following a meal.

VIAject™

VIAject™ is our proprietary formulation of injectable human insulin to be taken immediately prior to a meal or at the end of a meal. We formulated VIAject™ using our VIAdel™ technology to combine recombinant human insulin with specific ingredients generally regarded as safe by the FDA. VIAject™ 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 prevents re-association to the hexameric form. We believe that by favoring the monomeric form, VIAject™ 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. Because most human insulin that is sold for injection is in the hexameric form, the injected insulin appears to the body to be six times its actual size. This makes it more difficult for the body to absorb, as the insulin hexamer must first disassociate to form double insulin molecules and then single insulin molecules.

Potential Advantages of VIAject™ over Existing Insulin Treatments

We believe VIAject™ offers a number of potential advantages over currently available injectable insulin products.

- *Better Management of Blood Glucose Levels.* Based on our clinical trials to date, we believe that VIAject™ can improve the management of blood glucose levels in patients with diabetes. Specific observations include the following:
  - In our Phase I clinical trial in volunteers without diabetes, and in our Phase II clinical trial in patients with Type 1 diabetes, VIAject™ reached the blood and exerted blood glucose lowering activity more rapidly than the rapid-acting insulin analog, Humalog®, and the regular human recombinant insulin, Humulin® R. Accordingly, we believe VIAject™ more closely mimics the first-phase insulin release of healthy individuals at the beginning of a meal, which reduces the risk of hyperglycemia.
  - Our clinical trials also indicate that VIAject™ may allow for a lower dose of insulin to adequately cover a meal than Humulin® R and Humalog®. As a result, we believe the use of VIAject™ may reduce the amount of insulin that remains in the blood several hours after a meal. This may, in turn, reduce the risk of hypoglycemia. Consequently, we believe that VIAject™ may be safer than any other meal-time insulin products, and patients using VIAject™ may have fewer hypoglycemic episodes resulting in fewer emergency room visits.
- *Commercialization of VIAject™.* Our VIAject™ technology's ability to stabilize delicate peptides in both liquid and lyophilized formulations may provide commercialization advantages. In particular, we expect that the VIAject™ lyophilized formulation will be able to be shipped or stored with no refrigeration. We believe this will increase our market reach and collaboration opportunities in markets where refrigeration is costly or unavailable. Unlike other insulin products, the ability to freeze the liquid formulation may also increase the available shelf life of the product.

Clinical Trials of VIAject™

Phase I. In 2005, we completed a Phase I clinical trial of VIAject™. This was a single center, open label, five-way crossover study in which each of the ten healthy volunteers in the trial was exposed to the following five separate treatment conditions: three separate doses of VIAject™, one dose of Humulin® R, a regular human insulin, and one dose of Humalog®, a rapid-acting insulin analog. Volunteers received three separate injections of VIAject™ at dose levels of 12 international units (IU), 6 IU and 3 IU. Volunteers also

received one 12 IU injection for each of Humulin® R and Humalog®. International units are a standardized measure of the potency of insulin. All volunteers received insulin subcutaneously. After a screening visit, insulin administration and the evaluation procedures were performed during five subsequent treatment days.

The study employed a "glucose clamp" procedure, which is the standard procedure for safely studying the effects of insulin in healthy individuals. In the "glucose clamp" procedure, glucose is automatically infused into the volunteer's blood so that his or her blood glucose will be maintained at a healthy normal level of 90mg of glucose per deciliter of blood. The effect of insulin is to lower blood glucose, thereby requiring an infusion of glucose to maintain the normal glucose level. The rate at which glucose must be infused is called the glucose infusion rate, or GIR.

The primary objective of this trial was to estimate the pharmacodynamic activities of the tested insulins including the dose responsiveness of VIAject™. Pharmacodynamics refers to the time-course and ability of the insulin to lower blood glucose after administration. The primary pharmacodynamic measure in this trial was the GIR, from which we were able to derive several parameters, including the following:

- maximum GIR;
- time to maximum GIR; and
- time to 50% of maximum GIR.

The secondary objectives of this trial were to evaluate the safety and the pharmacokinetic profile after a single injection of VIAject™ in comparison to Humulin® R and Humalog®. Pharmacokinetics refers to the time-course and quantity of insulin in the serum of the blood of an individual after injection of insulin.

The table below indicates, for each treatment condition in the trial, the mean time to 50% of maximum GIR:

Treatment Condition	Minutes to 50% of Maximum GIR
Humulin® R 12 IU	66
Humalog® 12 IU	51
VIAject™ 12 IU	33
VIAject™ 6 IU	35
VIAject™ 3 IU	31

All three VIAject™ dose levels were faster than both Humulin® R and Humalog® in the time to reach 50% of the maximum GIR, which provides evidence of the insulin in VIAject™ reaching the blood faster than that of Humulin® R and Humalog®. This faster action for each dose of VIAject™ was statistically significant as compared to both Humilin® R and Humalog®.

The pharmacokinetic analysis showed a faster onset, peak and decline in plasma insulin concentrations for all three VIAject™ doses as compared to both Humulin® R and Humalog®, mimicking first phase insulin release.

In 2006, we analyzed the data from the Phase I clinical trial, utilizing a pharmacokinetic modeling program known as WinNonLin®. In this analysis, we measured the absorption half life of insulin, which is a pharmacokinetic measure of the speed at which insulin is absorbed into the blood. The absorption half life for a 12 IU dose was 22 minutes for VIAject™, 37 minutes for Humalog® and 71 minutes for Humulin® R. This faster action of VIAject™ was statistically significant as compared to both Humulin® R and Humalog®.

All treatments were well tolerated. No serious adverse events were reported in this trial.

Phase I/II Variability Study. Repeated administration of the same dose of both regular human insulin and rapid-acting insulin analogs are known to produce variable blood insulin level results in the same patients. This is known as the within-subject or intra-subject variability of insulin. In 2006, we completed a Phase I/II clinical trial of VIAject™ to compare the intra-subject variability of the timing and effect of repeated doses of VIAject™ to that of Humulin® R. This was a single-center, randomized, double blind, crossover, repeated

measures study in fourteen patients with Type 1 diabetes. In the trial, each patient received subcutaneous injections of VIAject™ and Humulin® R at a dose level of 0.1 IU/Kg body weight on three separate occasions. After a screening visit, insulin administration and evaluation procedures were performed during six subsequent treatment days. GIR was measured for each patient utilizing the glucose clamp procedure.

The primary objectives of this trial were (i) to compare the intra-subject variability of blood insulin concentration over time as measured by the standard deviation of the time to reach 50% of the maximum serum insulin concentration, and (ii) to compare the intra-subject variability of insulin effect over time as measured by the standard deviation of the time to reach 50% of the maximum GIR. The secondary objectives of this trial were to evaluate the safety and the pharmacokinetic profile after multiple doses of VIAject™ in comparison to Humulin® R.

In the trial, the within-subject variability of VIAject™ was less than that of Humulin® R. The standard deviation of the time to reach 50% of the maximum serum insulin concentration was 6 for VIAject™, as compared to 20 for Humulin® R, and for maximal concentrations, 16 for VIAject™, as compared to 39 for Humulin® R. In addition, the variability of the time to maximal pharmacodynamic effect was less for VIAject™ than for Humulin® R (36 vs. 74). These results were statistically significant. The standard deviation of the time to reach 50% of the maximum GIR was 17 for VIAject™, as compared to 32 for Humulin® R. However, this result was not statistically significant.

In the trial, we observed the following pharmacokinetic and pharmacodynamic results, which provide further evidence that VIAject™ reaches the blood faster than Humulin® R in patients with diabetes:

Pharmacokinetic and Pharmacodynamic Measures	VIAject™	Humulin® R	p-Value
Minutes to maximum GIR	99	154	<0.0015
Minutes to maximum serum insulin concentration	33	97	<0.0001
Minutes to 50% of maximum serum insulin concentration	8	32	<0.0001

All treatments were well tolerated. No serious adverse events were reported in this trial.

Phase II Meal Study. In 2006, we began a Phase II clinical trial to examine VIAject™'s ability to control blood glucose after Type 1 diabetic patients received a standardized meal. In the Phase II meal study of VIAject™, subjects received either VIAject™, Humulin® R (regular recombinant insulin) or Humalog® (rapid acting insulin analog) in conjunction with a standardized meal. Plasma insulin and blood glucose levels were monitored throughout the study. The patients' blood glucose was continuously monitored over the next eight hours in order to determine whether patients experienced hyperglycemic or hypoglycemic events. If the patient's blood glucose went below 60 mg/dl, a glucose infusion was initiated to keep the blood glucose above 60 mg/dl.

We compared the area under the curve, or AUC, of blood glucose at specified periods of time after a meal between the different treatments. The AUC of blood glucose concentrations for specified time intervals is a measure of the total amount of glucose in the blood over that specified time interval. The AUC for the first three hours after injection is taken is a measure of the degree of hyperglycemia experienced by the patient.

We initially performed a planned interim analysis on ten patients who had completed the study in time to be presented at the American Diabetes Association 2007 Annual Meeting. Administration of VIAject™ resulted in statistically significantly faster insulin absorption than Humulin® R and Humalog® and lower plasma insulin levels than both after three hours. The baseline corrected blood glucose profile following the meal was significantly lower during the early time periods of 0-120 minutes and 0-180 minutes, indicative of less hyperglycemia. The mean total glucose infused to maintain normal blood glucose levels was 5 times lower with VIAject™ than with regular human insulin, indicative of less hypoglycemia. The data showed that VIAject™ provides better postprandial blood glucose control with less hyperglycemia in the first three hours after the meal and less risk of hypoglycemia in the next five hours as compared to Humulin® R and Humalog®.

VIAject™ statistically significantly reduced hyperglycemia after a standardized meal when compared to Humulin® R. Humalog® did not significantly reduce hyperglycemia after a standardized meal when compared to Humulin® R. No statistically significant reduction was observed when comparing VIAject™ to Humalog® with respect to hyperglycemia. VIAject™ statistically significantly reduced hypoglycemia after a standardized meal when compared to Humulin® R. While the number of hypoglycemic events was fewer for VIAject™ compared to Humalog®, it did not reach statistical significance.

We also compared the AUC for blood glucose above and below the normal range of 80-140 mg/dl for the eight hours after the ingestion of the meal, which is a measure of glycemic variability. Humulin® R was 81,849 mg/dl* min. Humalog® was 57,423 mg/dl*min. less than Humulin® R. VIAject™ was 38,740 mg/dl*min, less than both Humulin® R and Humalog®.

The hypoglycemic events data from the meal study is summarized in the table below:

	Hypoglycemic Events per Treatment		
Hours Past Dose	Humulin® R	Humalog®	VIAject™
0-3 hours	0	7	4
3-8 hours	13	11	4
0-8 hours	13	18	8

In September 2007, we announced additional data from our interim analysis of the sixteen patients who had completed the study. This data demonstrated statistically significant and clinically relevant improved glycemic control compared to Humulin® R and Humalog®. Administration of VIAject™ resulted in statistically significantly faster insulin absorption than Humulin® R and Humalog® and lower plasma insulin levels than both after three hours. The data also demonstrated that VIAject™ provides better postprandial blood glucose control with less hyperglycemia in the first three hours after the meal and less risk of hypoglycemia in the next five hours as compared to Humulin® R and Humalog®.

Subsequently, in October 2007, we announced additional data from our interim analysis comparing VIAject™ directly with Humalog® in patients who regularly used Humalog® as their prandial insulin. The data demonstrated that VIAject™ provided better postprandial blood glucose control with less hyperglycemia in the first three hours after the meal and less risk of hypoglycemia in the next five hours as compared to Humalog®. We believe this data reinforces VIAject™'s superior pharmacokinetic and pharmacodynamic profile to the standard rapid-acting insulin analog, Humalog®.

Current Pivotal Phase III Clinical Trials. We held a meeting with the FDA in the first quarter of 2006 to discuss the results of our Phase II clinical studies and the design of our pivotal Phase III clinical trials for VIAject™. Based on that meeting, we commenced our two pivotal Phase III clinical trials of VIAject™ in September 2006. The trials are open-label, multi-center trials designed to compare the efficacy and safety of VIAject™ as compared to Humulin® R. One of the trials is testing VIAject™ in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. We expect to enroll approximately 400 patients in each trial. Patients will undergo a six-month treatment regimen. Approximately one-half of the patients in each trial will be treated with VIAject™ and the remainder with Humulin® R as their meal-time injection insulins.

The primary objective of the trials is to determine if VIAject™ is not inferior to Humulin® R in the management of blood glucose levels. The primary endpoint in the trials is the mean change in patients' glycosolated hemoglobin, or HbA1c, levels from baseline to the end of the study. Changes in HbA1c levels are a measure of patients' average blood glucose levels over the treatment period and an indication of how well the patients are controlling blood glucose levels. HbA1c is the FDA's preferred endpoint for diabetes trials.

Secondary endpoints in the trials include additional blood glucose measures, total daily insulin doses and changes in body weight. We are also assessing the safety of VIAject™ as compared to Humulin® R in these trials.

In March 2007, we performed a preliminary analysis of the unqualified data relating to changes in body weight for a total of 51 patients with Type 1 diabetes who had received at least six weeks of treatment in the

Phase III clinical trial. Of these 51 patients, 27 were in the VIAject™ treatment group and 24 were in the Humulin® R treatment group. The patients in the VIAject™ group lost on average 0.79 pounds while the patients in the Humulin® R treatment group gained on average 2.28 pounds over the six weeks of treatment. This difference between the treatment groups of 3.07 pounds was statistically significant, with a p-value of less than 0.038. The Phase III clinical trials are ongoing. Although these preliminary findings regarding changes in body weight are encouraging, our analysis was performed on a relatively small number of patients, after only six weeks of a six-month clinical trial. With more patients and longer treatment times, the final results of the trials may be different than those suggested by the changes in body weight observed to date.

In June 2007 we announced additional interim results of our Phase III clinical trials that demonstrated statistically significant daily meal-time dose reductions in patients with Type 1 and Type 2 diabetes using VIAject™, which were based on the March 2007 interim analysis. Type 1 patients receiving VIAject™ showed a 28% reduction in daily meal-time dose while control patients receiving Humulin® R showed a non-significant increase of less than 1%. Type 2 patients receiving VIAject™ showed a 49% reduction in daily meal-time dose while control patients receiving Humulin® R showed a non-significant increase of 2.3%.

In addition, we monitor safety regularly in these clinical trials. The major safety concern with patients taking insulin is the occurrence of hypoglycemic events. At the time of the preliminary analysis, we have had a total of 113 mild and moderate hypoglycemic events in our Phase III clinical trials, 73 in patients receiving Humulin® R and 40 in patients receiving VIAject™. This difference between VIAject™ and Humulin® R is statistically significant, with a p-value of less than 0.01. At the time of the preliminary analysis, we have had a total of four severe hypoglycemic events in our Phase III clinical trials. Of these four events, three were in patients receiving Humulin® R and one was in a patient with Type 1 diabetes in the VIAject™ group. The Phase III clinical trials are ongoing. The final safety results of the trials may be different than those suggested by the hypoglycemic events observed to date.

We expect to complete these two trials and, if the trials are successful, we intend to submit an NDA to the FDA for approval of VIAject™ by the end of 2008.

The VIAject™ formulation and presentation that we are using in our ongoing Phase III clinical trials is a two vial package, with one vial containing lyophilized insulin and the second vial containing 10 cc of the proprietary VIAject™ diluents. We are currently developing a liquid, premixed formulation in a variety of presentations including vials and cartridges for use in pen injectors. Like Humalog®, Novolog® and Apidra®, the liquid presentations of VIAject™ are stable when refrigerated. Based on studies we have performed, we anticipate that the same formulation of VIAject™ will be stable when frozen, as well, unlike currently available insulins. We are developing the lyophilized vial and all of the liquid presentations in both the 25 IU/cc and 100 IU/cc concentrations. Accordingly, we filed a new IND for VIAject™ frozen insulin and amended our current IND to include the two part 100 IU/cc insulin concentration.

VIAtab™

VIAtab™ is our formulation of recombinant human insulin, designed to be taken orally via sublingual administration. VIAtab™ tablets dissolve in approximately three minutes, providing the potential for rapid absorption of insulin into the blood. In addition, unlike other oral insulin products under development that must be swallowed, the sublingual delivery of VIAtab™ may avoid the destructive effects on insulin by the stomach and liver. We are developing VIAtab™ as a potential treatment for patients with Type 2 diabetes in the early stages of their disease. We believe that VIAtab™ may be a suitable treatment for these patients because of its potential rapid delivery and because it does not require injections.

In our preclinical *in vitro* and animal studies, we successfully delivered insulin by sublingual administration. We are currently in Phase I clinical testing of VIAtab™ in patients with Type 1 diabetes. During this phase, we test for changes in patients' blood insulin levels following administration of VIAtab™. Because Type 1 diabetics do not produce their own insulin, changes in their insulin levels provide evidence of VIAtab™'s delivery of insulin to their blood. If the trial is successful, we plan to initiate later stage clinical trials of VIAtab™ no earlier than the end of 2008.

Additional Pipeline Opportunities

In addition to our clinical insulin product candidates, we have used our VIAdel™ technology to develop two preclinical product candidates for the treatment of osteoporosis.

VIAmass™

VIAmass™ is a sublingual, rapid-acting formulation of PTH 1-34. PTH 1-34 is the active portion of the human parathyroid hormone and is used to treat and reverse osteoporosis. It is currently delivered by injection and manufactured by Eli Lilly under the trade name Forteo®. Parathyroid hormone is normally released by the body in a spike-like fashion. This rapid release profile is particularly important to achieving its desired clinical effect of bone strengthening and growth. In animal studies, when administered continuously as opposed to rapidly, PTH 1-34 caused bone loss, just the opposite of its desired clinical effect. Because PTH 1-34 requires rapid entry into the blood in order to provide effective treatment and because we believe that we can administer it in a sublingual fashion, we believe it is a good candidate for our VIAdel™ technology. We believe that a non-invasive formulation is preferred by most of the patients using this product who are older women with osteoporosis. To date, we have made formulations of PTH 1-34, characterized them, studied their stability and tested them in human sublingual cell culture models.

VIAcal™

VIAcal™ is a sublingual, rapid acting formulation of recombinant salmon calcitonin. Salmon calcitonin is another peptide hormone used to treat osteoporosis. It is administered by injection and as a nasal spray and is sold by various companies, including Novartis. The pharmacologic activity of salmon calcitonin is the same as that of the naturally produced human hormone, but salmon calcitonin is substantially more potent on a weight basis and has a longer duration of action in humans. Salmon calcitonin acts predominantly on bone to depress bone resorption. Because salmon calcitonin requires rapid entry into the blood and because we believe that we can administer it in a sublingual fashion, we believe it is a good candidate for our VIAdel™ technology. To date, we have made formulations of salmon calcitonin, characterized them, studied their stability and tested them in human sublingual cell culture models.

Our VIAdel™ Technology

Peptide hormones, such as insulin, parathyroid hormone, calcitonin and growth hormone, are valuable drugs used to treat a variety of important human diseases. Peptide hormones are, in general, relatively unstable and poorly absorbed into the blood from the gastrointestinal tract. As a result, they are typically given by subcutaneous injection. Because peptide hormones are charged molecules, their absorption from injection sites is inhibited and slowed. This is in contrast to their natural release into the blood, which is typically in one or more very rapid, spike-like, secretions. Slowing of the rate of absorption reduces the clinical efficacy of many peptide hormones, including insulin, parathyroid hormone and calcitonin in particular.

Our VIAdel™ technology consists of several proprietary models that we have developed to study the interaction of small molecules with peptide hormones and their effects on the stability, apparent molecular size, complexed state, surface charge distribution and rate of absorption and mechanisms of absorption of peptide hormones. These models have allowed us to develop proprietary formulations designed to increase the rate of absorption and stability of these peptide hormones, potentially allowing for improved efficacy by injection and for administration by non-invasive routes, such as sublingual administration.

We use our VIAdel™ technology to develop proprietary formulations of small molecules which form weak and reversible hydrogen bonds with their molecular cargo. By doing so, we believe that our formulations mask the charge on peptides. As a consequence, the peptides in our formulations face less resistance from cell membranes, which would generally repel them, thus allowing them to pass through cell membranes into the blood more rapidly and in greater quantities than other currently approved formulations of the same peptides. Our VIAdel™ technology is designed to allow us to develop formulations that stabilize delicate peptides which can result in longer shelf lives for our formulations. Furthermore, because we use our VIAdel™ technology to reformulate existing peptide drugs with ingredients that are generally regarded as safe by the FDA and because

our reformulations do not drastically alter the structure of these peptides, we believe that our VIAdel™ technology allows us to develop product candidates for which the Section 505(b)(2) approval pathway is available.

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. The process required by the FDA before prescription drug product candidates may be marketed in the United States 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 I clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase I clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.
- Phase II 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 III 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 III clinical trials depends upon clinical and statistical considerations for the product candidate and disease, but sometimes can include several thousand patients. Phase III 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. We cannot at this time predict when the clinical testing process will be completed, if at all. 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 submission of an NDA also is subject to the payment of user fees, but a waiver of the fees may be obtained under specified circumstances.

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 an approvable 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 IV 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.

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 than would be required under a full NDA. The degree to which an applicant may avoid conducting such studies varies depending on the drug, the amount and quality of data publicly available for the applicant to rely on, and 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 unique and complex drug in that it is a complex hormone molecule, which 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 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 7½ 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.

New Legislation. On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007, or FDAAA. This new legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. In addition, the new law significantly expands the federal government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

The FDA has not yet implemented many of the provisions of the FDAAA, so we cannot predict the impact of the new legislation on the pharmaceutical industry or our business. However, the requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval for new pharmaceutical products, or to produce, market and distribute existing products. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and our products. It is impossible to predict whether additional legislative

changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Regulations Outside the United States

In addition to regulations in the United States, we will be subject to a variety of 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. While we believe that product candidates using our VIAdel™ technology will be an improvement over existing products, our product candidates will compete against many products with similar indications.

If approved, our primary competition for VIAject™ will be rapid acting meal-time 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, VIAject™ may face competition from products employing non-invasive methods of insulin delivery, such as oral insulin pills, which are currently in development, or others which are in clinical development. Emisphere Technologies, Inc. is developing oral insulin in pill form. Emisphere is still in early-stage preclinical trials of its oral tablet. Generex has developed an oral spray that is currently in Phase II development. The development of insulin formulations that are taken orally, or swallowed, face problems because insulin is largely broken down in the digestive system and as a result much of the insulin delivered orally does not enter the blood and the timing and amount of dosage that does is variable and unpredictable.

Of all non-invasive methods for the delivery of insulin, pulmonary administration has generated some of the most promising results. MannKind's pulmonary Technosphere™ technology is a New Chemical Entity currently in Phase III clinical trials in Type 1 and Type 2 diabetic patients. Eli Lilly, in collaboration with Alkermes, is currently in Phase III clinical trials for pulmonary insulin delivery systems. The Eli Lilly/

Alkermes product, AIR®, is currently being tested in Type 1 diabetic patients. Novo Nordisk and Aradigm Corporation also have AERx®, a pulmonary insulin product under development. Phase III clinical trials for AERx® were halted due to poor results, but the re-initiation of the drug's Phase III program was announced on March 7, 2006. In addition, Kos Pharmaceuticals, Inc., recently acquired by Abbott, is also developing an inhaled formulation of insulin, but the product appears to be several years behind the competition.

Insulin administered as a nasal spray has been studied extensively but does not appear to be a practical route for insulin administration because without the addition of penetration enhancers, the bioavailability of the insulin is too low and too variable. Nasally administered insulin using penetration enhancers has produced irritation and destruction of the nasal passages with frequent use.

There are five main classes of drugs that are currently used to treat osteoporosis: bisphosphonates, selective estrogen receptor modulators, calcitonins, hormone replacement therapies and PTH. With the exception of PTH, these drugs are used to reduce bone loss. The market leading oral bisphosphonates, such as alendronate, which is manufactured by Merck under the trade name Fosomax®, and risedronate which is manufactured by Proctor & Gamble under the trade name Actonel®, are administered in a convenient oral form, but have poorly tolerated gastrointestinal side effects and tend to produce abnormal and deficient bone. Since VIAcal™ and VIAmass™ are administered sublingually, we believe these products will offer the convenience of an oral product while by-passing potential gastrointestinal side effects. Accordingly, we believe doctors and patients will be attracted to the safer efficacious treatments found in VIAcal™ and VIAmass™.

Unlike the drug classes that reduce bone loss, PTH actually rebuilds lost bone. Currently available PTH such as Eli Lilly's Forteo® is administered by injection. This may be an inconvenient method of administration for patients who suffer from osteoporosis, most of whom are elderly. Since VIAcal™ and VIAmass™ are administered sublingually, we believe these products will serve an unmet need and may make substantial inroads in the treatment of osteoporosis.

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 VIAject™ and VIAtab™, two product candidates in clinical trials. The patent will expire no earlier than January 2026.

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

- ten pending United States patent applications and corresponding foreign and international patent applications relating to our VIAject™ and VIAtab™ technology;
- one pending United States patent application and corresponding foreign patent applications 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;
- two pending United States patent applications and corresponding foreign patent applications relating to sublingual and/or oral delivery devices that can be used to deliver the VIAdel™ product; and
- one pending United States patent application and a corresponding international patent application relating to a device for mixing injectable drugs.

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 VIAject™ and VIAtab™ 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 is 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

While we believe our laboratory in Danbury, Connecticut is equipped to meet the limited manufacturing requirements of all of our product candidates through Phase II clinical trials, we intend to manufacture our product candidates by contracting with third parties which operate manufacturing facilities in accordance with cGMP. We have contracted with Catalent Pharma Solutions (formerly known as Cardinal Health — PTS, LLC), a large commercial manufacturer, to manufacture our VIAject™ product candidate to supply our Phase III clinical trials and our initial commercial requirements. This agreement has no specified termination date, but generally may be terminated upon sixty days advance notice by either party in the event of an uncured breach. We believe that the manufacturer complies with the relevant regulatory requirements. Working with our commercial manufacturer, we have manufactured all three commercial size batches necessary for regulatory approval. We believe that if this manufacturer becomes unable or unwilling to supply VIAject™ we will be able to promptly find a replacement manufacturer to facilitate the manufacturing of VIAject™.

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 November 2009; however, N.V. Organon has agreed to continue to supply us with insulin pursuant to the terms of the agreement until we have qualified a new insulin supplier. We are currently in the process of qualifying additional insulin suppliers, as well as discussing with N.V. Organon the implementation of a new commercial supply agreement. We believe that, prior to the termination of this agreement, we will have procured from N.V. Organon quantities of insulin sufficient to support our needs for at least three years following the commercial launch of our insulin product candidates.

Sales and Marketing

We currently have limited 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 late in or upon completion of clinical development. In entering into these collaboration agreements, our goal will be to maintain co-promotion or co-commercialization rights in the United States and potentially other markets. In order to implement our strategy successfully, we must develop a specialized sales and marketing organization with sufficient technical expertise.

We generally expect to retain commercial rights for our product candidates for which we receive marketing approvals in situations in which we believe it is possible to access the market through a focused, specialized sales force. In particular, we plan to focus on the pediatric market because we believe VIAject™ is particularly suited for the treatment of children with diabetes, the number of pediatric endocrinologists is relatively few and we believe this patient population is underserved.

Employees

At September 30, 2007 we had 30 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, 2007:

Name	Age	Position
Dr. Solomon S. Steiner	70	Chairman, President and Chief Executive Officer
Gerard Michel	44	Chief Financial Officer, Vice President, Corporate Development and Treasurer
Dr. Roderike Pohl	46	Vice President, Research
Erik Steiner	41	Vice President, Operations
Dr. Andreas Pfützner	47	Chief Medical Officer
R. Timmis Ware	71	Corporate Secretary and General Counsel

Dr. Solomon S. Steiner co-founded our company and has served as our Chairman, President and Chief Executive Officer since our inception in December 2003. 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. Dr. Steiner is Erik Steiner's father.

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., Microbology from The University of Rochester School of Medicine and Dentistry.

Dr. Roderike Pohl joined our company and has served as our Vice President, Research since our inception in December 2003. From August 2003 to November 2003, Dr. Pohl served as a scientific consultant with Steiner Ventures, LLC, or SV. From December 1998 to July 2003, Dr. Pohl served as Vice President of Preclinical Research at PDC, now MannKind Corporation. Dr. Pohl received a Ph.D. from the University of Connecticut, School of Pharmacy.

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 SV. 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.

Dr. Andreas Pfützner has served as our Vice President, Chief Medical Officer since April 2005 and since October 2004 has served on our scientific advisory board. In 1998, Dr. Pfützner founded the Institute for Clinical Research and Development in Mainz, Germany and serves as its Managing Director. Since 2001, Dr. Pfützner has been a professor of applied clinical research at the University of Applied Sciences Rheinbach. From 2000 to 2002, Dr. Pfützner was Senior Vice President of Medical and Regulatory Affairs at PDC and later MannKind Corporation. Dr. Pfützner holds an M.D. from University of Mainz, Germany and a Ph.D. from Rocheville University. Dr. Pfützner is our part time Chief Medical Officer, devoting approximately 25% of his time to our affairs.

Mr. R. Timmis Ware has served as our general counsel and corporate secretary since joining us in August 2005. From December 2001 to August 2005, Mr. Ware was in private practice. From June 1994 to December 2001, Mr. Ware served as general counsel and corporate secretary of PDC, now MannKind Corporation. Prior thereto, Mr. Ware was a partner at the law firm of Chadbourne & Parke, LLP. Mr. Ware is a member of the New York and Florida Bars and received an L.L.B. from New York University.

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 applicable to common stockholders was approximately $27.0 million for the year ended September 30, 2007. As of September 30, 2007, we had a deficit accumulated during the development stage of approximately $39.8 million. We have devoted substantially all of our time, money and efforts to the research and development of VIAject™, VIAtab™ and our preclinical product candidates. We have not completed development of any drugs. We expect to continue to incur significant and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- continue our ongoing Phase III clinical trials of VIAject™ in which we plan to treat 400 patients with Type 1 diabetes and 400 patients with Type 2 diabetes over a six-month period;
- conduct additional Phase I clinical development of VIAtab™ and subsequently initiate Phase II and Phase III clinical trials;
- continue the research and development of our preclinical product candidates, VIAmass™ and VIAcal™, and advance those product candidates into clinical development;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales and marketing infrastructure to commercialize products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development efforts and our obligations as a public company.

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 are only in the preliminary stages of these activities. 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 would 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, and all but VIAject™ are in early stages of development. Our product candidates will require significant additional development, clinical development, regulatory approvals and additional investment before they can be commercialized. We anticipate that VIAject™ will not be commercially available for several years, if at all.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our Phase III clinical trials of VIAject™, commence later stage clinical trials of VIAtab™ if our Phase I clinical development is successful and conduct preclinical testing of VIAmass™ and VIAcal™. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, securing commercial quantities of product from our manufacturers and distribution. We will need substantial additional funding and may be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or eliminate our research and development programs or commercialization efforts.

Based upon our current plans, we believe that our cash and cash equivalents will enable us to fund our anticipated operating expenses and capital expenditures for at least the next eighteen months. However, 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:

- the progress and results of our clinical trials of VIAject™ and VIAtab™;
- the progress of the development of the full line of VIAject™ insulin products;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for VIAmass™, VIAcal™ and other potential product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- 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;
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities;
- our degree of success in commercializing VIAject™ and our other product candidates; 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 most advanced product candidates, VIAject™ and VIAtab™. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, 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 will 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 depend heavily on the success of our most advanced product candidate, VIAject™. VIAtab™ is our only other product candidate which has undergone clinical development. We do not expect to advance any other product candidates into clinical trials any earlier than late 2008. Clinical trials of our product candidates may not be successful. If we are unable to commercialize VIAject™ and VIAtab™, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidates, VIAject™ and VIAtab™. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates. 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 commercial manufacturing arrangements with third-party manufacturers;
- launching commercial sales of the products, whether alone or in collaboration with others;
- acceptance of the products by patients, the medical community and third-party payors in the medical community;
- competition from other products; and
- a continued acceptable safety profile of the products following approval.

If we are not successful in completing the development and commercialization of our product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

The results of early stage clinical trials do not ensure success in later stage clinical trials.

To date, we have not completed the development of any products through commercialization. VIAject™ is currently being tested in two Phase III clinical trials in patients with Type 1 and Type 2 diabetes. If these trials are successful, we intend to submit an NDA under Section 505(b)(2) of the FFDCA to the FDA by the

end of 2008. We are currently in the Phase I stage of clinical testing of VIAtab™ in patients with Type 1 diabetes. If Phase I clinical development of VIAtab™ is successful, we plan to initiate a Phase II clinical trial no earlier than the end of 2008. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results. For example, the two interim results of our Phase II meal study of VIAject™ were based on data from the first 10 patients that completed the trial in time for presentation at the American Diabetes Association 2007 Annual Meeting and then 16 patients that completed the study. The final results of this trial may be different from those suggested by our interim analyses. Similarly, the final results from our Phase III clinical trials of VIAject™ may be different than those observed to date. In addition, the final safety and efficacy data from our Phase III clinical trials of VIAject™, which will be based on 400 Type 1 and 400 Type 2 diabetes patients, may be less favorable than the data observed to date in our Phase I and Phase II clinical trials. We cannot assure you that our clinical trials of VIAject™ or VIAtab™ will ultimately be successful. New information regarding the safety and efficacy of VIAject™ or VIAtab™ may arise from our continuing analysis of the data that may be less favorable than the data observed to date. In our clinical trials to date, patients took VIAject™ for a relatively small number of treatment days. VIAject™ may not be found to be effective or safe when taken for longer periods, such as the six-month period of our Phase III clinical trials.

Even if our early phase clinical trials are successful, we will need to complete our Phase III clinical trials of VIAject™ and conduct Phase II and Phase III clinical trials of VIAtab™ in larger numbers of patients taking the drug for longer periods before we are able to seek approvals to market and sell these product candidates from the FDA and similar regulatory authorities outside the United States. 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.

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 VIAject™ and VIAtab™ can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing of VIAmass™ and VIAcal™ and clinical trials of VIAject™ and VIAtab™ that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we had expected to be promising;
- 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 or 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.

The major safety concern with patients taking insulin is the occurrence of hypoglycemic events, which we monitor on a daily basis in our clinical trials. As of March 12, 2007, we have had a total of 113 mild and moderate hypoglycemic events in our Phase III clinical trials, 73 in patients receiving Humulin® R and 40 in patients receiving VIAject™. As of that date, we have also had a total of four severe hypoglycemic events, three in patients receiving Humulin® R and one in a patient receiving VIAject™.

The commercial success of any product candidates that we may develop, including VIAject™, VIAtab™, VIAmass™ and VIAcal™ 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 VIAject™, VIAtab™, VIAmass™ and VIAcal™, 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

factors, including the reimbursement policies of government and third-party payors and the effectiveness of our competitors in marketing their 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 technology;
- 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 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 and could delay the commercialization of our product candidates and have a material and adverse affect on our business.

A broad base of physicians, including primary care physicians, internists and endocrinologists, treat patients with diabetes. A large sales force is 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. 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 are subject to pricing pressures and uncertainties regarding Medicare reimbursement and reform.

Recent 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 into 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 proposed clinical trials of VIAject™. 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 meal-time 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. Emisphere Technologies, Inc. is developing oral insulin in pill form. Emisphere is still in early-stage preclinical trials of its oral tablet. Generex has developed an oral spray that is currently in Phase II development. Several companies are also developing alternative insulin systems for diabetes, including Novo Nordisk, Eli Lilly and Company in collaboration with Alkermes, Inc., MannKind Corporation, Emisphere Technologies, Inc. and Aradigm Corporation. In addition, a number of established pharmaceutical companies, including GlaxoSmithKline plc and Bristol-Myers Squibb Company, are developing proprietary technologies or have entered into arrangements with, or acquired, companies with technologies for the treatment of diabetes.

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 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 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. Although we have contracted with a large commercial manufacturer for VIAject™, there can be no assurance that we will be able to do so successfully with our remaining product candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques, processes and quality controls.

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 termination or nonrenewal of the agreement by the third party, 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 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 for 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 VIAject™ and VIAtab™ 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 currently have an agreement with a single insulin supplier that is responsible for providing all of the insulin that we use for testing and manufacturing VIAject™ and VIAtab™. If supply of recombinant human insulin and other materials becomes limited, or if our supplier does 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 future commercialization of VIAject™ and VIAtab™. 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 on 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 patent and have ten pending United States patent applications relating to our VIAdel™, VIAject™ and VIAtab™ technology. 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 VIAject™ and VIAtab™ product candidates have been known and used for many years and, therefore, are no longer subject to patent protection. Accordingly, our 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.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates, and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Securing FDA approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA. Our future products may not be demonstrated effective, may be demonstrated only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or may prevent or limit commercial use.

The process of obtaining FDA and other regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved, the nature of the disease or condition to be treated and challenges by competitors. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying agency interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

We believe that VIAject™ and VIAtab™ 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 a Section 505(b)(2) NDA. The FDA may not agree that our products are approvable under Section 505(b)(2). Insulin is a unique and complex drug in that it is a complex hormone molecule that is more difficult to replicate and has more complex and unpredictable effects in the body than many small molecule drugs. The availability of the Section 505(b)(2) pathway for insulin is even more controversial than for small molecule drugs, and the FDA may not accept this pathway for our insulin product candidates. The FDA has not published any guidance that specifically addresses insulin Section 505(b)(2) NDAs. No other insulin product has yet 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. 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 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. 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 VIAject™ and VIAtab™ are 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 comparable regulatory authorities. These requirements include 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. Discovery after approval of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with 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;

- 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 seizure;
- injunctions; or
- imposition of civil or criminal penalties.

In addition, our product labeling, advertising and promotion is 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 for uses that are not approved by the FDA as reflected in the product's approved labeling. 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.

Recently enacted legislation may 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 September 27, 2007, the President signed into law the FDAAA. This new legislation grants significant new powers to the FDA, many of which are aimed at improving drug safety and assuring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a significant impact on the pharmaceutical industry, the FDA has not yet implemented many of its provisions and the extent of the impact is not yet known. The new requirements and changes imposed by the FDAAA may make it more difficult, and more costly, to obtain and maintain approval of new pharmaceutical products and to produce, market and distribute existing products.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations 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 changed, 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 process 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, which we monitor on a daily basis in our clinical trials. As of March 12, 2007, we have had a total of 113 mild and moderate hypoglycemic events in our Phase III clinical trials, 73 in patients receiving Humulin® R and 40 in patients receiving VIAject™. As of that date, we have also had a total of four severe hypoglycemic events, three in patients receiving Humulin® R and one in a patient receiving VIAject™. 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. Solomon S. Steiner, our Chairman, President and Chief Executive Officer, Dr. Roderike Pohl, our Vice President, Research, and Gerard Michel, our Chief Financial Officer. Dr. Steiner and Dr. Pohl are the inventors of our VIAdel™ technology. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. With the exception of Dr. Steiner and Dr. Pohl, who each have employment agreements, all of our employees are "at will" and we currently do not have employment agreements with any of the other members of our management or scientific staff. 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. Other than a $1 million key person insurance policy on Dr. Steiner, we do not have key person life insurance to cover the loss of any of our other 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 expect to 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.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and sales and marketing. 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. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own shares representing more than 50% of our outstanding capital stock. As a result, these stockholders, if they act together, will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations and sales of all or substantially all of our assets, and will have significant control over our management and policies. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders. This significant concentration of stock ownership could also result in the entrenchment of our management and adversely affect the price of 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.

We may not be able to comply on a timely basis with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and the related rules of the Securities and Exchange Commission, beginning with our fiscal year ending September 30, 2008, we will be required to include in our annual report an assessment of the effectiveness of our internal control over financial reporting. Furthermore, our registered independent public accounting firm will be required to report on the effectiveness of our internal control over financial reporting. We have not yet completed our assessment of the effectiveness of our internal control over financial reporting. We restated our financial statements for the three- and nine-months ended June 30, 2007 and for the year ended September 30, 2006 to correct errors in the calculation of non-cash compensation expense related to options issued to non-employees. In connection with the restatement it was determined that we have had material weaknesses in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board. We addressed and resolved these material weaknesses. We are also in the process of documenting, reviewing and, where appropriate, improving our internal controls and procedures in preparation for becoming subject to the requirements of Section 404 of the Sarbanes-Oxley Act and the related rules. Implementing appropriate changes to our internal controls may entail substantial costs in order to modify our existing financial and accounting systems, take a significant period of time to complete, and distract our officers, directors and employees from the operation of our business. Moreover, these changes may not be effective in maintaining the adequacy or effectiveness of our internal controls. If we fail to complete the assessment on a timely basis, or if our independent registered public accounting firm cannot attest to our assessment, we could be subject to regulatory sanctions and a loss of public confidence. Also, the lack of effective internal control over financial reporting may adversely impact our ability to prepare timely and accurate financial statements.

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

Our stock price may 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.

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.

We will incur substantial costs as a result of operating as a public company, and our management will be 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 maintain office space and laboratory facilities of 29,700 square feet in Danbury, Connecticut. On July 23, 2007 and as amended on October 1, 2007, we entered into a lease agreement with Mulvaney Properties LLC for approximately 20,000 square feet of rentable office space located at 100 Saw Mill Road, Danbury, Connecticut for a seven year term beginning August 1, 2007 until July 31, 2014. Upon 180 days written notice prior to the expiration of the lease, we may renew the lease for one additional seven year term under the same terms and conditions. Our laboratory facility of approximately 9,700 square feet is subject to a lease that expires in January 2010. Our laboratory 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 current Good Manufacturing Practices ("cGMP").

We moved into our new corporate headquarters in the first quarter of fiscal year 2008. We expect a new full service laboratory, research and development facility intended to replace our current facility to be completed in fiscal 2010.

ITEM 3. *LEGAL PROCEEDINGS*

We currently are not involved in any legal proceedings.

ITEM 4. *SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS*

None.

PART II

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 May 11, 2007 through September 30, 2007, as reported on the NASDAQ Global Market:

Quarter Ended	High	Low
June 30, 2007	$21.89	$16.26
September 30, 2007	$17.33	$16.80

The closing price of our common stock, as reported by the NASDAQ Global Market, was $19.54 on December 14, 2007.

Holders

As of December 14, 2007, the number of holders of record of our common stock was 72.

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 2008 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 2007, 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, 2007 and the balance sheet data as of September 30, 2006 and 2007 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 period from inception to September 30, 2004 and the balance sheet data as of September 30, 2004 and 2005 set forth below from our audited financial statements, which are not included in this Annual Report. Our unaudited 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.

	December 3, 2003 (Inception) to September 30, 2004	Year Ended September 30, 2005	2006	2007
	(In thousands, except share and per share data)			
Statement of operations data:				
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	580	2,666	5,987	15,939
General and administrative	193	724	1,548	8,386
Total operating expenses	773	3,390	7,535	24,325
Other (income) and expense:				
Interest and other income	—	(9)	(182)	(1,902)
Interest expense	—	—	78	—
Loss on settlement of debt	—	—	627	—
Operating loss before tax provision	(773)	(3,381)	(8,058)	(22,423)
Tax provision	1	2	10	125
Net loss	(774)	(3,383)	(8,068)	(22,548)
Charge for accretion of beneficial conversion rights	—	—	(603)	—
Deemed dividend — warrants	—	—	—	(4,457)
Net loss applicable to common stockholders	(774)	(3,383)	(8,671)	(27,005)
Net loss per share — basic and diluted	$ (0.15)	$ (0.56)	$ (1.05)	$ (1.76)
Weighted average shares outstanding — basic and diluted	5,313,744	6,080,746	8,252,113	15,354,898

	As of September 30, 2004	2005	2006	2007
		(In thousands)		
Balance sheet data:				
Cash and cash equivalents	$ 221	$ 368	$ 17,539	$ 80,022
Working capital (deficit)	194	(98)	15,307	75,244
Total assets	611	1,195	18,659	82,506
Long-term debt	—	—	—	—
Deficit accumulated during the development stage	(774)	(4,157)	(12,828)	(39,833)
Total stockholders' equity	581	654	16,348	77,223

ITEM 7. *MANAGEMENT'S 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 endocrine disorders, such as diabetes and osteoporosis, which may be safer, more effective and convenient. We develop our product candidates by applying our proprietary formulation technologies to existing drugs in order to improve their therapeutic results. Our initial development efforts are focused on peptide hormones. We have two insulin product candidates currently in clinical trials for the treatment of diabetes and two preclinical product candidates for the treatment of osteoporosis.

Our most advanced product candidate is VIAject™, a proprietary injectable formulation of recombinant human insulin designed to be absorbed into the blood faster than the currently marketed rapid-acting insulin analogs. We are currently conducting two pivotal Phase III clinical trials of VIAject™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. In addition to VIAject™, we are developing VIAtab™, a sublingual tablet formulation of insulin. We are currently in the Phase I stage of clinical testing of VIAtab™ in patients with Type 1 diabetes. Our preclinical product candidates for the treatment of osteoporosis are VIAmass™, a sublingual rapid-acting formulation of parathyroid hormone 1-34, and VIAcal™, a sublingual rapid-acting formulation of salmon calcitonin.

We have developed all of our product candidates utilizing our proprietary VIAdel™ technology which allows us to study the interaction between peptide hormones and small molecules. We use our technology to reformulate existing peptide drugs with small molecule ingredients that are generally regarded as safe by the FDA to improve their therapeutic effect by entering the blood more rapidly and in greater quantities.

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 and prior to that, 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 applicable to common stockholders was $27.0 million for the year ended September 30, 2007. As of September 30, 2007, we had a deficit accumulated during the development stage of $39.8 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. Research and development and general and administrative expenses represent approximately 59% and 31%, 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.

In April 2007, the Company effected a 0.7085 for one (0.7085:1) reverse stock split. All references in the Management's Discussion and Analysis of Financial Condition and Results of Operations, financial statements and comments on the units of common stock or per share amounts are reflective of the reverse split for all periods reported.

In May 2007, we completed our initial public offering of 5,750,000 shares of common stock primarily with institutional investors at a price to the public of $15.00 per share, with net proceeds totaling approximately $78.8 million. The completion of the initial public offering resulted in the conversion of our

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.

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 costs 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.

We use our employee and infrastructure resources across multiple research projects, including our drug development programs. To date, we have not tracked expenses related to our product development activities on a program-by-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, we estimate that the majority of our research and development expenses incurred to date are attributable to our VIAject™ program. The following table illustrates, for each period presented, our research and development costs by nature of the cost.

	December 3, 2003 (Inception) to September 30, 2004	Year Ended September 30,			December 3, 2003 (Inception) to September 30, 2007
		2005	2006	2007	
		(In thousands)			
Research and development expenses:					
Pre-clinical expenses	$495	$1,261	$1,575	$ 1,983	$ 5,314
Manufacturing expenses	13	241	1,264	2,141	3,659
Clinical/regulatory expenses	72	1,164	3,148	11,815	16,199
Total	$580	$2,666	$5,987	$15,939	$25,172

The successful development of our product candidates is highly uncertain. If our ongoing Phase III clinical trials of VIAject™ are successful, we intend to submit an NDA to the FDA for this product candidate line by the end of 2008. We are currently in the Phase I stage of clinical testing of VIAtab™ in patients with Type 1 diabetes. If the Phase I development is successful, the earliest we plan to initiate later stage clinical trials of VIAtab™ would be the end of 2008. Development of a full line of VIAject™ insulin products has progressed more rapidly than we originally anticipated. Given the priority being placed on the development of our VIAject™ product line, we now expect to submit INDs for VIAcal™ and VIAmass™ no earlier than late in 2008. However, 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:

- the progress and results of our clinical trials of VIAject™ and VIAtab™;
- the progress of the development of the full line of VIAject™ insulin products:
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for VIAmass™, VIAcal™ and other potential product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the cost 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;
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities;
- our degree of success in commercializing VIAject™ and our other product candidates; and
- our ability to establish and maintain collaborations and the terms and success of those 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 a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of the clinical development of a product candidate, we could be required to expend significant additional financial resources and time on the completion of that clinical development program.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and non-cash stock-based compensation for administrative, finance, business development, human resources, legal and information systems support personnel. In addition, general and administrative expenses include business insurance and professional services costs.

On July 23, 2007, we entered into a lease agreement, amended on October 1, 2007, with Mulvaney Properties LLC for approximately 20,000 square feet located in Danbury, Connecticut, or the Leased Premises. The lease provides for a seven year term beginning August 1, 2007 until July 31, 2014. We have agreed to use the leased premises only for offices, laboratories, research, development and light manufacturing. Upon 180 days written notice prior to the expiration of the lease, we may renew the lease for one additional seven year term under the same terms and conditions.

Also on July 23, 2007, we entered into an amendment to each of the following existing agreements between us and Mulvaney: (1) Lease Agreement, dated February 2, 2004, as amended, for the premises located at 6 Christopher Columbus Avenue, Danbury, Connecticut, or the First Lease and (2) Lease Agreement, dated October 19, 2006, for the premises located at 8 Christopher Columbus Avenue, Danbury, Connecticut, or the Second Lease. We have the option to terminate the First Lease by giving 90 days prior notice to Mulvaney. We have the option to terminate the Second Lease by giving 60 days prior notice to Mulvaney.

In September 2007, we gave our notice to terminate the lease on 8 Christopher Columbus Avenue, effective October 31, 2007. We moved into our new corporate headquarters in the first quarter of fiscal year 2008. We expect a new full service laboratory, research and development facility intended to replace our current facility, will be completed in fiscal 2010.

General and administrative expenses consist primarily of salaries and related expenses for personnel, including stock-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 increase, among others, for the following reasons:

- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue the development of our product candidates;
- we expect to incur additional expenses related to the entry into the new leased premises;
- we expect to incur additional expenses as we advance discussions and negotiations in connection with strategic collaborations for commercialization of our product candidates;
- we may also begin to incur expenses related to the sales and marketing of our product candidates as we approach the commercial launch of any product candidates that receive regulatory approval; and
- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, accounting and investor relation fees associated with being a public company.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents, resulting primarily from the $78.8 million in net proceeds received from our initial public offering in May 2007. In November 2006, our Board of Directors approved investment policy guidelines, the primary objectives of which are the preservation of capital, the maintenance of liquidity, maintenance of appropriate fiduciary control and maximum return, subject to our business objectives and tax situation.

Our interest expense consists of interest incurred on promissory notes that we issued in 2006 as part of our mezzanine financing. In July 2006, in connection with our Series B convertible preferred stock financing, all of these promissory notes were repaid with shares of our Series B convertible preferred stock and warrants. As of September 30, 2007, we had no interest-bearing indebtedness outstanding.

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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our 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 other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value 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.

Stock-Based Compensation

Effective October 1, 2005, we adopted SFAS No. 123(R), which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value. We adopted SFAS No. 123(R) using the retrospective method. Under this method, compensation cost is measured and recognized for all share-based payments granted subsequent to October 1, 2004. We issued no options prior to that date. The fair value of the stock underlying the options is a significant factor in determining credits or charges to operations appropriate for the stock-based payments to both employees and non-employees. Between December 23, 2004 and May 27, 2005, we granted options to purchase an aggregate of 385,432 shares of our common stock at an exercise price of $1.41 per share. Between November 1, 2005 and November 1, 2006, we granted options to purchase an aggregate of 603,302 shares of our common stock at an exercise price of $5.65 per share. In December 2006, we granted options to purchase an aggregate of 235,375 shares of our common stock at an exercise price of $12.63 per share. In January 2007, we granted options to purchase an aggregate of 63,767 shares of our common stock at an exercise price of $12.63 per share. In May 2007, we granted options to purchase an aggregate of 200,000 shares of our common stock at an exercise price of $15.00 per share. In June 2007, we granted options to purchase an aggregate of 240,000 shares of our common stock at an exercise price of $18.16 per shares. In July 2007, we granted options to purchase an aggregate of 75,000 shares of our common stock at an exercise price of $18.76 per share.

Our Board of Directors determined the exercise price for the shares of common stock underlying options granted between December 2004 and May 2005 based upon the price per share at which we intended to offer and which we subsequently offered and sold our Series A convertible preferred stock to outside investors. That offering commenced in February 2005. For the options granted between December 2004 and May 2005, our Board of Directors also considered that VIAtab™ had just entered into Phase I clinical trials in March 2005 and VIAject™ had just entered into Phase I clinical trials in May 2005. We had achieved no significant clinical development or regulatory milestones with respect to these two product candidates. We had not sufficiently

developed our product candidates to be able to reasonably evaluate the probability of commercial success. Our Board of Directors recognized that significant additional funding would be required to continue our product development efforts and our corporate operations. Our Board of Directors did not know if those funds would be available to us. Given our stage of development, our Board of Directors could not reasonably contemplate a corporate collaboration, the sale of our company or an initial public offering. Our Board of Directors considered the high degree of uncertainty considering our future prospects and relevant economic and market conditions both generally and based on their experience in the biopharmaceutical industry.

In connection with the preparation for our initial public offering of our common stock, we reassessed the valuations of our common stock prior to December 2006 and between December 2006 and January 2007. As a result, we reassessed the fair value of our common stock as of July 14, 2005, July 19, 2006 and December 19, 2006, respectively.

We selected the Black-Scholes valuation model as the most appropriate valuation method for stock option grants to employees and members of our Board of Directors. The fair value of these stock option grants is estimated as of their date of grant using the Black-Scholes valuation method. Our compensation committee adopted the valuations of an independent third party appraiser in determining the fair market value of our common stock for the Black-Scholes model. For all options granted prior to July 14, 2005, we used a fair market value of $0.83 per share; for options granted between July 15, 2005 and July 19, 2006, we used a fair market value of $4.69 per share; for options granted after July 19, 2006, we used a fair market value of $12.63 per share; for options granted on May 10, 2007, we used a fair market value of $8.67; for options granted on June 5, 2007, we used a fair market value of $10.59; and for options granted on July 24, 2007, we used a fair market value of $11.59.

Because we lack 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 SFAS No. 123(R), particularly line of business, stage of development, size and financial leverage. We will continue to consistently apply this process using the same comparable companies until 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, 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 stock warrants or 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 method, 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, 2007, we issued to these non-employees options to purchase an aggregate of 342,111 shares of our common stock. Because we must revalue these options for accounting purposes each reporting period, the amount of the non-cash stock-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 year ended September 30, 2007, the non-cash stock-based compensation expense related to these options was $0.6 million, of which $0.3 million is reflected in research and development expenses and $0.3 million is reflected in general and administrative expenses.

For the year ended September 30, 2007, the stock-based compensation expense was $4.2 million, of which $0.7 million is reflected in research and development expenses and $3.5 million is reflected in general and administrative expenses. For the year ended September 30, 2006, the stock-based compensation expense related to these options was $1.1 million, of which $0.2 million is reflected in research and development expenses and $0.9 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. As of September 30, 2007, we had federal net operating loss carryforwards of $30.5 million, Connecticut state net operating loss carryforwards of $30.4 million and federal research and development tax credit carryovers of approximately $1.0 million, all of which expire starting in 2024.

The Internal Revenue Code contains provisions that may limit the net operating loss and credit carryforwards available to be used in any given year as a result of certain historical changes in the ownership interests of significant stockholders. As a result of the cumulative impact of our equity issuances over the past two years, a change of ownership, as defined in the Internal Revenue Code occurred upon our issuance of Series B convertible preferred stock in July 2006. As a result, our total net operating losses will be subject to an annual base limitation.

At September 30, 2007, we recorded a 100% valuation allowance against our net deferred tax asset of approximately $13.8 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.

Results of Operations

Year Ended September 30, 2007 Compared to Year Ended September 30, 2006

Revenue. We did not recognize any revenue during the years ended September 30, 2007 or 2006.

Research and Development Expenses. Research and development expenses were $15.9 million for the year ended September 30, 2007, an increase of $9.9 million, or 166%, from $6.0 million for the year ended September 30, 2006. This increase was primarily attributable to increased research and development costs related to our continuing two pivotal Phase III clinical trials for VIAject™ that we commenced in September 2006. Specific increases in research and development expenses included $8.3 million related to increased clinical trial expenses in 2007; $0.6 million related to increased manufacturing expenses in 2007 for the process development, scale-up and manufacture of commercial batches of VIAject™ to support our clinical trials and regulatory submissions; and $1.1 million related to increased personnel costs, non-cash stock-based compensation expenses and consulting fees. Research and development expenses for the year ended September 30, 2007 include $0.4 million in stock-based compensation expense related to options granted to employees and $0.3 million in stock-based compensation expense related to options granted to non-employees.

We expect our research and development expenses to increase in the future as a result of increased development costs related to our clinical VIAject™ and VIAtab™ product candidates and as we seek to advance our preclinical VIAmass™ and VIAcal™ product candidates into clinical development. The timing and amount of these expenses will depend upon the outcome of our ongoing clinical trials, particularly the costs associated with our ongoing Phase III clinical trials of VIAject™ and our Phase I and planned Phase II clinical trials of VIAtab™. The timing and amount of these expenses will also depend on the potential advancement of our preclinical programs into clinical development and the related expansion of our clinical development and regulatory organization, regulatory requirements and manufacturing costs.

General and Administrative Expenses. General and administrative expenses were $8.4 million for the year ended September 30, 2007, an increase of $6.9 million, or 442%, from $1.5 million for the year ended September 30, 2006. This increase is primarily attributable to a $3.8 million increase in personnel expense. The balance of the increase was attributable to increases in insurance expenses, depreciation expenses, and higher legal and consulting fees associated with becoming a public company. General and administrative expenses for the year ended September 30, 2007 include $3.2 million in non-cash stock-based compensation

expense related to options granted to employees and $0.3 million in non-cash stock-based compensation expense related to options granted to non-employees.

We expect our general and administrative expenses to continue to increase in the future as a result of an increased payroll as we add personnel necessary for the management of the anticipated growth of our business, expanded infrastructure and higher consulting, legal, accounting, investor relations and other expenses associated with being a public company.

Interest and Other Income. Interest and other income increased to $1.9 million for the year ended September 30, 2007 from $0.2 million for the year ended September 30, 2006. The increase was due to higher balances of cash and cash equivalents in 2007, resulting primarily from the $78.8 million in net proceeds received from our initial public offering in May 2007.

Interest Expense. Interest expense of approximately $78,000 for the year ended September 30, 2006 consisted of interest incurred on the promissory notes issued in our mezzanine financing. In July 2006, all of the promissory notes were repaid using shares of our Series B convertible preferred stock and warrants in connection with our Series B convertible preferred stock financing. For the year ended September 30, 2007, we had no interest expense.

Loss on Settlement of Debt. In July 2006, we completed our Series B convertible preferred stock financing. In connection with that transaction, we exercised our option to repay the promissory notes that we had issued in our mezzanine financing with shares of Series B convertible preferred stock and warrants. Due to the contractual terms of our mezzanine financing, these investors effectively received a 25% premium on the principal amount of the promissory notes that were a part of the mezzanine financing units. As a result of this 25% premium, we recorded a loss on settlement of debt of $0.6 million. No equivalent charge to stockholders was incurred in the year ended September 30, 2007.

Charge for Accretion of Beneficial Conversion Rights. We recorded a beneficial conversion charge related to the issuance of our Series B convertible preferred stock and the conversion option embedded therein. In accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, we accreted the charge immediately and have shown a $0.6 million charge for accretion of beneficial conversion rights in the year ended September 30, 2006. No equivalent expense was incurred in the year ended September 30, 2007.

Deemed Dividend — Warrants. On March 20, 2007, we offered the holders of warrants to purchase an aggregate of 78,183 shares of Series B convertible preferred stock and an aggregate of 2,558,724 shares of 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 such warrants on a combination of cashless and cash exercise basis. We issued 2,636,907 shares of common stock and received aggregate cash proceeds of $0.4 million in connection with such exercises. As a result of the discounted exercise price, we recorded a non-cash deemed dividend of approximately $4.5 million for the warrants that were exercised in the year ended September 30, 2007. No equivalent charge to stockholders was incurred in the year ended September 30, 2006.

Net Loss Applicable to Common Stockholders and Net Loss per Share. Net loss applicable to common stockholders was $27.0 million, or $(1.76) per share, for the year ended September 30, 2007 compared to $8.7 million, or $(1.05) per share, for the year ended September 30, 2006. The increase in net loss was primarily attributable to the increased expenses described above and the non-cash deemed dividend charge of $4.5 million related to the discounted exercise price of our warrants. We expect our losses to increase in the future as we incur increased clinical development costs to advance our VIAject™ and VIAtab™ product candidates through the clinical development process and as our general and administrative costs rise as our organization grows to support this higher level of clinical activity.

Year Ended September 30, 2006 Compared to Year Ended September 30, 2005

Revenue. We did not recognize any revenue during the years ended September 30, 2006 or 2005.

Research and Development Expenses. Research and development expenses were $6.0 million for the year ended September 30, 2006, an increase of $3.3 million, or 124.6%, from $2.7 million for the year ended September 30, 2005. This increase was primarily attributable to increased research and development costs related to our continued development of VIAject™, for which we conducted two Phase II clinical trials during the year ended September 30, 2006. We also commenced our two pivotal Phase III clinical trials for VIAject™ in September 2006, for which we incurred trial start-up costs during the fiscal year. Specific increases in research and development expenses included $1.5 million related to increased clinical trial expenses in 2006; $1.1 million related to increased manufacturing expenses in 2006 for the process development, scale-up and manufacture of commercial batches of VIAject™ to support our clinical trials and regulatory submissions; and $0.5 million related to increased personnel costs and consulting fees. Research and development expenses for the year ended September 30, 2006 include $36,000 in stock-based compensation expense related to options granted to employees and $187,000 in stock-based compensation expense related to options granted to non-employees.

General and Administrative Expenses. General and administrative expenses were $1.5 million for the year ended September 30, 2006, an increase of $0.8 million, or 113.8%, from $0.7 million for the year ended September 30, 2005. Our initiation of performance-based bonuses accounted for approximately $0.3 million of that increase. The balance of the increase was primarily attributable to higher levels of legal and consulting fees. General and administrative expenses for the year ended September 30, 2006 include $0.2 million in stock-based compensation expense related to options granted to employees and $0.7 million in stock-based compensation expense related to options granted to non-employees.

Interest and Other Income. Interest and other income increased to $0.2 million for the year ended September 30, 2006 from $9,000 for the year ended September 30, 2005. The increase was due to our higher balances of cash and cash equivalents in 2006, resulting from the $21.2 million in cash proceeds that we received from our Series B convertible preferred stock and warrant financing in July 2006.

Interest Expense. Interest expense of approximately $78,000 for the year ended September 30, 2006 consisted of interest incurred on the promissory notes issued in our mezzanine financing. In July 2006, all of the promissory notes were repaid using shares of our Series B convertible preferred stock and warrants in connection with our Series B convertible preferred stock financing. As of September 30, 2006, we had no interest-bearing indebtedness outstanding.

Loss on Settlement of Debt. In July 2006, we completed our Series B convertible preferred stock financing. In connection with that transaction, we exercised our option to repay the promissory notes that we had issued in our mezzanine financing with shares of Series B convertible preferred stock and warrants. Due to the contractual terms of our mezzanine financing, these investors effectively received a 25% premium on the principal amount of the promissory notes that were a part of the mezzanine financing units. As a result of this 25% premium, we recorded a loss on settlement of debt of $0.6 million. No equivalent expense was incurred in the prior year.

Charge for Accretion of Beneficial Conversion Rights. We recorded a beneficial conversion charge related to the issuance of our Series B convertible preferred stock and the conversion option embedded therein. In accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, we accreted the charge immediately and have shown a $603,000 charge for accretion of beneficial conversion rights in the year ended September 30, 2006.

Net Loss Applicable to Common Stockholders and Net Loss per Share. Net loss applicable to common stockholders was $8.7 million, or $(1.05) per share, for the year ended September 30, 2006 compared to $3.4 million, or $(0.56) per share, for the year ended September 30, 2005. The increase in net loss was primarily attributable to the increased 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 have funded our research and development operations primarily 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. In May 2007, we completed our initial public offering and received proceeds, after deducting underwriting commissions and discounts of $78.8 million.

At September 30, 2007, we had cash and cash equivalents totaling approximately $80.0 million. To date, we have invested our excess funds in a bank-managed money market fund. We plan to continue to invest our cash and cash equivalents (including the net proceeds we received from our initial public offering in accordance with our approved investment policy guidelines, which set forth our policy to hold investments securities to maturity.

Net cash used in operating activities was $15.5 million for the year ended September 30, 2007, $3.9 million for the year ended September 30, 2006 and $2.4 million for the year ended September 30, 2005. Net cash used in operating activities for the year ended September 30, 2007 primarily reflects the net loss for the period, offset in part by non-cash stock-based compensation, depreciation and amortization expenses and increases in accrued expenses and accounts payable and a decrease in deferred compensation expenses. Net cash used in operating activities for the year ended September 30, 2006 primarily reflects the net loss for the period, offset in part by depreciation and changes in accounts payable, the loss on settlement of debt, other accrued expenses and deferred compensation.

Net cash used in investing activities was $1.4 million for the year ended September 30, 2007, $0.3 million for the year ended September 30, 2006 and $0.6 million for the year ended September 30, 2005. Net cash used in investing activities in each period primarily reflects purchases of property and equipment and leasehold improvement costs for our new corporate headquarters. The decrease from 2005 to 2006 was primarily related to reduced purchases of property and equipment.

Net cash provided by financing activities was $79.4 million for the year ended September 30, 2007, $21.4 million for the year ended September 30, 2006 and $3.1 million for the year ended September 30, 2005. Net cash provided by financing activities in 2007 primarily reflects the proceeds from our initial public offering. Net cash provided by financing activities in 2006 primarily reflects the proceeds from our mezzanine and Series B convertible preferred stock financings. Net cash provided by financing activities in 2005 primarily reflects the proceeds from our Series A convertible preferred stock financing.

On May 16, 2007, we completed an initial public offering of 5,750,000 shares of our common stock at a price to the public of $15.00 per share. The offering resulted in gross proceeds of $86.3 million. We received net proceeds from the offering of approximately $78.8 million after deducting underwriting discounts and commissions and additional offering expenses. The remaining net proceeds were invested in cash, cash equivalents and short-term investments, in accordance with our investment policy.

Funding Requirements

We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses and capital expenditures for at least the next eighteen months. 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. 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:

- the progress and results of our clinical trials of VIAject™ and VIAtab™;
- the progress of the development of the full line of VIAject™ insulin products;
- the scope, progress, results and costs of preclinical development and laboratory testing and clinical trials for VIAmass™, VIAcal™ and other potential product candidates;
- the costs, timing and outcome of regulatory reviews of our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- 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;
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities;
- our degree of success in commercializing VIAject™ and our other product candidates; and
- our ability to establish and maintain collaborations and the terms and success of those collaborations, including the timing and amount of payments that we might receive from potential strategic collaborators.

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 quarters and 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.

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 delay, reduce the scope of or eliminate some or all of our research and development programs, 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, 2007 (in thousands).

	Total	Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
Operating lease obligations	$3,561	$532	$1,544	$1,029	$456
Total fixed contractual obligations	$3,561	$532	$1,544	$1,029	$456

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which

permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 also includes an amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, which applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are assessing the impact of SFAS No. 159 and anticipate that the adoption of this accounting pronouncement will not have a material effect on our financial statements.

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, however, the FASB has agreed to defer for one year the effective date for certain non-financial assets and liabilities. We anticipate that the adoption of this accounting pronouncement will not have a material effect on our financial statements.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. FIN 48 is effective for us beginning October 1, 2007. We are in the process of evaluating the effect that FIN 48 will have on our financial statements.

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 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. Our current intention is to hold longer term investments to maturity. 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.

Because most of our transactions are denominated in United States dollars, we do not have any 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*

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, 2007. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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.

As previously reported in Amendment No. 1 to our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2007, our Chief Executive Officer and former Chief Financial Officer determined that, as of June 30, 2007, we had a material weakness in our internal control over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board. Specifically, as of June 30, 2007, we had a material weakness relating to our controls over accounting for stock options in that our procedures did not operate effectively to detect errors in the calculation of non-cash share-based compensation expense arising from the granting of stock options. To remedy the material weakness, we have implemented enhanced procedures that are designed to provide for additional management oversight of our accounting activities to ensure that we will properly record non-cash share-based expense in the future.

As a result of that material weakness and because the period ended September 30, 2007 represents the first accounting period in which we were able to evaluate the steps we implemented to remedy the material weakness, 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 not effective. However, notwithstanding the material weakness discussed above, our Chief Executive Officer and Chief Financial Officer have concluded that the financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

Except for the enhanced procedures implemented as noted above, no change in our internal control over financial reporting occurred during the fiscal quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

None.

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 2008 annual meeting of stockholders (the "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*

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/ SOLOMON S. STEINER

Dr. Solomon S. Steiner
President and Chief Executive Officer
Date: December 21, 2007

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/ SOLOMON S. STEINER Solomon S. Steiner	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	December 21, 2007
/s/ GERARD MICHEL Gerard Michel	Chief Financial Officer, Vice President, Corporate Development and Treasurer (Principal Financial and Accounting Officer)	December 21, 2007
/s/ ALBERT CHA Albert Cha	Director	December 21, 2007
/s/ DAVID KROIN David Kroin	Director	December 21, 2007
/s/ IRA W. LIEBERMAN Ira W. Lieberman	Director	December 21, 2007
/s/ DANIEL LORBER Daniel Lorber	Director	December 21, 2007
/s/ BRIAN J.G. PEREIRA Brian J.G. Pereira	Director	December 21, 2007
/s/ CHARLES SANDERS Charles Sanders	Director	December 21, 2007
/s/ SAMUEL WERTHEIMER Samuel Wertheimer	Director	December 21, 2007
/s/ SCOTT A. WEISMAN Scott A. Weisman	Director	December 21, 2007

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 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)).
4.4	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	Form of Indemnity Agreement entered into between the registrant and each of Albert Cha, Robert Feldstein, David Kroin, Daniel Lorber, Ira Lieberman, Charles Sanders, Roderike Pohl, and Solomon Steiner, Paul Sekhri, Erik Steiner, Samuel Wertheimer, R. Timmis Ware, Andreas Pfützner, and Scott Weisman (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.2	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)).
10.3	2005 Employee Stock Purchase Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.4	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)).
10.5	Amended and Restated Employment Agreement, dated March 20, 2007, as amended November 20, 2007, between the registrant and Solomon S. Steiner (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 20, 2007).
10.6	Amended and Restated Employment Agreement, dated March 20, 2007, between the registrant and Roderike Pohl (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504))
10.7	Amended and Restated Employment Agreement, dated November 1, 2006, between registrant and F. Scott Reding (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.8	Amended and Restated Consulting Agreement entered into on November 13, 2007, effective June 5, 2007, between the Company and Dr. Andreas Pfützner (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 14, 2007).
10.9†	Supply Agreement made on April 4, 2005 by and between Diosynth B.V. and the registrant (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.10†	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)).
10.11	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
10.12	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)).
10.13	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)).
10.14	Commercial Lease, dated July 23, 2007, by and between the Registrant's and Mulvaney Properties LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.15	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).
10.16	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).
10.17	Severance Agreement, dated November 14, 2007, by and between the registrant and F. Scott Reding (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 14, 2007).
10.18	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).
10.19	Form of Incentive Stock Option Agreement for 2004 Amended and Restated Stock Incentive Plan.
10.20	Form of Option Agreement for 2005 Non-Employee Directors' Stock Option Plan.
10.21	Executive Officer Compensation Summary.
10.22	Non-employee Director Compensation Summary.
23.1	Consent of BDO Seidman, 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.

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BIODEL INC.

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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, 2006 and 2007, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2007 and for the period from December 3, 2003 (inception) to September 30, 2007. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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, 2006 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2007 and for the period from December 3, 2003 (inception) to September 30, 2007, in conformity with accounting principles generally accepted in the United States.

/s/ BDO Seidman, LLP

New York, New York
December 11, 2007

Biodel Inc.
(A Development Stage Company)

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

	September 30, 2006	September 30, 2007
ASSETS		
Current:		
Cash and cash equivalents	$ 17,539	$ 80,022
Prepaid and other assets	79	505
Total current assets	17,618	80,527
Property and equipment, net	644	1,717
Intellectual property, net	208	262
Deferred public offering costs	189	—
Total assets	$ 18,659	$ 82,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current:		
Accounts payable	$ 1,357	$ 2,187
Accrued expenses:		
Clinical trial expenses	—	1,164
Payroll and related	186	822
Accounting and legal fees	—	335
Other	255	680
Income taxes payable	13	95
Due to related party	250	—
Deferred compensation	250	—
Total current liabilities	2,311	5,283
Commitments		
Stockholders' equity:		
Preferred stock, $.01 par value; 50,000,000 shares authorized:		
Series A convertible preferred stock, 1,050,000 shares authorized, 569,000 and 0 shares issued and outstanding, respectively, with a liquidation preference of $2,845 and an 8% non-cumulative dividend	6	—
Series B convertible preferred stock, 6,500,000 shares authorized, 6,198,179 and 0 shares issued and outstanding, respectively, with a liquidation preference of $24,421	62	—
Common stock, $.01 par value; 100,000,000 shares authorized; 5,360,430 and 20,160,836 issued and outstanding, respectively	54	202
Additional paid-in capital	29,054	116,854
Deficit accumulated during the development stage	(12,828)	(39,833)
Total stockholders' equity	16,348	77,223
Total liabilities and stockholders' equity	$ 18,659	$ 82,506

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, 2007
	2005	2006	2007	
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,666	5,987	15,939	25,172
General and administrative	724	1,548	8,386	10,851
Total operating expenses	3,390	7,535	24,325	36,023
Other (income) and expense:				
Interest and other income	(9)	(182)	(1,902)	(2,093)
Interest expense	—	78	—	78
Loss on settlement of debt	—	627	—	627
Operating loss before tax provision	(3,381)	(8,058)	(22,423)	(34,635)
Tax provision	2	10	125	138
Net loss	(3,383)	(8,068)	(22,548)	(34,773)
Charge for accretion of beneficial conversion rights	—	(603)	—	(603)
Deemed dividend — warrants	—	—	(4,457)	(4,457)
Net loss applicable to common stockholders	$ (3,383)	$ (8,671)	$ (27,005)	$(39,833)
Net loss per share — basic and diluted	$ (0.56)	$ (1.05)	$ (1.76)	
Weighted average shares outstanding — basic and diluted	6,080,746	8,252,113	15,354,898	

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	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

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

	2005	2006	2007	December 3, 2003 (Inception) to September 30, 2007
Cash flows from operating activities:				
Net loss	$(3,383)	$(8,068)	$(22,548)	$(34,773)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	189	241	254	705
Founder's compensation contributed to capital	63	—	—	271
Share-based compensation for employees and directors	20	213	3,567	3,800
Share-based compensation for non-employees	344	989	657	1,990
Loss on settlement of debt	—	627	—	627
Write-off of loan to related party	41	—	—	41
Increase in prepaid expenses	(22)	—	(430)	(455)
Increase (decrease) in:				
Accounts payable	33	1,295	830	2,188
Income taxes payable	2	10	255	268
Deferred compensation	187	63	(500)	(250)
Accrued expenses	134	706	2,406	3,246
Total adjustments	991	4,144	7,039	12,431
Net cash used in operating activities	(2,392)	(3,924)	(15,509)	(22,342)
Cash flows from investing activities:				
Purchase of property and equipment	(551)	(180)	(1,315)	(2,403)
Acquisition of intellectual property	(44)	(161)	(66)	(281)
Loan to related party	—	—	—	(41)
Net cash used in investing activities	(595)	(341)	(1,381)	(2,725)
Cash flows from financing activities:				
Options exercised	—	—	5	5
Warrants exercised	—	—	423	423
Loan from Steiner Ventures, LLC	154	(154)	—	—
Deferred public offering costs	—	(190)	(1,268)	(1,458)
Stockholder contribution	514	—	—	1,660
Net proceeds from sale of Series A preferred stock	2,466	—	—	2,466
Net proceeds from sale of common stock	—	—	80,213	80,213
Proceeds from bridge financing	—	2,575	—	2,575
Net proceeds from sale of Series B preferred stock	—	19,205	—	19,205
Net cash provided by financing activities	3,134	21,436	79,373	105,089
Net increase in cash and cash equivalents	147	17,171	62,483	80,022
Cash and cash equivalents, beginning of period	221	368	17,539	—
Cash and cash equivalents, end of period	$ 368	$17,539	$ 80,022	$ 80,022
Supplemental disclosures of cash flow information:				
Cash paid for interest and income taxes was:				
Interest	$ —	$ 9	$ —	$ 9
Income taxes	1	2	44	47
Non-cash financing and investing activities:				
Receivable due for warrants exercised				
Receivable due for Series B preferred stock issued	$ —	$ 50	$ —	$ 50
Settlement of debt with Series B preferred stock	—	3,202	—	3,202
Accrued expenses settled with Series B preferred stock	—	150	—	150
Deemed dividend — warrants	—	—	4,457	4,457
Accretion of fair value of beneficial charge on preferred stock	—	603	—	603
Conversion of convertible preferred stock to common stock	—	—	68	68

See accompanying notes to financial statements.

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 endocrine disorders, such as diabetes and osteoporosis. The Company develops product candidates by applying proprietary formulation technologies to existing drugs in order to improve their therapeutic results. The Company's initial development efforts are focused on peptide hormones. The Company has two insulin product candidates currently in clinical trials for the treatment of diabetes. Additionally, the Company has two preclinical product candidates for the treatment of osteoporosis.

The Company has developed all of its product candidates utilizing its proprietary VIAdel™ technology that allows the Company to study the interaction between peptide hormones and small molecules.

Basis of Presentation

The Company is in the development stage, as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises", 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 12). 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 $2,666, $5,987 and $15,939 for the years ended September 30, 2005, 2006 and 2007, 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, 2007, cash equivalents of $79.6 million are primarily held in money market accounts.

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 maturities.

Intellectual Property

The intangible asset consists primarily of costs associated with prosecuting patents for the Company's technology and is amortized using the straight-line method over twenty years. If the Company determines that a patent will not be granted or will not result in future revenues, the costs related to such patent will be expensed in full on the date of that determination. In addition, the Company amortizes expenses for the useful life of its patents over 20 years because its patents are used in the United States and overseas (20 year life). The Company expects the patented technology to generate revenues for at least 20 years. Amortization expense for the years ended September 30, 2005, 2006 and 2007 was $1, $6 and $13, respectively.

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 less. 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 life for each asset category is as follows: Furniture & Fixture — 7 years, Leasehold improvements — life of lease, Laboratory equipment — 7 years, Manufacturing equipment 5 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, 2006 and 2007.

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.

Concentration of Risks and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. 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, 2007, the Company had a deficit accumulated during the development stage of approximately $39,800. 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 VIAject™ and three other product candidates, launch and commercialize the product candidates, 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

Effective October 1, 2005, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or SFAS No. 123 (Revised 2004) ("SFAS 123(R)"), "Share-Based Payments" on a retrospective basis, to account for awards granted under the Company's Stock Incentive Plan. SFAS 123(R) requires the Company to recognize 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 (Black-Scholes pricing 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 i) the weighted average vesting period and ii) the contractual life of the option, 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 criteria set forth in SFAS 123(R), particularly 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 warrants or stock options granted to non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes model, if that value is more reliably measurable than the fair value of the consideration or service received. The fair value of these instruments are periodically revalued as the options vest, and are recognized as expense over the related period of service or vesting period, whichever is

(In thousands, except share and per share amounts)

longer. The total cost expensed for options granted to non-employees for the years ended September 30, 2005, 2006 and 2007 was $344, $989 and $657, respectively.

The Company expenses ratably over the vesting period the cost of the stock options granted to employees and directors. The total compensation cost expensed for the years ended September 30, 2005, 2006 and 2007 was $20, $213 and $3,567, respectively. At September 30, 2007, the total compensation cost related to non-vested options not yet recognized is $8,640 which will be recognized over the next three years assuming the employees complete their service period for vesting of the options. The Black-Scholes pricing model assumptions are as follows and were determined as discussed above:

	Year Ended September 30,		
	2005	2006	2007
Expected life (in years)	5.25	5.25	5.25
Expected volatility	60%	60%	60-70%
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.62% - 3.88%	3.77% - 4.90%	4.23% - 4.96%
Weighted-average grant date fair value	$ 0.42	$ 2.67	$ 11.09

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board, (the "FASB"), issued Statement of Financial Accounting Standards No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities"*, or SFAS No. 159, which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 also includes an amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, which applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company is assessing the impact of SFAS No. 159 and anticipates that the adoption of this accounting pronouncement will not have a material effect on its financial statements.

In September 2006, the FASB issued SFAS No. 157, *"Fair Value Measurements."* This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, however, the FASB has agreed to defer for one year the effective date for certain non-financial assets and liabilities. The Company anticipates the adoption of this accounting pronouncement will not have a material effect on its financial statements.

In June 2006, the FASB issued Interpretation No. 48, *"Accounting for Uncertainty in Income Taxes"*, ("FIN 48"). This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *"Accounting for Income Taxes"*. This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken on a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. FIN 48 is effective for the Company beginning October 1, 2007. The Company is in the process of evaluating the effect this pronouncement will have on its financial statements.

(In thousands, except share and per share amounts)

3. Net Loss per Share

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 antidilutive.

The amount of options and warrants excluded are as follows:

	Year Ended September 30,		
	2005	2006	2007
Warrants for Common Stock	—	3,417,254	—
Common shares underlying warrants for Series A Preferred Stock	198,025	198,025	198,025
Common shares underlying warrants for Series B Preferred Stock	—	111,406	—
Stock options	385,432	786,812	1,685,974

4. Property and equipment

Property and equipment consists of the following:

	Year Ended September 30,	
	2006	2007
Furniture and fixtures	$ 77	$ 108
Leasehold improvements	539	466
Construction-in-progress	—	526
Laboratory equipment	352	854
Manufacturing equipment	—	102
Computer equipment and other	120	346
Total	1,088	2,402
Less: Accumulated depreciation and amortization	444	685
	$ 644	$1,717

Depreciation expense for the years ended September 30, 2005, 2006 and 2007 was $188, $235 and $543, respectively.

5. 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.

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 8) 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 pricing 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, Chairman and Chief Executive 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 (see Note 9) 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 9). 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 (see Note 8) 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 pricing 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 8) 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 Biodel 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 Biodel, 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 pricing 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 pricing 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.

The director paid the monies due for the Investment; however the payment was received after September 30, 2006. Therefore, the $50 amount due has been accounted for as a receivable at September 30, 2006 and has been included in prepaid and other assets on the balance sheet.

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 owes 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 has 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 has reflected the balance as deferred compensation at September 30, 2006. The balance was paid in July 2007.

Related Party Loans

In 2004, the Company issued a non-collateralized loan to an executive officer for $41. The loan and accrued interest were forgiven in November 2004 and the Company recorded a general and administrative expense for this amount in the year ended September 30, 2005. In December 2004, the Board of Directors adopted a policy prohibiting extending loans to the Company's officers and directors.

In 2004, SV loaned $150 to the Company which was repaid in July 2006 with interest.

6. Commitments

Employment Agreements

The Company entered into two employment agreements with the Chief Executive Officer and the Vice President of Research & Development for a term of three years, effective December 31, 2004.

The total base salaries for both employees' agreements are $575. Bonuses are at the discretion of, and awarded by, the Board of Directors.

(In thousands, except share and per share amounts)

In November 2006, the Company entered into an employment agreement with its Chief Financial Officer and Treasurer and in March 2007 revised the agreement for a term of two years. In November 2007, that Chief Financial Officer and Treasurer resigned to pursue other interests.

Leases

As of September 30, 2007, the Company leased three facilities in Danbury, Connecticut with Mulvaney Properties, LLC, controlled by a non-affiliated stockholder of the Company. The first two lease agreements dated February 2, 2004 and October 19, 2006 were under a three-year and thirty-eight month operating agreements. These two leases provide for annual basic lease payments of $87, plus operating expenses. On September 28, 2006, the Company elected to renew the February 2, 2004 lease through January 31, 2010. In September 2007, the Company gave its 60 day notice, on the October 19, 2006 lease, to terminate its lease effective October 31, 2007 and rent was paid through October 31, 2007.

In July 2007, the Company entered into a lease agreement, with Mulvaney Properties LLC, controlled by a non-affiliated stockholder of the Company, for approximately 20,000 square feet located in Danbury, Connecticut, and on October 1, 2007 amended the agreement to increase the term from a five year to a seven year term beginning August 1, 2007 until July 31, 2014. The renewal option was also amended from a five year to a seven year term.

Lease expense for the years ended September 30, 2005, 2006 and 2007 were $73, $79 and $195, respectively.

Minimum lease payments under these agreements as of September 30, 2007, as well as equipment leases subsequently entered into, are as follows:

Years Ending September 30,	
2008	$ 532
2009	550
2010	508
2011	486
2012	504
2013 and each year thereafter	981
Total	$3,561

Purchase Commitments

As of September 30, 2007, the Company had leasehold improvements, computer equipment and furniture purchase commitments of approximately $1.5 million associated with renovations to its new corporate headquarters.

(In thousands, except share and per share amounts)

7. Income Taxes

Taxes are as follows:

	September 30,		
	2005	2006	2007
Current expense			
Federal	$—	$—	$ —
State	2	10	125
Deferred expense	—	—	—
Actual tax provision	$ 2	$10	$125

At September 30, 2007, the Company had available federal net operating loss carryforwards of approximately $30,500 which expire commencing in fiscal 2024 through 2027 and $30,400 of state net operating loss carryforwards, which expire commencing in 2024 through 2027. The Company also has federal and state research and development credit carryovers of approximately $1,000 , which expire commencing in fiscal 2024.

Under Section 382 of the Internal Revenue Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the Company's ability to use its pre-change of control net operating loss carry forward and other pre-change tax attributes against its post-change income may be limited.

Due to the cumulative impact of the Company's equity issuances over the past two years, a change of ownership occurred upon the issuance of the Company's Series B convertible preferred stock in July 2006. As a result, the total net operating losses will be subject to an annual base limitation. The amounts above are shown gross of the limitation.

(In thousands, except share and per share amounts)

The major components of deferred tax assets and valuation allowances and deferred tax liabilities at September 30, 2006 and 2007 are as follows:

	September 30, 2006	September 30, 2007
Deferred Tax Assets		
Net operating losses	$ 4,824	$ 12,664
Research and development credit	313	953
Depreciation of fixed assets	55	126
Deferred compensation	100	—
Accrued vacation	—	19
Accrued severance	—	31
Amortization	1	—
Total deferred tax asset	5,293	13,793
Deferred Tax Liabilities		
Amortization of intangibles	$ —	$ 2
Total deferred tax liabilities	—	2
Net Deferred Tax Asset	$ 5,293	$ 13,791
Valuation allowance	$(5,293)	$(13,791)
Net Deferred Tax Asset	$ —	$ —

The entire gross deferred tax asset is offset by a valuation allowance. During the current fiscal year, the Company performed a back-to-tax reconciliation that adjusted to the deferred tax assets and valuation allowance by approximately $800. As the Company has not yet achieved profitable operations, management believes the tax benefits as of September 30, 2007 did not satisfy the realization criteria set forth in SFAS 109 and therefore has recorded a valuation allowance for the entire deferred tax asset.

The Company files its tax returns on a calendar year basis. For the years ended September 30, 2005, 2006 and 2007, the Company only had to pay state taxes.

The following reconciles the amount of tax expense at the federal statutory rate and taxes on loss as reflected in operations:

	September 30, 2005	September 30, 2006	September 30, 2007
Federal statutory rate	34.00%	34.00%	34.00%
Federal taxes at statutory rate	$(1,150)	$(2,942)	$(9,080)
Tax expense on permanent differences	36	1,159	2,958
Tax benefit on research and business credits	(85)	(217)	(186)
State taxes, net of federal tax effect	1	8	33
State benefit on net operating losses	(226)	(383)	(1,350)
Valuation allowance increase	1,441	2,401	7,672
Other	(15)	(16)	78
Actual tax provision	$ 2	$ 10	$ 125

8. 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.

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 $86.3 million. We received net proceeds from the offering of approximately $78.8 million 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 (1¾%) 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 in accordance with Emerging Issues Task Force (EITF) 00-19, "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock" (EITF 00-19), and concluded they should be classified as equity on the balance sheet.

As a result of the conversion option, the Company considered ("EITF") No. 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" ("EITF 98-5") and EITF No. 00-27, "Application of Issue No. 98-5 to Certain Convertible Instruments" (EITF 00-27). The Company determined that the issuance of the Series A convertible preferred stock did not result in a beneficial conversion feature calculated in accordance with EITF Issue 98-5.

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 and 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 (see Note 9).

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 in accordance with EITF 00-19 and concluded they should be classified as equity on the balance sheet.

As a result of the conversion option, the Company considered EITF 98-5 and determined that the issuance of the Series B convertible preferred stock resulted in a beneficial conversion feature in the amount of $603.

(In thousands, except share and per share amounts)

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.

Shares Reserved for Future Issuance

As of September 30, 2007, the Company reserved shares of common stock for future issuance as follows:

2004 stock incentive plan	4,700,000
2005 employee stock purchase plan	1,300,000
2005 Non-employee directors' stock option plan	500,000
Exercise of warrants issued to placement agent	198,025
	6,698,025

2004 Stock Incentive Plan, as amended

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. A total of 4,700,000 options to purchase the equivalent number of shares of common stock may be issued pursuant to the Stock Incentive Plan. No awards may be granted under the plan after October 1, 2014.

The Plan shall 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.

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. Offering periods are twenty-seven months in length. The compensation cost in connection with the plan as of September 30, 2007 was $9, in accordance with SFAS No. 123(R) and Financial Accounting Standards Board, Technical Bulletin No. 97-1 (As Amended) *"Accounting under Statement 123 for Certain Employee*

(In thousands, except share and per share amounts)

Stock Purchase Plan with a Look-Back Option "FTB No. 97-1". The Purchase Plan is considered compensation under SFAS No. 123(R) and FTB No. 97-1.

An aggregate of 1,300,000 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, 2007, a total of 1,300,000 shares were reserved and available for issuance under this plan. As of September 30, 2007, the Company had not issued any shares under the Purchase Plan. Subsequently, the Company issued shares on its first purchase date of November 9, 2007.

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 will receive an option to purchase 10,000 shares of common stock on an annual basis commencing with the first annual meeting of stockholders held after the completion of the Company's initial public offering. These shares vest immediately. 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.

From September 30, 2004 through September 30, 2007, the Company granted stock options with exercise prices as follow:

Grants Made During Quarter Ended	Number of Options Granted	Weighted Average Exercise Price	Weighted Average Fair Value per Share	Weighted Average Intrinsic Value per Share
December 31, 2004	301,828	$ 1.41	$ .83	$ —
June 30, 2005	83,604	1.41	.83	—
December 31, 2005	292,265	5.65	4.69	—
March 31, 2006	38,969	5.65	4.69	—
September 30, 2006	130,368	5.65	9.39	3.74
December 31, 2006	377,075	10.00	12.63	2.63
March 31, 2007	63,767	12.63	12.63	—
June 30, 2007	440,000	16.72	9.51	7.21
September 30, 2007	75,000	18.76	11.26	7.50

The fair value per share is being recognized as compensation expense over the applicable vesting period. The fair value per share for award granted as of June 30, 2007 and September 30, 2007 were calculated using the Black-Scholes model.

(In thousands, except share and per share amounts)

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 were determined contemporaneously with the grants.

The following table summarizes the stock option activity through September 30, 2007:

	Number	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balance, September 30, 2004	—	—	
Granted	385,432	1.41	
Outstanding balance, September 30, 2005	385,432	1.41	
Granted	461,602	5.65	
Forfeited, expired	60,222	3.40	
Outstanding balance, September 30, 2006	786,812	3.23	
Granted	955,842	13.96	
Exercised	3,542	1.41	$ 56
Forfeited, expired	53,138	5.65	
Outstanding balance, September 30, 2007	1,685,974	$ 6.80	$17,753
Exercisable shares, September 30, 2007	583,398	$ 7.17	$ 5,927

The following table summarizes option data for currently outstanding and exercisable options as of September 30, 2007:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 1.41	350,007	64 Months	$ 1.41	231,685	$ 1.41
$ 5.65	521,825	75 Months	$ 5.65	151,713	$ 5.65
$12.63	299,142	87 Months	$12.63	—	$12.63
$15.00	200,000	91 Months	$15.00	200,000	$15.00
$18.16	240,000	92 Months	$18.16	—	$18.16
$18.76	75,000	94 Months	$18.76	—	$18.76
Total	1,685,974	84 Months	$ 6.80	583,398	$ 7.17

9. Bridge Financing Units

Between February and May 2006, the Company completed a Bridge Financing whereby it issued and sold 103 Units. Each Unit consisted of an interest-bearing promissory note (the "Note") and a warrant. Gross proceeds received were $2,575 and fees incurred totaled $227.

The principal amount of each Note was $25 bearing interest at the rate of 7% per annum payable on the Maturity Date. The "Maturity Date" was designated as the date which was the earliest of (i) twelve months following the issue date of the Note, (ii) the date of the closing of an initial public offering of securities of the Company pursuant to a registration statement filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended, (iii) the date of the closing of a sale (or the closing of the last of a series of sales) of a separate class of securities of the Company after the closing of the Bridge Financing, the net

proceeds of which, in the aggregate, was equal to or exceeded $10,000, (iv) the date any class of securities of the Company became subject to registration, or was registered, under the Securities Exchange Act of 1934, as amended or (v) the date of first exercise.

Each warrant consisted of the right to purchase for a period of seven years from the earlier to occur of the (i) Next Round Closing (defined below) or the (ii) Maturity Date of the Notes such number of shares of common stock of the Company as equals the quotient obtained by dividing $13 by the Next Round Price. The Next Round Closing meant when the net proceeds from a subsequent financing or series of financings, in the aggregate, equaled or exceeded $10,000. The Next Round Price meant the price paid per share of common stock sold at the next transaction.

At the Next Round Closing, the Company had the right, at its option, to settle its obligations relating to the Units using the securities of the Company issued at the Next Round Closing at a conversion rate that results when $0.80 of the principal amount of the Notes is deemed to be equivalent to $1.00. Thus, the investors who purchased the Units would receive a 25% premium on the principal if the units were to be settled with equity securities issued at the Next Round. Accrued but unpaid interest on the Notes was to be paid in cash at the time of the Next Round Closing.

On July 19, 2006, the Company completed the Series B Preferred Stock financing (the Next Round Closing). The Company exercised its right to repay the Bridge Financing Units utilizing the Series B Preferred Stock and Series B warrants. As a result of the 25% premium, the Company recorded a loss on settlement of debt of $627.

The Company evaluated the warrants in accordance with EITF 00-19 and concluded they should be classified as equity on the balance sheet. The Company considered that the warrants were not contractually issuable until the earlier to occur of the (i) Next Round Closing or the (ii) Maturity Date of the notes and that the bridge financing was intended to be settled at the Next Round Closing which was in progress at the time of issuance of the Bridge Financing Units and was subsequently completed approximately four months later. As such, the Company ascribed minimal value to the warrants given the short expected term of the warrants.

In connection with the Units issuance, the Company entered into a registration rights agreement with the purchasers of these Units. After one hundred and eighty (180) days following the completion of a public offering, the Unit holders may require the Company, on more than one occasion, to file a registration statement. The Company is required to use its best efforts to have the registration statement declared effective.

10. 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, 2007, the Company had not elected to make any contributions to the plan.

11. Warrant

On March 20, 2007, the Company offered the holders of warrants to purchase an aggregate of 149,125 shares of its Series B convertible preferred stock and an aggregate of 3,417,255 shares of its 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. The Company issued an aggregate of 2,636,907 shares of common stock and received aggregate cash proceeds of $423 in connection with such exercises.

As a result of the discounted exercise price, the Company recorded a deemed dividend charge of approximately $4,500 for the warrants that were exercised in the fiscal quarter ended March 31, 2007.

12. 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 are 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.

13. 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, 2007. 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 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 per share amounts)

	December 31, 2006	March 31, 2007	June 30, 2007 (Restated)(1)	September 30, 2007
Revenue	$ —	$ —	$ —	$ —
Net loss	$ (3,668)	$ (5,215)	$ (5,295)	$ (8,370)
Net loss applicable to common stockholders	$ (3,668)	$ (9,672)	$ (5,295)	$ (8,370)
Basic and diluted net loss per common share	$ (0.31)	$ (0.82)	$ (0.30)	$ (0.42)
Weighted average common shares basic and diluted	11,769,773	11,803,228	17,669,169	20,160,836

Quarter Ended
(in thousands except per share amounts)

	December 31, 2005	March 31, 2006	June 30, 2006	September 30, 2006
Revenue	$ —	$ —	$ —	$ —
Net loss	$ (1,151)	$ (1,344)	$ (2,268)	$ (3,305)
Net loss applicable to common stockholders	$ (1,151)	$ (1,344)	$ (2,268)	$ (3,908)
Basic and diluted net loss per common share	$ (0.16)	$ (0.18)	$ (0.31)	$ (0.36)
Weighted average common shares basic and diluted	7,372,153	7,373,433	7,374,216	10,937,016

(1) The Company previously restated the quarter ended June 30, 2007 financial statement to properly reflect the accounting for stock options that the Company granted pursuant to its 2005 Non-Employee Directors' Stock Option Plan.

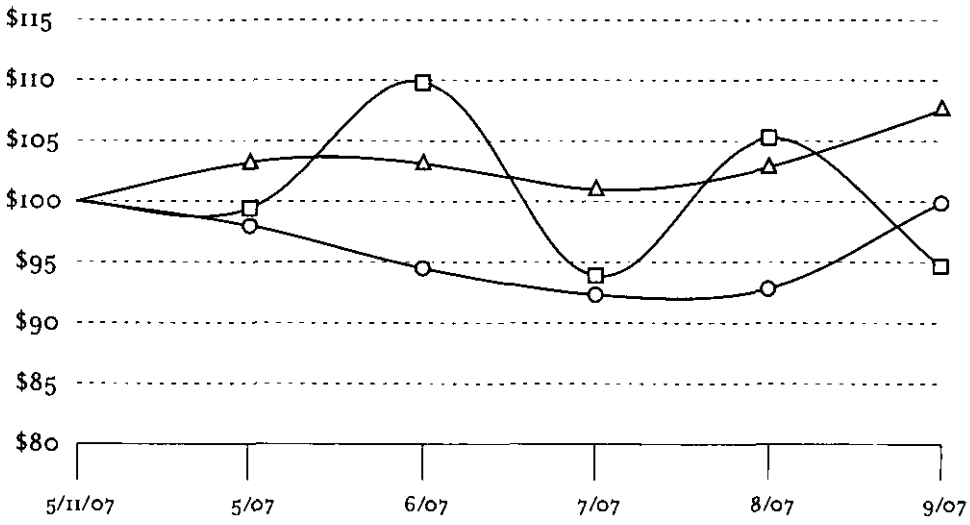
14. Subsequent Events

Former Chief Financial Officer Severance Agreement

On November 13, 2007, F. Scott Reding, the Company's former Chief Financial Officer, Chief Accounting Officer and Treasurer, resigned from all his positions with the Company. In connection with Mr. Reding's resignation, the Company and Mr. Reding entered into a severance agreement that established the terms of Mr. Reding's separation of employment. Pursuant to the severance agreement, Mr. Reding received a lump sum payment of approximately $91, less taxes and withholdings, and the Company has reimbursed Mr. Reding for certain legal fees. In addition, pursuant to the severance agreement, Mr. Reding will receive a continuation of salary and certain benefits until November 30, 2009. Furthermore, the Company accelerated the vesting of options to purchase 54,575 shares of common stock at an exercise price of $5.65 per share and options to purchase an additional 35,425 shares of common stock at an exercise price of $5.65 per share remain exercisable through the original expiration date. In connection with Mr. Reding's resignation, options to purchase 51,700 shares at an exercise price of $5.65 and 25,000 shares at an exercise price of $18.16 per share were forfeited. The estimated charge of $450 for the lump sum payment, salary and benefit continuation for two years and option acceleration modification estimated charge of $750 will be recorded in the first quarter of fiscal 2008.

COMPARISON OF CUMULATIVE TOTAL RETURN*

AMONG BIODEL INC., THE NASDAQ COMPOSITE INDEX



	5/11/07	5/07	6/07	7/07	8/07	9/07
Biodel Inc.	$100.00	$99.33	$110.00	$93.89	$105.17	$94.67
NASDAQ Composite	$100.00	$103.30	$103.25	$101.01	$102.70	$107.57
NASDAQ Pharmaceutical	$100.00	$97.97	$94.49	$92.33	$92.80	$99.85

* $100 invested on 5/11/07 in stock or 4/30/07 in index-including reinvestment of dividends.
Fiscal year ending September 30.

CORPORATE INFORMATION

BIODEL MANAGEMENT

Solomon S. Steiner, Ph.D.
Chairman, President and Chief Executive Officer

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

SCIENTIFIC ADVISORY BOARD

Joseph V. Brady, Ph.D.
Professor at Johns Hopkins University

James Costin, M.D.
Consultant, former Vice President of Research at Carter-Wallace, Inc.

Thomas Forst, M.D.
President and Medical Director of The Institute for Clinical Research and Development

Professor Lutz Heinemann, Ph.D.
Chief Executive Officer and Head of Business Development of the Profil Institute for Metabolic Research, Ltd.

John Laragh, M.D.
Director of the Cardiovascular Center at the New York Presbyterian Hospital-Cornell Medical Center

Daniel Lorber, M.D., F.A.C.P., C.D.E.
Medical Director, Diabetes Control Foundation, Diabetes Care and Information Center
Director of Endocrinology, The New York Hospital Medical Center of Queens
Clinical Associate Professor of Medicine, Weill Medical College of Cornell University

Jerrold Olefsky, M.D.
Professor of Medicine at the University of California, San Diego

Professor Andreas Pfützner, M.D., Ph.D.
Founder of the Institute for Clinical Research and Development

Ralf Rosskamp, M.D.
Executive Vice President Research and Development, Ikaria Holdings, Inc.

BOARD OF DIRECTORS

Solomon S. Steiner, Ph.D.
Chairman of the Board
President and Chief Executive Officer, Biodel, Inc.

Albert Cha, M.D., Ph.D.
Managing Partner, Vivo Ventures

David Kroin
Managing Director, Great Point Partners, LLC

Ira W. Lieberman, Ph.D.
President and Chief Executive Officer, LIPAM International, Inc.
Former Senior Economic Advisor, Open Society Institute

Daniel Lorber, M.D., F.A.C.P., C.D.E.
Medical Director, Diabetes Control Foundation, Diabetes Care and Information Center
Director of Endocrinology, The New York Hospital Medical Center of Queens
Clinical Associate Professor of Medicine, Weill Medical College of Cornell University

Brian J.G. Pereira, M.D.
President and CEO, AMAG Pharmaceuticals
Former President and CEO, New England Health Care Foundation

Charles Sanders, M.D.
Former CEO, Glaxo Inc.
Former General Director, Massachusetts General Hospital
Former Professor of Medicine, Harvard Medical School

Samuel Wertheimer, Ph.D.
Principal, OrbiMed Advisors, LLC
Former Fellow, Memorial Sloan-Kettering Cancer Center

Scott A. Weisman
Managing Member, Etico Capital LLC
Former Managing Director, McGinnSmith & Company, Inc.
Former securities attorney and Partner, Kelley Drye & Warren LLP

HEADQUARTERS

Biodel Inc.
100 Saw Mill Road
Danbury, CT 06810
203 796 5000

TRANSFER AGENT

Continental Stock Transfer
17 Battery Place
New York, NY 10004
212 509 4000

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

BDO Seidman, LLP, New York, NY

SHAREHOLDER INQUIRIES

All shareholder inquiries related to the Company's stock should be directed to:

Biodel Inc. Investor Relations
shareholders@biodel.com

COMMON STOCK

NASDAQ Symbol: BIOD

SEC FORM 10-K

A copy of the Company's annual report to the Securities and Exchange Commission on Form 10-K will be available without charge upon written request to Biodel Inc.

100 Saw Mill Road, Danbury, CT 06810, or via the Company's website at www.biodel.com.

ANNUAL MEETING

Biodel will hold its Annual General Meeting of Shareholders at 10:00 a.m. on February 28, 2008, at the Company's headquarters in Danbury, CT.

SAFE HARBOR

This annual report contains certain forward-looking statements. For a discussion of forward-looking statements please see Part 1, Item 1 of our annual report on Form 10-K for 2007.

END