UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☑	**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended September 30, 2015**

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

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

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

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

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

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☑

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock of the registrant held by non-affiliates was approximately $29 million based on the price at which the common stock was last sold on the NASDAQ Capital Market on March 31, 2015.

The number of shares outstanding of the registrant's common stock, as of November 30, 2015, was 64,148,271.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement, or the 2016 Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2015, for its 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report. With the exception of the portions of the 2016 Proxy Statement expressly incorporated into this

BIODEL INC.

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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:

- the success of our efforts, and those of our advisors, in exploring, and possibly executing on, our strategic alternatives, while preserving our cash balance to the extent practicable;
- the progress, timing or success of our research and development and clinical programs for our product candidates, particularly our glucagon emergency management, or GEM, product candidate, which comprises lyophilized glucagon and an aqueous diluent in an automatic reconstitution device, and our concentrated ultra-rapid-acting insulin product candidate, BIOD-531, which uses regular human insulin, or RHI, as the active pharmaceutical ingredient in a concentration of 400 units per milliliter;
- our ability to conduct the development work necessary to finalize the formulation and presentation of our GEM product candidate, as well as the preclinical studies, clinical trials and manufacturing activities necessary to support the submission of a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for that product candidate;
- the ability and willingness of our existing strategic partners, service providers and suppliers, upon which we rely in the advancement of our product candidates, to meet the obligations set forth in our agreements with them, including Unilife Medical Solutions, Inc., or Unilife, which is responsible for designing and manufacturing the device intended for use with our GEM product candidate, as well as delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA;
- the results of our real-time stability programs for our glucagon-, RHI-, and insulin analog-based product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project long term stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of our product candidates;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA;
- the degree of clinical utility of our product candidates, particularly with regard to our ultra-rapid-acting insulin formulations, which have not yet been shown to be clinically superior to existing rapid-acting insulin analogs;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves;
- our ability to enforce our patents for our product candidates and our ability to secure additional patents for our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies or delivery devices, that could enable a room-temperature rescue product in a portable, easy to use presentation;

- the ability of our contract manufacturing organizations or collaborators to timely and properly produce our products in our final dosage form and in the quantities we may require;

- our ability to secure adequate supplies of active pharmaceutical ingredients to support our product development programs and, if successful, the commercialization one or more product candidates;

- our ability to maintain the listing of our common stock on the NASDAQ Capital Market;

- our capabilities and strategies for manufacturing, marketing and commercializing a product candidate; and

- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report, particularly in Item 1A of this Annual Report, and in our other public filings with the Securities and Exchange Commission that could cause actual results or events to differ materially from the forward-looking statements that we make.

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

PART I

ITEM 1: *BUSINESS*

Overview

We are a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. We develop our product candidates by applying our formulation technologies to existing drugs in order to improve their therapeutic profiles. Our glucagon formulations and presentations are designed to be stable at room temperature and are intended for use by caregivers with little to no medical training as a rescue treatment for diabetes patients experiencing severe hypoglycemia. Our proprietary insulin formulations are designed to be more rapid-acting than the formulations currently available to Type 1 and Type 2 diabetes patients. We refer to these as "ultra-rapid-acting" insulin formulations.

Our lead glucagon product candidate is a glucagon emergency management, or GEM, drug-device combination that is intended to treat diabetes patients experiencing severe hypoglycemia, or very low concentrations of blood glucose. GEM is comprised of lyophilized glucagon and an aqueous diluent in a proprietary injection device from Unilife Medical Solutions, Inc., or Unilife. The GEM device is a dual-chamber design that automatically reconstitutes lyophilized glucagon immediately prior to injection and features automatic needle retraction on full dose delivery. GEM is designed with the goal of optimizing its ease of use for patient caregivers in an emergency.

In the third quarter of calendar year 2014, we submitted an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for our GEM product candidate. We have completed a Phase 1 clinical trial to assess the pharmacokinetic and pharmacodynamic profiles of BIOD-961, the reconstituted glucagon formulation intended for use in the GEM device. In the Phase 1 clinical trial, the overall pharmacokinetic and pharmacodynamic profiles of BIOD-961 were statistically indistinguishable from the two comparator glucagon formulations marketed by Eli Lilly and Novo Nordisk. In April 2015, we announced results from a formative human factors study of our GEM product candidate in which the GEM device demonstrated a substantial improvement in ease-of-use, frequency of successful administration and reduction in the error rate when compared to the commercially available glucagon kits. Despite these advancements, the timing of the development program for our GEM product candidate is uncertain. Further progress requires at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. However, Unilife has informed us that the projected GEM device development timelines were no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them have been unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair Trade Practices Act, or CUTPA, and alleged breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

In addition to our GEM product candidate, we are developing ultra-rapid-acting proprietary insulin formulations that are designed to be more rapid-acting than the formulations currently available to Type 1 and Type 2 diabetes patients. BIOD-531, a concentrated ultra-rapid-acting insulin formulation, combines recombinant human insulin, or RHI, with our proprietary combination of excipients to increase the rate of absorption following subcutaneous injection when compared to other commercially available insulin formulations, including "rapid-acting" mealtime insulin analogs such as Humalog®, marketed by Eli Lilly, NovoLog®, marketed by Novo Nordisk, and Apidra®, marketed by Sanofi. BIOD-531 contains 400 units of RHI per milliliter (instead of the standard 100 units per milliliter), and is formulated with EDTA, citrate and magnesium sulfate. When delivered by subcutaneous injection, BIOD-531 is characterized by a rapid onset of action and a prolonged duration of action, which we believe could address an unmet medical need for a concentrated insulin with an initial rate of absorption superior to that of existing concentrated insulins and prandial/basal premixed insulins and comparable or superior to that of existing rapid-acting insulin analogs.

In addition to our RHI-based ultra-rapid-acting insulin formulations, we have used our proprietary excipients to develop pre-clinical analog-based ultra-rapid-acting insulin formulations using either insulin lispro, the active pharmaceutical ingredient in Humalog®, or insulin aspart, the active pharmaceutical ingredient in NovoLog®.

In December 2015, we announced that our board of directors approved a plan to explore strategic alternatives to further realize value from our pipeline assets while preserving our cash balance to the extent practicable. We intend to retain an advisor to assist us in the process of evaluating our strategic alternatives.

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

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

Patients with diabetes, particularly those with Type 1 diabetes, are also at risk for abnormally low levels of blood glucose, known as hypoglycemia, which can result from excessive insulin between meals. Hypoglycemia can result in loss of mental acuity, confusion, increased heart rate, hunger, sweating and faintness. At very low glucose levels, hypoglycemia can result in loss of consciousness, coma and even death. According to the American Diabetes Association, or ADA, patients with Type 1 diabetes have a serious hypoglycemic event an approximate average of once per year, many of which require hospital emergency room visits.

Insulin Therapy and Its 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-term, 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 medications. These non-insulin medications may be limited in their ability to manage the disease effectively and can have significant side effects. 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 often involves administering several injections of insulin each day. These injections consist of administering a long-acting basal injection one or two times per day and an injection of a rapid-acting insulin or RHI at mealtime. Although this treatment regimen is accepted as effective, it has limitations. 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 recombinant 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 reasons, intravenous injection of insulin before each meal is not a practical therapy.

One of the key improvements in insulin treatments was the introduction in the 1990s and 2000s of rapid-acting insulin analogs, such as Humalog®, NovoLog® and Apidra®. However, even with the rapid-acting insulin analogs, peak insulin levels typically occur within 50 to 70 minutes following the injection. Because the rapid-acting insulin analogs do not adequately mimic the first-phase insulin release, diabetic patients 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 hypoglycemia.

Additional complications of insulin therapy can arise if a patient's response to insulin diminishes with the progression of the disease. Some patients with Type 2 diabetes have severe insulin resistance, resulting in the need to take more than 150 units of insulin per day to control blood glucose elevations. In order to reduce the volume of insulin needed for each injection, many of these patients use Humulin® R U-500, a presentation of Humulin® R containing 500 units of RHI per milliliter (instead of the standard 100 units per milliliter). Humulin® R U-500, which is indicated for Type 1 and Type 2 diabetes patients who require more than 200 units of insulin per day, has a long duration of action, but its onset of action is very slow and therefore is not ideally suited to cover the elevation of glucose levels associated with meals. Humulin® R U-500 is currently the only concentrated insulin on the U.S. market. Many other patients with Type 2 diabetes and lesser degrees of insulin resistance use mixes of prandial and basal insulins, which offer a combination of shorter- and longer-acting insulins in the convenience of one injection. However, the mealtime component of these "pre-mixed" insulin formulations is typically absorbed more slowly than what is required to optimally cover the elevation of glucose levels associated with meals. Examples of these "pre-mixed" insulins include Humalog® Mix 75/25, Humalog® Mix 50/50 and NovoLog® Mix 70/30.

Glucagon Rescue Treatment and Its Limitations

Hypoglycemia is often treated by the oral administration of carbohydrates, such as orange juice or glucose tablets. However, in the case of severe hypoglycemia, the patient often experiences neurologic compromise, such as loss of consciousness or seizure. In these emergency cases, it is typically unsafe for carbohydrates to be administered by mouth and the patient requires the assistance of another person. In such cases, an injection of glucagon can be administered to help quickly raise the patient's blood glucose concentration.

Glucagon, like insulin, is a hormone secreted by the pancreas. Glucagon opposes the action of insulin by promoting the breakdown of glycogen into glucose in the liver, thereby raising the levels of blood glucose. Although glucagon injections are useful in treating severe hypoglycemia, glucagon is inherently unstable in a liquid solution. Therefore, injectable glucagon for the treatment of severe hypoglycemia is currently available only as a rescue kit consisting of a vial containing a dry powder of glucagon and a syringe containing a liquid solution. Two such kits are currently available to patients - the Glucagon Emergency Rescue Kit, marketed by Eli Lilly, and the GlucaGen® HypoKit™, marketed by Novo Nordisk. To administer glucagon with either kit, the liquid solution in the pre-filled syringe must first be injected into the vial with the dry powder, the contents need to be adequately mixed and then the solution is drawn back into the syringe. After the glucagon powder is dissolved, it is injected into the patient. In order to properly administer the glucagon, a caregiver must follow this multi-step process in a situation typically made challenging by the patient's condition.

Our Development of a Glucagon Rescue Product

We believe that the complexity of the currently available rescue kits and the training required for proper administration of glucagon using those kits has resulted in the underuse of glucagon as a rescue treatment for diabetes patients experiencing severe hypoglycemia. In June 2013, we announced plans to develop our GEM product candidate in collaboration with Unilife. The GEM device is a dual-chamber design that automatically reconstitutes lyophilized glucagon immediately prior to injection and features automatic needle retraction on full dose delivery. The GEM device is designed with the goal of optimizing its ease of use for patient caregivers in an emergency.

BIOD-961 is our reconstituted formulation of glucagon intended for use in the GEM device. Our design in formulating BIOD-961 was to make it comparable to the glucagon formulations used in the marketed rescue kits. We believe that in order to receive approval from the FDA to market our GEM product candidate we must, among other things, demonstrate that BIOD-961 meets the FDA's requirements for pharmacokinetic and pharmacodynamic bioequivalence when compared to a reconstituted glucagon formulation from either of the two marketed rescue kits as well as conduct a summative human factors study with the GEM device to validate the instructions for use and operation of the device.

We submitted an IND to the FDA for our GEM product candidate in the third calendar quarter of 2014. In the first calendar quarter of 2015, we announced topline results from Study 6-101, a Phase 1 clinical trial that assessed the pharmacokinetic and pharmacodynamic profiles of BIOD-961 compared to both of the marketed glucagon rescue formulations. Study 6-101 was a randomized, single-center, double blind, six-period cross over study in 15 healthy volunteers who received each glucagon administered subcutaneously and intramuscularly in a randomized treatment sequence. The objectives of the clinical trial were to compare the pharmacokinetic and pharmacodynamic profiles, as well as to assess safety profiles, of the three test glucagons. Although Study 6-101 was designed as an exploratory comparison, standard regulatory criteria for bioequivalence were satisfied when comparing BIOD-961 to Eli Lilly's Glucagon Emergency Rescue Kit and Novo Nordisk's GlucaGen® HypoKit™. Nausea was the most common adverse event for all glucagon formulations. The incidence of adverse events was similar among treatments.

In the second calendar quarter of 2015, we announced results from a formative human factors study of the GEM device. The study was designed to compare the usability and performance of the GEM device to the currently marketed glucagon kits under simulated emergency conditions and to determine the impact of previous experience with the glucagon kits and training. The study was conducted with a total of 24 volunteers, split across three participant groups. The first group consisted of eight caregivers of diabetic patients and first responders, all of whom were familiar with at least one of the marketed glucagon kits. The second group consisted of eight caregivers of diabetic patients and first responders who had no previous experience with the marketed glucagon kits. The third group consisted of eight adults with no relationship to a diabetes patient and who had no previous experience with the marketed glucagon kits. With each of these groups, the GEM device demonstrated the potential for a substantial improvement in ease-of-use and successful delivery of rescue glucagon in an emergency when compared to the marketed products. All participants who were asked to compare the GEM device to the commercial glucagon kits preferred the GEM device.

Given the positive results from Study 6-101 and the formative human factors study described above, we intend to finalize the design of the GEM device and conduct a pivotal clinical trial with BIOD-961 delivered to clinical trial participants in the proposed commercial GEM device. The pivotal clinical trial would assess the pharmacokinetic and pharmacodynamic profiles of BIOD-961 compared to one of the marketed glucagon rescue formulations. However, the timing of the development program for our GEM product candidate is uncertain. Further progress requires that Unilife deliver to us at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. However, Unilife informed us that the projected GEM device development timelines were no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them were unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair

Trade Practices Act, or CUTPA, and alleged breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

We also believe that the development of novel room temperature stable liquid formulations of glucagon could overcome the limitations of the marketed rescue kits. In addition to our GEM product candidate, we are currently assessing several formulations of liquid glucagon in preclinical studies that we intend for use with Becton Dickinson and Company's Uniject disposable injection system.

Our Development of Ultra-Rapid-Acting Insulin Formulations

Our proprietary ultra-rapid-acting insulin formulations are designed to be absorbed into the blood faster than the currently marketed rapid-acting insulin analogs. One of the key features of our formulation technology is that it allows the RHI or insulin analog to disassociate, or separate, from the six molecule, or hexameric, form to the single molecule, or monomeric, form and inhibits re-association to the hexameric form. We believe that by favoring the monomeric form, our formulations may allow for more rapid delivery of insulin into the blood because insulin in the form of a single molecule is absorbed more efficiently into the bloodstream. Based upon our preclinical and clinical data, we believe our RHI- and insulin analog-based formulations may produce a profile of insulin levels in the blood that is preferable to the profile typically observed when using the currently marketed "rapid-acting" insulin analogs.

Early Development of Ultra-Rapid-Acting insulin Formulations

We have conducted Phase 1, Phase 2 and Phase 3 clinical trials comparing the performance of our ultra-rapid-acting insulin formulations to marketed insulins. An early formulation known as Linjeta™ was studied in two pivotal Phase 3 clinical trials that began in 2007. Our pivotal Phase 3 clinical trials were open-label, parallel group, randomized trials conducted at centers in the United States, Germany and India. The trials were designed to compare the efficacy and safety of Linjeta™ to Humulin® R, which is a branded form of RHI. One of the trials tested Linjeta™ in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. We enrolled more than 400 patients in each trial for a six month treatment period. Approximately one-half of the patients in each trial were treated with Linjeta™ and the remainder with Humulin® R. The primary objective of the trials was to determine if Linjeta™ was not inferior to Humulin® R in the management of blood glucose levels, as measured by the mean change in patients' HbA1c levels from baseline to the end of the trial. HbA1c levels are a measure of patients' average blood glucose levels over a period of approximately 3 months. HbA1c is the FDA's preferred endpoint for diabetes trials. Approximately 400 patients with Type 1 and Type 2 diabetes who completed the pivotal Phase 3 clinical trials elected to participate in a long term safety extension trial in which all patients were treated with Linjeta™ as their mealtime insulin. The last patient visit in the extension trial was in February 2010.

In December 2009, we submitted an NDA to the FDA under section 505(b)(2) of the FFDCA for clearance to market Linjeta™ as a treatment for diabetes. In November 2010, the FDA issued a complete response letter to our NDA. The complete response letter included comments related to clinical trials, statistical analysis and chemistry, manufacturing and controls and tolerability issues relating to localized discomfort upon injection. The FDA requested that we conduct two new Phase 3 clinical trials using our preferred commercial formulation of Linjeta™, one in patients with Type 1 diabetes and the other in patients with Type 2 diabetes prior to resubmitting the NDA.

Based upon the complete response letter and subsequent feedback that the FDA provided to us, we decided to study newer RHI-based formulations in earlier stage clinical trials. In the third calendar quarter of 2012 we began enrolling patients in a Phase 2 clinical trial of BIOD-123, a newer ultra-rapid-acting insulin formulation that combines RHI with EDTA, citrate and magnesium sulfate. The addition of magnesium sulfate was intended to improve the formulation's tolerability upon injection, as compared to Linjeta™. The clinical trial was a randomized, open label, parallel group study conducted at 32 investigative centers in the United States. In the clinical trial, 132 patients with Type 1 diabetes were randomized to receive either BIOD-123 or Humalog® to use as their mealtime insulin during an 18-week treatment period. Both arms of the study used insulin glargine, sold as Lantus®, as the basal insulin. The clinical trial was designed to evaluate HbA1c control as the primary endpoint, and secondary endpoints included postprandial glucose excursions, glycemic variability, hypoglycemic event rates and weight changes. Following randomization, subjects entered a six-

week dose titration period during which basal insulin and then prandial insulin doses were titrated in order to reach standard ADA recommended preprandial glucose targets. Upon completion of the titration period, patients entered a "relative stable dosing period" for an additional 12 weeks.

The Phase 2 clinical trial of BIOD-123 completed patient dosing in the second calendar quarter of 2013, and in September 2013 we announced preliminary results from the trial. BIOD-123 achieved the primary endpoint of noninferiority for HbA1c relative to Humalog®. The mean HbA1c change from baseline in the BIOD-123 group was -0.08 ± 0.064% and -0.25± 0.063% in the Humalog® group. The 95% confidence interval (-0.01, 0.35) of the between group differences in change from baseline HbA1c did not exceed the FDA-designated threshold of 0.40%, thereby establishing non-inferiority. HbA1c change during the stable dosing period was similar in both treatment groups. During this period, the mean change in HbA1c in the BIOD-123 group was -0.01% and in the Humalog® group was +0.02%. Additionally, we observed comparable weight gain, mean hypoglycemia event rates and postprandial glucose excursions between the treatment groups, as well as some trends in favor of BIOD-123 in regard to postprandial glucose excursions to a liquid meal challenge test. Comparable safety and adverse event profiles were observed in the clinical trial, with the exception of an increased frequency of injection site pain associated with BIOD-123, which appeared to be clinically minor, short-lived and distinctly superior to the toleration profile we observed with Linjeta™ in our earlier Phase 3 clinical trials.

We believe that a pharmaceutical company with expertise in diabetes and a significant commercial infrastructure will be in the best position to maximize the value of BIOD-123, and we therefore do not have plans to advance BIOD-123 into Phase 3 pivotal trials without the assistance of a strategic partner.

Development of BIOD-531 and Insulin Analog-Based Formulations

In November 2013, we announced that we had selected BIOD-531 as our lead candidate for a concentrated ultra-rapid-acting insulin formulation. In preclinical studies in diabetic swine, BIOD-531 demonstrated a more rapid rate of absorption and onset of action, along with a similar duration of action, when compared to Humulin® R U-500, a presentation containing 500 units of RHI per millimeter. In other preclinical studies, BIOD-531 also demonstrated a more rapid rate of absorption and onset of action when compared to Humalog® Mix 75/25. We believe BIOD-531 could address an unmet medical need for an insulin with an initial rate of absorption superior to that of Humulin® R U-500 and prandial/basal pre-mixed insulins. BIOD-531 contains 400 units of RHI per milliliter (instead of the standard 100 units per milliliter), and, like BIOD-123, is formulated with EDTA, citrate and magnesium sulfate.

Study 3-150—Phase 1 clinical trial comparing BIOD-531 to Humulin® R U-500 and Humalog® Mix 75/25. In February 2014, we announced the results from Study 3-150, a Phase 1 clinical trial comparing BIOD-531 to the marketed products Humulin® R U-500 and Humalog® Mix 75/25. Study 3-150 assessed the pharmacokinetic, pharmacodynamic and injection site toleration profiles of single doses of the study drugs in non-diabetic obese volunteers. The clinical trial included 1.0 unit per kilogram and 0.5 unit per kilogram doses of BIOD-531, as well as a 1.0 unit per kilogram dose of Humulin® R U-500 and a 0.5 unit per kilogram dose of Humalog® Mix 75/25. Topline results from the clinical study were as follows:

- When comparing 1.0 unit per kilogram doses of BIOD-531 and Humulin® R U-500, BIOD-531 was associated with an increased rate of absorption as measured by multiple pharmacokinetic parameters, including a 92% shorter time to Early ½ Tmax (11.0 ± 1.9 min) versus Humulin® R U-500 (135.3 ± 34.9 min), a 43% shorter time to Tmax (223.8 ± 62.3 min) versus Humulin® R U-500 (393.3 ± 58.3 min) and a 765% increase in early insulin exposure as measured by AUCins0-30min (2966 ± 383 mU*min/L) versus Humulin® R U-500 (343 ± 74 mU*min/L). BIOD-531 was associated with a more rapid glucose lowering effect as measured by multiple pharmacodynamic parameters including a 169% increase in AUCGIR0-60min (108.5 ± 22.0 mg/kg) versus Humulin® R U-500 (40.4 ± 10.0 mg/kg). These differences were all statistically significant.

- When comparing 0.5 unit per kilogram doses of BIOD-531 and Humalog® Mix 75/25, BIOD-531 was associated with an increased rate of absorption as measured by multiple pharmacokinetic parameters, including a 66% shorter time to Early ½ Tmax (16.4 ± 4.9 min) versus Humalog® Mix 75/25 (47.9 ± 2.6 min), an 18% shorter time to Tmax (131.3 ± 43.4 min) versus Humalog® Mix 75/25 (160.0 ± 11.9 min) and a 917% increase in early insulin exposure as measured by AUCins0-30min (1200 ± 141 min)

versus Humalog® Mix 75/25 (118 ± 22 mU*min/L). BIOD-531 was associated with a more rapid glucose lowering effect as measured by multiple pharmacodynamic parameters including a 375% increase in AUCGIR0-60min (68.9 ± 13.4 mg/kg) versus Humalog® Mix 75/25 (14.5 ± 4.7 mg/kg). With the exception of Tmax, these differences were all statistically significant.

- Pharmacodynamic measurements for BIOD-531, including time to the end of the glucose lowering effect (TGIR Last), at both 1 U/kg (1170.0 ± 59.3 min) and 0.5 U/kg (1076.2 ± 50.7 min) doses, suggested the potential for BIOD-531 to provide basal insulin needs. Mean visual analog scores and absolute severity scores were very low for all participants, suggesting excellent injection site tolerability. There were no statistically significant differences among the treatment groups.

- Mean visual analog scores and absolute severity scores were very low for all participants, suggesting excellent injection site tolerability. There were no statistically significant differences among the treatment groups.

Study 3-152— Phase 2a clinical trial comparing BIOD-531 to Humalog® Mix 75/25 and Humulin® R U-500 in diabetes patients who use between 50 and 110 units of insulin per day. In August 2014, we announced the results from Study 3-152, a Phase 2a clinical trial comparing BIOD-531 to the marketed products Humalog® Mix 75/25 and Humulin® R U-500. Study 3-152 assessed glucose profiles of Type 2 diabetic subjects who use between 50 and 110 units of insulin per day after a single subcutaneous injection of 0.6 U/kg doses of the study drugs administered with a standardized breakfast on separate days in a randomized four arm cross-over sequence in which subjects received pre-meal BIOD-531, pre-meal Humalog® Mix 75/25, pre-meal Humulin® R U-500 and post meal BIOD-531. In order to assess the duration of glucose lowering, subjects received a standardized lunch at 330 minutes (5.5 hours) after test insulin dosing at breakfast, but with no insulin administered at that time. Blood glucose levels were measured every five minutes during the 720 minutes (12 hours) after test insulin dosing at breakfast. Topline results from the clinical study were as follows:

- When comparing 0.6 unit per kilogram doses of BIOD-531 and Humalog® Mix 75/25 administered prior to a meal, BIOD-531 was associated with superior glucose control throughout the day of observation. A single dose of BIOD-531 administered immediately before breakfast (pre-meal) achieved significantly lower mean glucose concentrations than did Humalog® Mix 75/25 administered immediately before breakfast. The mean glucose concentration after breakfast was 167.8 ± 10.4 mg/dl with BIOD-531 treatment compared to 205.1 ± 8.3 mg/dl with Humalog® Mix 75/25 treatment ($p < 0.001$). Mean glucose concentrations were also significantly improved after lunch with pre-meal BIOD-531. Over the course of the entire day of observation, pre-meal BIOD-531 was associated with an average glucose concentration of 177.8 ± 11.9 mg/dl compared to 225.1± 10.7 mg/dl with Humalog® Mix 75/25 treatment ($p < 0.001$). The percentage of glucose readings within the target range of 70-180 mg/dl was increased more than two-fold following BIOD-531 treatment (46.3 ± 8.4%) compared to Humalog® Mix 75/25 treatment (20.6 ± 5.9 %; p=0.002). Likewise, the post-breakfast area under the curve for the glucose excursion and the mean maximal glucose concentrations after breakfast and after lunch were significantly improved with pre-meal BIOD-531 treatment compared to Humalog® Mix 75/25 treatment.

- When comparing 0.6 unit per kilogram doses of BIOD-531 and Humulin® R U-500 administered prior to the meal, BIOD-531 was associated with superior glucose control. Mean glucose concentrations after the standardized breakfast were 167.8 ± 10.4 mg/dl with BIOD-531 treatment compared to 193.1 ± 8.3 mg/dl with Humulin® R U-500 treatment (p=0.006). Over the entire day of observation, mean glucose concentrations were 177.8 ± 11.9 mg/dl with BIOD-531 treatment compared to 197.2 ± 8.8 mg/dl with Humulin® R U-500 treatment (p=0.042). Over the course of the entire day of observation, glucose concentrations were in the target range of 70-180 mg/dl 46.3 ± 8.4% of the time with BIOD-531 treatment compared to 29.1 ± 6.1% of the time with Humulin® R U-500 treatment (p=0.032).

- When comparing 0.6 unit per kilogram doses of BIOD-531 administered twenty minutes after the start of the meal to 0.6 unit per kilogram doses of both Humalog® Mix 75/25 and Humulin® R U-500 administered prior to a meal, BIOD-531 demonstrated superior glucose control compared to either comparator. Mean glucose concentrations over the course of the day were 178.3 ± 11.2 mg/dl for post-meal BIOD-531 treatment compared to 225.1 ± 10.7 for pre-meal Humalog® Mix 75/25 treatment

($p < 0.001$). The percentage of readings within the 70-180 mg/dl target range was 46.2 ± 7.6% for post-meal BIOD-531 treatment compared to 20.6 ± 5.9% for pre-meal Humalog® Mix 75/25 treatment (p=0.003) and 29.1 ± 6.1% for pre-meal Humulin® R U-500 treatment (p=0.040).

- Mean visual analog scores and absolute severity scores were low for all participants, suggesting excellent injection site tolerability. There were no statistically significant differences in 100 mm visual analog scores among the treatment groups.

Study 3-151— *Phase 2a clinical trial comparing BIOD-531 to Humalog® Mix 75/25 and Humulin® R U-500 in diabetes patients who use greater than 150 units of insulin per day or greater than 100 units of insulin at a single dosing session.* In January 2015, we announced the results from Study 3-151, a Phase 2a clinical trial comparing BIOD-531 to the marketed products Humalog® Mix 75/25 and Humulin® R U-500. Study 3-151 assessed glucose profiles of diabetic subjects who use greater than 150 units of insulin per day or greater than 100 units of insulin at a single dosing session. During each visit, subjects in the clinical trial received three standardized meals and two doses of the study drug, one dose with breakfast and the other dose with dinner. Blood glucose levels were measured over a period of 24 hours. Topline results from the clinical study were as follows:

- When comparing 1.2 U/kg and 0.8 U/kg doses of BIOD-531 and Humalog ® Mix 75/25 administered prior to breakfast and dinner, respectively, BIOD-531 was associated with superior glucose control during the post-breakfast period (the primary efficacy endpoint for the study) and throughout the 24-hour period of observation. BIOD-531 administered before breakfast achieved significantly lower mean glucose concentrations than did Humalog® Mix 75/25 administered before breakfast. The mean glucose concentration in the 330 minutes after breakfast was 164.6 ± 11.8 mg/dl with BIOD-531 treatment compared to 179.9 ± 10.0 mg/dl with Humalog® Mix 75/25 treatment (p=0.009). The percentage of glucose readings within the target range of 70-180 mg/dl in this post-breakfast period was increased following BIOD-531 treatment (65.3 ± 10.4%) compared to Humalog® Mix 75/25 treatment (49.0 ± 9.0%, p=0.004). Mean glucose concentrations were also significantly improved in the period from breakfast to dinner with pre-meal BIOD-531. Over the course of the breakfast to dinner period, pre-meal BIOD-531 was associated with an average glucose concentration of 165.0 ± 14.8 mg/dl compared to 184.9 ± 12.9 mg/dl with Humalog® Mix 75/25 treatment (p=0.007). The percentage of glucose readings within the target range of 70-180 mg/dl in this breakfast to dinner period was increased following BIOD-531 treatment (67.0 ± 10.7%) compared to Humalog® Mix 75/25 treatment (49.0 ± 9.7%, p=0.011).

- When comparing 1.2 U/kg and 0.8 U/kg doses of BIOD-531 and Humulin® R U-500 administered prior to breakfast and dinner, respectively, BIOD-531 was also associated with superior post-breakfast glucose control. Mean glucose concentrations in the 330 minutes after the standardized breakfast were 164.6 ± 11.8 mg/dl with BIOD-531 treatment compared to 178.0 ± 7.3 mg/dl with Humulin® R U-500 treatment (p=0.019). Over the course of the entire period of observation, glucose concentrations for BIOD-531 were similar to that seen with Humulin® R U-500 treatment.

- When comparing 1.2 U/kg in the 0.8 units per kilogram doses of BIOD-531 dosed 20 minutes after the start of the standardized breakfast and dinner, respectively, compared to the same doses of Humalog® Mix 75/25 administered prior to breakfast and dinner, BIOD-531 demonstrated superior glucose control over the 24-hour period of observation. Mean glucose concentrations over the 24-hour period were 149.8 ± 11.8 mg/dl for post-meal BIOD-531 treatment compared to 172.6 ± 14.0 mg/dl for pre-meal Humalog® Mix 75/25 treatment (p=0.006). The percentage of readings within the 70-180 mg/dl target range was 71.5 ± 8.1% for post-meal BIOD-531 treatment compared to 55.7 ± 9.9% for pre-meal Humalog® Mix 75/25 treatment (p=0.025). Post-meal dosing of BIOD-531 resulted in similar overall glycemic control as observed with pre-meal Humulin® R U-500 treatment.

- Mean visual analog scores and absolute severity scores were low for all treatment groups, suggesting excellent injection site tolerability. There were no statistically significant differences in the 100 mm visual analog scores among the treatment groups.

In November 2015, we announced the initiation of Study 3-157, a Phase 2a clinical trial to evaluate BIOD-531 against a state-of-the-art basal-bolus insulin regimen and in combination with a GLP-1 analog. Study 3-157 is designed to evaluate glucose control achieved with BIOD-531 in patients with Type 2 diabetes

and test the hypothesis that two or three doses of BIOD-531 alone can achieve equivalent glucose control to a commonly used intensive insulin regimen in which two different insulins are injected a total of four times per day. In addition, Study 3-157 is designed to evaluate the clinical efficacy of co-treatment with Victoza®, a leading GLP-1 analog. Pre-clinical studies indicate that BIOD-531 can be stably co-formulated with liraglutide, the active pharmaceutical ingredient in Victoza®.

We intended that the results of Studies 3-150, 3-152 and 3-157, and that of our commercial analysis for BIOD-531, which we conducted with the assistance of an industry consultant, would inform our development program for this product candidate by helping us target the optimal patient populations and commercial opportunity for BIOD-531. Furthermore, we could consider re-commencing enrollment for Phase 2b Study 3-250 in the second calendar quarter of 2016. Study 3-250 is a randomized, open-label, parallel group study in patients with insulin-treated Type 2 diabetes. The clinical trial was temporarily the subject of a partial clinical hold while we addressed a request by the FDA to provide additional data concerning the investigational syringes used to deliver BIOD-531 in the clinical trial. The FDA removed the partial clinical hold in September 2015. However, in December 2015, we announced that our board of directors approved a plan to explore strategic alternatives to further realize value from our pipeline assets while preserving our cash balance to the extent practicable. As part of this plan, patient enrollment in BIOD-531 Study 3-157 and Study 3-250 is suspended.

In addition to BIOD-531, we have developed pre-clinical ultra-rapid-acting insulin formulations using our proprietary excipients in combination with either insulin lispro, the active pharmaceutical ingredient in Humalog®, or insulin aspart, the active pharmaceutical ingredient in NovoLog®.

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. We intend to seek FDA approval for our product candidates in an NDA, and not under an application submitted for approval as a biologic under the Public Health Service Act. The process required by the FDA before a drug product candidate may be marketed in the United States under an NDA generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or 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, and the acceptance for filing of the NDA by the FDA;
- 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. A clinical trial hold 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, monitors the clinical centers proposing to conduct the clinical trial and must review and approve the plan for any clinical trial before it commences. 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 informed consent form signed by the trial participants and must monitor the study until completed.

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

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

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

- Phase 2 clinical trials are conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.

- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and proposed indications, but sometimes can include several thousand patients. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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

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

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the

additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. An applicant receiving a complete response letter may resubmit the application with data and information addressing the FDA's concerns or requirements, withdraw the application without prejudice to a subsequent submission of a related application or request a hearing on whether there are grounds for denying approval of the application. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market. The agency may also impose requirements that the NDA holder conduct new studies, make labeling changes, implement Risk Evaluation and Mitigation Strategies, and take other corrective measures.

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

Because we are developing new formulations of previously approved chemical entities, such as insulin and glucagon, 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 pursuant to Section 505(b)(2) NDAs. There is no specific guidance available for Section 505(b)(2) NDAs for insulin or glucagon. In addition, while there is precedent for a glucagon product being approved under a Section 505(b)(2) NDA, we are not aware of any insulin product that 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 product candidates 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 a 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 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. Marketing exclusivity provisions under the FFDCA can delay the submission or the approval of Section 505(b)(2) NDAs, thereby delaying a product approved under Section 505(b)(2) from entering the market. The FFDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity generally prohibits the submission of a Section 505(b)(2) NDA for any drug product containing the active moiety during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years. In that case, if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of the Section 505(b)(2) NDA may automatically be stayed until 7.5 years after the NCE approval date. The FFDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the 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 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 cGMP. In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

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

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

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

Regulations Outside the United States

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

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

Competition

The pharmaceutical industry is characterized by intense competition and rapidly evolving technology. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs and drug formulations that target endocrine disorders. If approved, our product candidates will compete against many products with similar indications.

If approved, our GEM product candidate would face significant competition. Eli Lilly and Novo Nordisk currently market injectable glucagon rescue kit products. We are aware of several additional glucagon rescue product candidates. Eli Lilly has acquired worldwide rights to a clinical-stage intranasal glucagon product candidate developed by Locemia Solutions, or Locemia, a privately held specialty pharmaceutical company. Locemia's product candidate uses a proprietary glucagon nasal powder formulation that is delivered in a single-use device. Xeris Pharmaceuticals, Inc., or Xeris, is developing a clinical-stage glucagon product candidate that is stabilized using non-aqueous solvents to suppress glucagon fibrillation. At the 2014 Annual Meeting of the American Diabetes Association, Xeris presented data from a Phase 2, double-blind, crossover, comparative pharmacology study in healthy non-diabetic volunteers in which the Xeris candidate formulation demonstrated pharmacodynamic bioequivalence to a marketed comparator (although the pharmacokinetic profiles of the 2 glucagon formulations were significantly different). In April 2015, Xeris announced that it was awarded a Small Business Innovation Research Phase I grant to advance the company's non-aqueous glucagon candidate. Zosano Pharma Corporation, or Zosano, is developing a clinical-stage glucagon formulation delivered intra-dermally by a micro needle patch. In addition, Zealand Pharma A/S, a pharmaceutical company based in Denmark, is developing a clinical-stage glucagon analog that is designed to be more stable than glucagon while maintaining glucagon's clinical efficacy.

Our concentrated ultra-rapid acting insulin product candidate, BIOD-531, if approved, would face significant competition from insulin formulations currently on the market and, potentially, from development stage insulin formulations and other treatment systems. Humulin® R U-500 is commonly used to treat diabetes patients with severe insulin resistance, and pre-mixed insulins, such as Humalog® Mix 75/25, is commonly used to treat diabetes patients and lesser degrees of insulin resistance. Newer combination products may also compete with BIOD-531. For example, a combination of insulin degludec, an ultra-long-acting basal insulin developed by Novo Nordisk, and NovoLog® is approved in Europe and may be approved in the United States within the next few years. Also, combinations of basal insulin and GLP-1 analogs have either been approved or are in later stages of development; these products are believed to offer some measure of postprandial glucose control in addition to the control offered by a basal insulin. Furthermore, Thermalin Diabetes, LLC and Adocia Inc. have announced plans to develop a novel concentrated insulin-analog based formulation with fast absorption.

If approved, the primary competition for our BIOD-123 ultra-rapid-acting insulin product candidate will be rapid-acting mealtime injectable insulins. There are several approved injectable rapid-acting mealtime insulin analogs currently on the market including Humalog®, marketed by Eli Lilly and Company, NovoLog®, marketed by Novo Nordisk, and Apidra®, marketed by Sanofi. These rapid-acting insulin analogs provide improvement over "regular" mealtime insulin, including faster subcutaneous absorption, an earlier and greater insulin peak and more rapid post-peak decrease. Both Humalog® and NovoLog® have limited remaining patent protection in the United States and Europe. The possible introduction of lower priced brands or substitutable generic versions of these products could negatively impact the revenue potential of our ultra-rapid-acting product candidates should any be approved.

Intellectual Property and Proprietary Technology

The technologies for our ultra-rapid-acting insulin formulations have been developed exclusively by our employees, without input from third parties.

In October 2007 the United States Patent and Trademark Office issued U.S. Patent No. 7,279,457 encompassing our ultra-rapid-acting insulin formulations. If all maintenance fees are paid, the patent will expire no earlier than January 2026. In addition, a related European Patent, EP 1 740 154, was granted in June 2009 and expires in March 2025 in the designated countries if all annuity fees are paid. Two additional European applications on this technology, EP2 319 500 and EP2 106 790, have been issued and, in October 2014, were successfully defended in a third party opposition before the Opposition Division of the European Patent Office. Related applications have been granted in Australia, Canada and Japan. Additional applications with claims directed to formulations containing insulin, insulin derivatives or analogs are currently pending in the U.S. and foreign patent offices.

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 ultra-rapid-acting insulin formulations and our liquid glucagon formulations have been known and used for many years and, therefore, are no longer subject to patent protection, except in proprietary combinations. Accordingly, our patent and pending applications are directed to the particular formulations of these ingredients in our products, and to their use. Although we believe our formulations and their uses are or will be 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 have entered into a customization and commercial supply agreement with Unilife Medical Solutions, Inc., a wholly owned subsidiary of Unilife Corporation, to acquire an exclusive, sublicensable, worldwide license to a proprietary device platform of dual-chamber devices for use with glucagon. Under the terms of the agreement, Unilife Medical Solutions, Inc. will control the patent protection relating to the devices and be the sole owner of improvements thereto.

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

Manufacturing

We do not have the facilities required to manufacture our product candidates for use in clinical trials. Therefore, we intend to manufacture our product candidates by contracting with third parties that operate manufacturing facilities in accordance with cGMP.

We have terminated an earlier supply agreement with N.V. Organon (subsequently acquired by Amphastar Pharmaceuticals, Inc., a specialty pharmaceutical development and manufacturing company), under which we have purchased the RHI we have used to formulate all of our RHI-based product candidates, including BIOD-

123 and BIOD-531. We intend to use existing supplies of RHI to support the further development BIOD-531, as well as enter into one or more development stage RHI supply agreements, as necessary.

We have entered into a commercial supply agreement with Bachem AG, a Swiss corporation, for the supply of all of the glucagon we will need for the testing and manufacturing of our GEM product candidate. The initial term of our agreement with Bachem AG will expire in July 2017. We believe that the quantities of glucagon that we have rights to acquire under this agreement will be sufficient to allow us to complete our current and anticipated future clinical trials of our glucagon rescue product candidates and to support the potential commercial launch of our GEM product candidate.

We have entered into a customization and commercial supply agreement with Unilife Medical Solutions, Inc., a wholly owned subsidiary of Unilife Corporation, to acquire an exclusive, sublicensable, worldwide license to a proprietary device platform of dual-chamber devices for use with glucagon. Under the terms of the agreement, Unilife will develop and be the sole supplier of the device intended for use with our dual-chamber glucagon rescue product candidate. Additionally, Unilife is responsible for delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA. The initial term of our agreement with Unilife Medical Solutions, Inc. will expire in 2028. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged breaches of contract in connection with the GEM program.

We have entered into manufacturing agreement with Cangene bioPharma Inc., doing business as Emergent BioSolutions, or Emergent, under which Emergent will fill and finish the GEM device, using lyophilized glucagon and an aqueous diluent. During the term of the agreement following validation of the manufacturing process, we are required to purchase, and Emergent is obligated to deliver to us, one manufactured lot of the GEM device every quarter. We would expect to reserve and commit to additional manufacturing capacity with Emergent following the commercial launch of our GEM product candidate, if successful. Either party may terminate the agreement without cause upon thirty-six months prior written notice.

Sales and Marketing

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

Employees

At November 30, 2015 we had 24 full time-employees 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, 2015:

Name	Age	Position
Dr. Errol B. De Souza	62	President and Chief Executive Officer
Gary G. Gemignani	50	Chief Financial Officer
Paul S. Bavier	43	General Counsel and Secretary, Chief Administrative Officer and Vice President of Corporate Development

Dr. Errol De Souza joined our management and board of directors in March 2010. Dr. De Souza has over two decades of experience in the biopharmaceutical industry. From March 2009 until March 2010, Dr. De Souza was a pharmaceutical and biotechnology consultant. From April 2003 to January 2009, Dr. De Souza was president and chief executive officer of Archemix Corporation, a privately held biopharmaceutical company focused on aptamer therapeutics. From September 2002 to March 2003, he was president, chief executive officer and a director of Synaptic Pharmaceuticals Corporation, a publicly traded biopharmaceutical company that was acquired by H. Lundbeck A/S in March 2003. Dr. De Souza is a member of the board of directors of each of the following publicly traded companies: Bionomics Ltd. and Targacept, Inc. Dr. De Souza received his B.A. (Honors) in physiology and his Ph.D. in neuroendocrinology from the University of Toronto and he completed his postdoctoral fellowship in neuroscience at The Johns Hopkins University School of Medicine.

Mr. Gary Gemignani joined our company in September 2014. He has over 25 years of experience in accounting, strategic planning and financing in the life sciences industry and has held senior leadership and management roles at Novartis, Prudential Financial, Wyeth and Arthur Andersen. Mr. Gemignani was most recently with Champions Oncology where he served as Chief Financial Officer and Executive Vice President from 2011 to 2013, with responsibility for raising capital, investor relations and all financial operations. From 2010 to 2011, Mr. Gemignani was the Executive Vice President, Chief Operating Officer and Chief Financial Officer for Coronado Biosciences Inc., responsible for financial operations, strategic planning and business development activities. He also served as the Executive Vice President, Chief Operating Officer and Chief Financial officer of Gentium S.P.A from 2006 to 2010. Mr. Gemignani received a Bachelor's Degree in Accounting from St. Peter's College.

Mr. Paul Bavier is our General Counsel and Secretary, Chief Administrative Officer and Vice President of Corporate Development. From December 2013 to November 2014, he served as our General Counsel, Chief Compliance Officer and Secretary. Mr. Bavier served as our General Counsel and Secretary from 2008 to 2013, and as our Deputy General Counsel from 2007 to 2008. Prior to joining Biodel, Mr. Bavier was the Assistant General Counsel at Gerber Scientific, Inc., a publicly held integrated automation equipment and software company with global operations. He also served as Associate Counsel in the corporate law group of The Hartford Financial Services Group, Inc. Mr. Bavier began his legal career as an associate in the corporate law department of Ropes & Gray LLP in Boston. He holds a B.A. from Middlebury College and a J.D. from the University of Michigan Law School.

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 product commercialization or profitability.

Since our inception in December 2003, we have incurred significant operating losses. Our net losses were approximately $18.7 million for the fiscal year ended September 30, 2015. As of September 30, 2015, we had a deficit accumulated since inception of approximately $248.3 million. We have invested a significant portion of our efforts and financial resources in the development of our RHI- and insulin analog-based ultra-rapid-acting insulin product candidates, including BIOD-123, BIOD-531, BIOD-238, BIOD-250, and our prior Linjeta™ formulation. More recently, we have invested an increasing portion of our efforts and financial resources in the development of our GEM product candidate; however, timing of the development program for our GEM product candidate is uncertain. Further progress requires that Unilife deliver to us at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. Unilife has informed us, however, that the projected GEM device development timelines are no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them have been unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair Trade Practices Act, or CUTPA, and alleged breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

We expect to continue to incur significant operating losses for at least the next several years as we may:

- explore various strategic alternatives with the assistance of an advisor, and possibly execute on one such alternative;
- continue our efforts to confirm the development timelines for the Unilife device intended for use with our GEM product candidate, including through formal legal proceedings;
- pay milestone payments to Unilife in connection with the production and delivery of registration batches of our GEM product candidate to support the submission of an NDA with the FDA;
- conduct later stage clinical trials with our GEM product candidate, including at least one pivotal clinical trial required for FDA approval of an NDA, and commence targeted commercialization activities;
- conduct clinical trials with our BIOD-531 product candidate, including possibly a Phase 2, parallel group study in patients with Type 2 diabetes over several treatment periods;
- conduct the required stability, preclinical and human factors and user acceptability studies to support the approval of the GEM device and one or more insulin injection devices intended for use with BIOD-531; and
- purchase active pharmaceutical ingredients and other materials in support of our product candidates.

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

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

We are an early stage company with no commercial products. All of our product candidates are in the initial stages of development. Our product candidates will require significant additional clinical development, regulatory approvals and related investment before they can be commercialized. We expect to continue to incur significant research and development expenses as we continue our formulation work and advance these programs through clinical trials. Unless we are successful in consummating a strategic partnership to develop and commercialize an ultra-rapid-acting insulin formulation or a glucagon rescue presentation, we would need to raise substantial additional capital to develop and commercialize competitive products. Such financing may not be available on terms acceptable to us, or at all. If we are unable to obtain financing on favorable terms, our business, results of operations and financial condition may be materially adversely affected.

Based upon our current plans, we believe that our existing cash, cash equivalents and restricted cash will be sufficient to fund our anticipated operating expenses and capital expenditures at least through the first calendar quarter of 2017. 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 success of our efforts, and those of our advisors, in exploring, and possibly executing on, our strategic alternatives, while preserving our cash balance to the extent practicable;
- the progress, timing or success of our research and development and clinical programs for our product candidates, particularly our GEM and BIOD-531 product candidates;
- our ability to conduct the development work necessary to finalize the formulation and presentation of our GEM product candidate, as well as the preclinical studies, clinical trials and manufacturing activities necessary to support the submission of an NDA to the FDA for that product candidate;
- the ability and willingness of our existing strategic partners, service providers and suppliers, upon which we rely in the advancement of our product candidates, to meet the obligations set forth in our agreements with them, including Unilife, which is responsible for designing and manufacturing the device intended for use with our GEM product candidate, as well as delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA;
- the results of our real-time stability programs for our glucagon-, RHI-, and insulin analog-based product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project long term stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of our product candidates;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- the degree of clinical utility of our product candidates, particularly with regard to our ultra-rapid-acting insulin formulations, which have not yet been shown to be clinically superior to existing rapid-acting insulin analogs;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves;
- our ability to enforce our patents for our product candidates and our ability to secure additional patents for our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies or delivery devices, that could enable a room-temperature rescue product in a portable, easy to use presentation;

- the ability of our contract manufacturing organizations or collaborators to timely and properly produce our products in our final dosage form and in the quantities we may require;

- our ability to secure adequate supplies of active pharmaceutical ingredients to support our product development programs and, if successful, the commercialization one or more product candidates;

- our capabilities and strategies for manufacturing, marketing and commercializing a product candidate; and

- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

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, which are not favorable to us or our stockholders. If we raise additional funds through collaboration, strategic alliance or licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

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

We commenced active operations in January 2004. Our operations to date have been limited to organizing and staffing our company, developing and securing our technology and undertaking preclinical studies and clinical trials of our product candidates. We have limited experience completing large-scale, pivotal clinical trials and we have not yet demonstrated our ability to obtain regulatory approval to market a product, 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 relatively new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We may need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to the Development and Commercialization of Our Product Candidates

We have depended heavily on the success of our glucagon emergency rescue and ultra-rapid-acting mealtime insulin development programs.

We have invested a significant portion of our efforts and financial resources in the development of our glucagon emergency rescue and ultra-rapid-acting insulin product candidates. We submitted an IND to the FDA for our GEM product candidate in the third calendar quarter of 2014, and in the first calendar quarter of 2015, we announced positive topline results from Study 6-101, which compared our candidate glucagon formulation, BIOD-961, to the glucagon formulations marketed by Eli Lilly and Novo Nordisk. However, the timing of the development program for our GEM product candidate is dependent the ability of Unilife to deliver to us at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. However, Unilife informed us that the projected GEM device development timelines were no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them were unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair Trade Practices Act, or CUTPA, and alleged

breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

Since November 2010, when the FDA issued a complete response letter to our NDA for our Linjeta™ product candidate, we have studied newer formulations of ultra-rapid-acting insulins in earlier stage clinical trials. Clinical trials of our first two new RHI-based formulations, BIOD-105 and BIOD-107, did not achieve satisfactory results. A subsequent RHI-based formulation, BIOD-123, met the primary non-inferiority endpoint in a Phase 2 clinical trial. To date, however, we have been unable to engage a strategic partner in the advancement of the candidate formulation into later stages of development, and we have no plans to do so on our own. Most recently, we have selected BIOD-531 as our lead candidate for a concentrated ultra-rapid-acting RHI-based formulation based on positive results we observed in early stage clinical trials. The results of our earlier stage clinical trials may not be predictive of results we may generate in later stage clinical trials. We have not studied BIOD-531 in multi-dose outpatient clinical trials, which may be more representative of the product candidate's intended use as a long-term therapy. Additionally, we have manufactured a limited number of larger-scale batches of BIOD-531 from which to generate real-time stability data.

Our development of an RHI- or insulin analog-based formulation may not be successful; some formulations may have different regulatory requirements to obtain marketing approval from the FDA.

While we have significant experience with the technology we use to develop ultra-rapid-acting insulin formulations, we cannot assure you that our program to advance RHI- or insulin analog-based formulations will be successful or will offer improvements over the Linjeta™ formulation that we submitted to the FDA in our NDA. Some of our formulations offer advantages in terms of injection site toleration, but may not perform as well as the Linjeta™ formulation in terms of the overall pharmacokinetic and pharmacodynamic profile. Some of our insulin analog-based formulations under development appear to be absorbed as rapidly as Linjeta™, but are less stable in accelerated testing. For example, BIOD-238 and BIOD-250 do not demonstrate stability characteristics consistent with our target product profile. Accordingly, we are continuing our formulation development work to improve the stability characteristics of our ultra-rapid-acting insulin analog-based formulations. We may be unable to develop new RHI- or insulin analog-based formulations with pharmacokinetic, pharmacodynamic, stability and injection site toleration characteristics that are acceptable to us, a potential strategic partner or the FDA.

Furthermore, the regulatory requirements for any alternate formulation may not meet our expectations or may be different from those applicable to the formulation of Linjeta™ submitted in our NDA. For example, advancing any formulation based on an insulin analog may necessitate our conducting additional toxicology work prior to initiation of clinical trials in the United States. While BIOD-238 and BIOD-250, which are formulated by adding our proprietary excipients to the marketed presentation of Humalog®, were the subject of a Phase 1 clinical trial in Australia, we expect that we would need to conduct toxicology studies before advancing our insulin analog-based formulations into a Phase 1 clinical trial in the United States.

Our development of a glucagon rescue product candidate may not be successful; we have limited experience with developing drug-device combination products and rely heavily on the performance of third parties collaborators and consultants.

Our experience with the manufacture, testing and analysis of pharmaceutical preparations of glucagon in preclinical studies is limited, and we have not yet concluded any clinical trials using glucagon as an active pharmaceutical ingredient. Additionally, we have never prepared or submitted an NDA to the FDA for a drug-device combination product, such as our GEM product candidate, and we therefore rely heavily on the expertise of third-party collaborators and consultants, such as Unilife, which is responsible for the design and the development phase manufacturing of the GEM device, as well as for the device-specific portions of any NDA we may submit to the FDA. If we, or our consultants and collaborators, do not adequately anticipate or address technical and regulatory challenges that we may face in the development of our GEM product candidate, our business may be significantly harmed.

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

We have not completed the development of any products through commercialization. In October 2010, the FDA notified us that it would not approve our NDA for the Linjeta™ formulation, and we subsequently

advanced alternate formulations, including BIOD-105, BIOD-107, BIOD-123, BIOD-125, BIOD-238, BIOD-250 and BIOD-531into the clinic and discontinued development of earlier formulations of Linjeta™. The outcomes of preclinical testing and clinical trials of our product candidates may not be predictive of the success of future clinical trials. For example, despite promising preclinical data, BIOD-105 and BIOD-107 did not meet our preferred target product profile in Phase 1 clinical trials, and we discontinued development of these formulations. In addition, interim or preliminary results of a clinical trial do not necessarily predict final results. We cannot assure you that the clinical trials of any of our product candidates will ultimately be successful. New information regarding the safety, efficacy, toleration and stability may arise that may be less favorable than the data observed to date.

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

- successful completion of preclinical development and clinical trials;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;
- establishing that, with regard to our ultra-rapid-acting insulin formulations, the formulations are well-tolerated in chronic use;
- establishing that, with regard to our GEM product candidate, the commercial presentation can be administered effectively by patient caregivers with limited or no training;
- establishing commercial manufacturing capabilities through arrangements with third-party manufacturers;
- launching commercial sales of the products, whether alone or in collaboration with others;
- competition from other products; and
- continued acceptable safety profiles of the products following approval.

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

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

- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we currently anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate, any of which would result in significant delays;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;

- the supply, stability or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate; and

- the effects of our product candidates may not be the desired effects, may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

- be delayed in obtaining or discontinue our efforts to obtain marketing approval;

- 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 redesigned 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 commercial success of any product candidates that we may develop 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 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 are established, physicians may elect not to recommend these product candidates for a variety of reasons including the reimbursement policies of government and third-party payors, the effectiveness of our competitors in marketing their products and the possibility that patients may experience more injection site discomfort than they experience with competing products.

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

- the willingness and ability of patients and the healthcare community to adopt our products;

- the ability to manufacture our product candidates in sufficient quantities with acceptable quality and to offer our product candidates for sale at competitive prices;

- the perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits of our product candidates compared to those of competing products or therapies;

- the convenience and ease of administration of our product candidates relative to existing treatment methods;

- the label and promotional claims allowed by the FDA, such as, in the case of an RHI- or insulin analog-based formulation, claims relating to glycemic control, hypoglycemia, weight gain, injection site discomfort, expiry dating and required handling conditions;

- the pricing and reimbursement of our product candidates relative to existing treatments; and

- marketing and distribution support for our product candidates.

Our ultra-rapid-acting insulin formulations have not yet been shown to be clinically superior to existing rapid-acting insulin analogs or other marketed comparators, such as Humulin® R U-500 and Humalog® Mix 75/25. It may be difficult for us to demonstrate superiority in the future because we anticipate that the primary endpoint of any pivotal clinical trial that we might conduct with an ultra-rapid-acting insulin product candidate would be non-inferiority to the comparator drug product. In addition, we are aware of other companies with expertise in protein stabilization that are developing novel formulations and presentations of stable glucagon. If these formulations and presentations are easier to administer than our GEM product candidate, our GEM product candidate, even if approved by the FDA, may not achieve commercial success.

The successful development of our product candidates may depend upon our ability to collaborate with or license technology from third parties.

BIOD-531 is at an early stage of development. In order for us to meet our projected milestones for this program, we must obtain a reliable source of active pharmaceutical ingredient and other related materials and supplies, including insulin injection devices or syringes that may be unique to BIOD-531 and its insulin concentration. In addition, with regard to our GEM product candidate, we are dependent upon proprietary licenses and supply arrangements we have with third parties, such as Unilife, which is responsible for designing and manufacturing the GEM device, as well as delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA. If we are unable to establish or maintain these licenses and supply arrangements, our efforts to commercialize our product candidates may be materially harmed.

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

Our current strategy for developing, manufacturing and commercializing our product candidates includes securing collaborations with leading pharmaceutical and biotechnology companies, including those that hold patents covering the currently marketed insulin analogs. To date, we have not entered into any out-licensing collaborations with pharmaceutical or biotechnology companies. We face significant competition in seeking appropriate collaborators. In addition, collaboration agreements are complex and time-consuming to negotiate, document and implement. For all these reasons, it may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all. Even if we do enter into any such collaboration, the collaboration may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

If we fail to enter into collaborations, or if our collaborations are unsuccessful, we may be required to establish our own direct sales, marketing, manufacturing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and we have little experience in doing so. Because of our

size, we would be at a disadvantage to our potential competitors to the extent they collaborate with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or provide the same degree of market research or marketing support. In addition, our competitors would have a greater ability to devote research and development resources toward expansion of the indications for their products. We cannot assure our 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 potential revenues and prospects for profitability will suffer.

Our potential future revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of any 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.

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.

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 liability insurance that we believe is sufficient to cover us from potential damages arising from past or future clinical trials of our ultra-rapid-acting insulin formulations and other product candidates that we may advance into the clinic. 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.

If approved, our GEM product candidate would face significant competition. Eli Lilly and Novo Nordisk currently market injectable glucagon rescue kit products. We are aware of several additional glucagon rescue product candidates. Eli Lilly has acquired worldwide rights to a clinical-stage intranasal glucagon product candidate developed by Locemia Solutions, or Locemia, a privately held specialty pharmaceutical company. Locemia's product candidate uses a proprietary glucagon nasal powder formulation that is delivered in a single-use device. Xeris Pharmaceuticals, Inc., or Xeris, is developing a clinical-stage glucagon product candidate that is stabilized using non-aqueous solvents to suppress glucagon fibrillation. At the 2014 Annual Meeting of the American Diabetes Association, Xeris presented data from a Phase 2, double-blind, crossover, comparative pharmacology study in healthy non-diabetic volunteers in which the Xeris candidate formulation demonstrated pharmacodynamic bioequivalence to a marketed comparator (although the pharmacokinetic profiles of the 2 glucagon formulations were significantly different). In April 2015, Xeris announced that it was awarded a Small Business Innovation Research Phase I grant to advance the company's non-aqueous glucagon candidate. Zosano Pharma Corporation, or Zosano, is developing a clinical-stage glucagon formulation delivered intra-dermally by a micro needle patch. In addition, Zealand Pharma A/S, a pharmaceutical company based in Denmark, is developing a clinical-stage glucagon analog that is designed to be more stable than glucagon while maintaining glucagon's clinical efficacy.

Our concentrated ultra-rapid acting insulin product candidate, BIOD-531, if approved, would face significant competition from insulin formulations currently on the market and, potentially, from development stage insulin formulations and other treatment systems. Humulin® R U-500 is commonly used to treat diabetes patients with severe insulin resistance, and pre-mixed insulins, such as Humalog® Mix 75/25, is commonly used to treat diabetes patients and lesser degrees of insulin resistance. Newer combination products may also compete with BIOD-531. For example, a combination of insulin degludec, an ultra-long-acting basal insulin developed by Novo Nordisk, and NovoLog® is approved in Europe and may be approved in the United States within the next few years. Also, combinations of basal insulin and GLP-1 analogs have either been approved or are in later stages of development; these products are believed to offer some measure of postprandial glucose control in addition to the control offered by a basal insulin. Furthermore, Thermalin Diabetes, LLC and Adocia Inc. have announced plans to develop a novel concentrated insulin-analog based formulation with fast absorption.

If approved, the primary competition for our BIOD-123 ultra-rapid-acting insulin product candidate will be rapid-acting mealtime injectable insulins. There are several approved injectable rapid-acting mealtime

insulin analogs currently on the market including Humalog®, marketed by Eli Lilly and Company, NovoLog®, marketed by Novo Nordisk, and Apidra®, marketed by Sanofi. These rapid-acting insulin analogs provide improvement over "regular" mealtime insulin, including faster subcutaneous absorption, an earlier and greater insulin peak and more rapid post-peak decrease. Both Humalog® and NovoLog® have limited remaining patent protection in the United States and Europe. The possible introduction of lower priced brands or substitutable generic versions of these products could negatively impact the revenue potential of our ultra-rapid-acting product candidates should any be approved.

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. 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 current 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 on a timely basis, or that our contract manufacturers will not be able to manufacture our products in their final dosage form. In any such case, clinical development and commercialization of our product candidates could be delayed, prevented or impaired.

We do not currently own or operate manufacturing facilities for commercial production of our product candidates. We have limited experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our current strategy is to outsource to third parties all of the manufacturing required for our product candidates, including the component parts of the GEM device and activities associated with assembling, filling, finishing and packaging that device.

Under our customization and commercial supply agreement with Unilife, Unilife will develop and be the sole supplier of the GEM device. The initial term of our agreement with Unilife will expire in 2028. However, timing of the development program for our GEM product candidate is uncertain. Further progress requires at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. Unilife has informed us, however, that the projected GEM device development timelines are no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them have been unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair Trade Practices Act, or CUTPA, and alleged breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

We have entered into a manufacturing agreement with Emergent, under which Emergent will fill and finish the GEM device, using lyophilized glucagon and an aqueous diluent. During the term of our agreement with Emergent following validation of the manufacturing process, we are required to purchase, and Emergent is obligated to deliver to us, one manufactured lot of the GEM device every quarter. However, we would likely require additional manufacturing capacity in order for any commercial launch of our GEM product candidate to be successful.

With regard to our ultra-rapid-acting insulin formulations, including BIOD-531, we have recently relied on the University of Iowa for manufacturing services. We do not have any commercial manufacturing agreements in place with third parties to support these product candidates.

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible refusal by or inability of the third party to support our manufacturing programs in a time frame that we would otherwise prefer.

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

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

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

We rely on third parties for design and engineering expertise relating to the development of devices we may use to administer the pharmaceutical preparations of our product candidates.

The success of certain of our product candidates is likely to depend heavily on the design of the devices being used for the administration of our pharmaceutical preparations. For example, the GEM device, which is based on an existing technology platform developed by Unilife Corporation, is being customized by Unilife for use in an emergency situation. We do not have internal engineering expertise relating to medical devices, and we therefore rely on Unilife to provide such expertise. If our collaboration with Unilife is not successful in this regard, our program to develop our GEM product candidate will be materially harmed. Additionally, in order to maximize the commercial potential of our ultra-rapid-acting insulin product candidates, we will likely depend on one or more manufacturers of insulin pen injection devices or syringes to supply us with a commercially acceptable device. To date, we have not entered into any agreements for the supply of insulin pen injection devices or syringes, and we cannot assure you that any such devices will be available on terms that will be acceptable to us, if at all.

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

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

If our suppliers of active pharmaceutical ingredients and other production materials fail to deliver materials and provide services needed for the production of our product candidates in a timely and sufficient manner, or if they fail to comply with applicable regulations, clinical development or regulatory approval of our product candidates, 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 insulin, glucagon and other materials, such as vials, cartridges, prefilled syringes and, potentially, drug injection devices, 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 and glucagon in accordance with cGMP. We can make no assurances that our suppliers will comply with cGMP.

We have entered into a commercial supply agreement with Bachem AG for the supply of all of the glucagon we will need for the testing and manufacturing of our GEM product candidate. The initial term of our agreement with Bachem AG will expire in July 2017. We believe that the quantities of glucagon that we have rights to acquire under this agreement will be sufficient to allow us to complete our current and anticipated future clinical trials of our GEM product candidate and to support any potential commercial launch of the product candidate.

We have terminated an earlier supply agreement with N.V. Organon (subsequently acquired by Amphastar Pharmaceuticals, Inc., a specialty pharmaceutical development and manufacturing company), under which we have purchased the RHI we have used to formulate all of our RHI-based product candidates. We intend to use existing supplies of RHI to support the further development of BIOD-531, as well as enter into one or more development stage RHI supply agreements, as necessary. We do not have any plans, however, to commit to quantities of RHI that may be required to support the potential commercial launch of one or more of our RHI-based product candidates.

If we are unable to procure sufficient quantities of glucagon or insulin from our current or any future supplier, if supply of RHI, glucagon and other materials otherwise becomes limited, or if our suppliers do not meet relevant regulatory requirements, and if we were unable to obtain these materials in sufficient amounts, in a timely manner and at reasonable prices, we could be delayed in the manufacturing and possible commercialization of our product candidates, which may have a material adverse effect on our business. We would incur substantial costs and manufacturing delays if our suppliers are unable to provide us with products or services approved by the FDA or other regulatory agencies.

Risks Related to Our Intellectual Property

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

The following factors are important to our success:

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

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. 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 individual active and inactive ingredients in our ultra-rapid-acting insulin formulations and our stable glucagon presentations have been known and used for many years and, therefore, are no longer subject to patent protection, except in proprietary combinations. Accordingly, our patent and pending applications are directed to the particular formulations of these ingredients in our products, and to their use. Although we

believe our formulations and their uses are or will be patented and provide a competitive advantage, our patents may not prevent others from marketing formulations using the same active and inactive ingredients in different combinations.

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. Accordingly, the fact that we have obtained certain patent rights in the United States does not guarantee that we will be able to obtain the same or similar rights elsewhere. Even if we are granted patents in foreign countries, we cannot guarantee that we will be able to enforce our rights effectively.

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. For example, in late July 2013, a third party initiated administrative proceedings to oppose two of our more recent patents that have been granted by the European Patent Office in connection with our ultra-rapid-acting insulin formulations. While we were successful in defending the opposition before the Opposition Division of the European Patent Office in October 2014, the decision in those proceedings has been appealed. 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 the FDA does not believe that our product candidates satisfy the requirements for the Section 505(b)(2) approval procedure, or if the requirements for our product candidates under Section 505(b)(2) are not as we expect, the approval pathway will take longer and cost more than anticipated and in either case may not be successful.

We believe our ultra-rapid-acting insulin formulations and our stable glucagon presentation for use as a rescue product 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 and glucagon, 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 pursuant to Section 505(b)(2) NDAs. There is no specific guidance available for Section 505(b)(2) NDAs for insulin or glucagon. In addition, while there is precedent for a glucagon product being approved under a Section 505(b)(2) NDA, we are not aware of any insulin product that 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 product candidates 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.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain 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.

Even if one of our product candidates is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

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

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

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

- restrictions on such products' manufacturers or manufacturing processes;
- restrictions on the marketing or distribution of a product;
- requirements that we conduct new studies, make labeling changes, and implement Risk Evaluation and Mitigation Strategies;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product embargo and/or seizure;
- injunctions; or
- imposition of civil or criminal penalties.

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on Errol De Souza, our President and Chief Executive Officer and Gary Gemignani, our Chief Financial Officer. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. Replacing key employees may be

difficult and time-consuming because of the limited number of individuals in our industry with the skills and experiences required to develop, gain regulatory approval of and commercialize our product candidates successfully. We generally do not maintain key person life insurance to cover the loss of any of our employees.

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

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

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

Risks Related to Our Common Stock

Our strategic alternatives process may not result in a successful corporate transaction or liquidity event.

We have previously announced that our Board of Directors has approved a plan to explore our strategic alternatives. Any process of exploring strategic alternatives includes market risk and other uncertainties. There can be no assurance that the aforementioned exploration of strategic alternatives will result in the successful consummation of a liquidity event or other corporate transaction, on a basis that will provide any specific level of value to our common stockholders or other security holders, or at all. We do not currently have an investment bank formally engaged with respect to the strategic alternatives process, however, our plan is to engage an investment banking firm with respect to such an engagement.

Our failure to meet continued listing compliance criteria in accordance with Nasdaq Stock Market rules could result in Nasdaq delisting our common stock.

Nasdaq Stock Market listing rules require us to maintain certain closing bid price, stockholders equity, and other financial metric criteria. On September 21, 2015, we received a written notice from the Nasdaq Stock Market LLC, or NASDAQ, indicating that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Rules for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our common stock for the 30 consecutive business days from August 6, 2015 to September 16, 2015, we no longer meet the minimum bid price requirement.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have been granted a 180 calendar day compliance period, or until March 21, 2016, to regain compliance with the minimum bid price requirement. During the compliance period, our common stock will continue to be listed and traded on the Nasdaq Capital Market. To regain compliance, the closing bid of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. In the event we are not in compliance by March 21, 2016, we may be afforded a second 180 calendar day grace period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would be required to provide written notice of our intention to cure the minimum bid price deficiency by effecting a reverse stock split, if necessary. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other NASDAQ listing criteria.

In the event that we were delisted from the Nasdaq Capital Market, our common stock would become significantly less liquid, which would likely adversely affect its value. Although our common stock would likely be traded over-the-counter or on other less liquid trading platforms, these types of listings involve more risk and trade less frequently and in smaller volumes than securities traded on the Nasdaq Capital Market.

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.

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

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

- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;

- general economic, industry and market conditions; and

- the other factors described in this "Risk Factors" section.

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

As a result of our May 2011 registered direct offering and June 2012 private placement, we have outstanding warrants to purchase 2,256,929 shares of our common stock at $9.92 per share and 2,749,469 shares of our common stock at $2.66 per share. The $9.92 per share warrants expire in May 2016 and the $2.66 per share warrants expire in June 2017. We also have outstanding shares of Series B preferred stock that are convertible into 1,909,410 shares of common stock. The exercise of these warrants for, or the conversion of shares of Series B preferred stock into, shares of common stock would be substantially dilutive to the outstanding shares of common stock. Any dilution or potential dilution may cause our stockholders to sell their shares, which would contribute to a downward movement in the stock price of our common stock.

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

We have paid no cash dividends on our common 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 incur substantial costs as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 29,300 square feet of office space and laboratory facilities in Danbury, Connecticut. Our corporate headquarters are located at 100 Saw Mill Road, Danbury, Connecticut, in approximately 19,500 square feet of rentable office space. The lease for our corporate headquarters expires in July 2019. Our laboratory facilities are located at 6 and 8 Christopher Columbus Avenue, Danbury, Connecticut, in approximately 7,200 and 2,600 square feet of rentable laboratory and office space, respectively. The leases for our facilities at 6 and 8 Christopher Columbus Avenue expire in January 2016.

ITEM 3. *LEGAL PROCEEDINGS*

In July 2013, a third party initiated administrative proceedings in Munich, Germany before the European Patent Office to oppose two of our patents that have been granted in connection with our ultra-rapid-acting

insulin formulations—EP 2 319 500 and EP2 106 790. The opponent was listed as Dr. Armin K. Bohmann. The opponent requested that the patents be revoked, alleging that the subject matter was not patentable, the inventions were not adequately disclosed and the subject matter extended beyond the subject of the applications. In an October 2014 ruling, which the opponent has appealed, the Opposition Division of the European Patent Office found that all claims of both patents are novel and inventive.

In September 2015, we filed a complaint in Superior Court in the State of Connecticut (Judicial District of Danbury) against Unilife. The complaint contains two counts. The First Count seeks injunctive relief pending arbitration of certain contract claims relating to our GEM program. The Second Count seeks compensatory and punitive damages from Unilife based on its alleged violation of the Connecticut Unfair Trade Practices Act in connection with our GEM program. In November 2015, we also filed a demand for arbitration with the American Arbitration Association relating to alleged breaches by Unilife of its contractual obligations to develop and supply the injection device intended for use with our GEM product candidate.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

PART II

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

Market Information

From May 2007 through May 10, 2012, our common stock traded on the NASDAQ Global Market, and, since May 11, 2012, our common stock has traded on the NASDAQ Capital Market, in each case under the symbol "BIOD."

The following table sets forth the high and low sale prices per share for our common stock on the NASDAQ Capital Market in each of the quarters within our two most recent fiscal years.

Fiscal Quarter Ended	High	Low
December 31, 2013	$ 3.23	$ 1.93
March 31, 2014	$ 3.71	$ 2.23
June 30, 2014	$ 2.94	$ 1.97
September 30, 2014	$ 2.21	$ 1.61
December 31, 2014	$ 1.68	$ 1.20
March 31, 2015	$ 2.00	$ 1.14
June 30, 2015	$ 1.34	$ 0.99
September 30, 2015	$ 1.13	$ 0.39

Nasdaq Stock Market listing rules require us to maintain certain closing bid price, stockholders equity, and other financial metric criteria. On September 21, 2015, we received a written notice from the Nasdaq Stock Market LLC, or Nasdaq, indicating that we were not in compliance with the minimum bid price requirement set forth in Nasdaq Rules for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our common stock for the 30 consecutive business days from August 6, 2015 to September 16, 2015, we no longer meet the minimum bid price requirement.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have been granted a 180 calendar day compliance period, or until March 21, 2016, to regain compliance with the minimum bid price requirement. During the compliance period, our common stock will continue to be listed and traded on the Nasdaq Capital Market. To regain compliance, the closing bid of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. In the event we are not in compliance by March 21, 2016, we may be afforded a second 180 calendar day grace period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would be required to provide written notice of our intention to cure the minimum bid price deficiency by effecting a reverse stock split, if necessary. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

In the event that we were delisted from the Nasdaq Capital Market, our common stock would become significantly less liquid, which would likely adversely affect its value. Although our common stock would likely be traded over-the-counter or on other less liquid trading platforms, these types of listings involve more risk and trade less frequently and in smaller volumes than securities traded on the Nasdaq Capital Market.

Holders

As of November 30, 2015, the number of holders of record of our common stock was 31.

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.

ITEM 6 SELECTED FINANCIAL DATA

Not required for smaller reporting company filers.

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 included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Form 10-K (see Part I-Item 1A above) for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. We develop our product candidates by applying our formulation technologies to existing drugs in order to improve their therapeutic profiles. Our glucagon formulations and presentations are designed to be stable at room temperature and are intended for use by caregivers with little to no medical training as a rescue treatment for diabetes patients experiencing severe hypoglycemia. Our proprietary insulin formulations are designed to be more rapid-acting than the formulations currently available to Type 1 and Type 2 diabetes patients. We refer to these as "ultra-rapid-acting" insulin formulations.

Our lead glucagon product candidate is a glucagon emergency management, or GEM, drug-device combination that is intended to treat diabetes patients experiencing severe hypoglycemia, or very low concentrations of blood glucose. GEM is comprised of lyophilized glucagon and an aqueous diluent in a proprietary injection device from Unilife Medical Solutions, Inc., or Unilife. The GEM device is a dual-chamber design that automatically reconstitutes lyophilized glucagon immediately prior to injection and features automatic needle retraction on full dose delivery. GEM is designed with the goal of optimizing its ease of use for patient caregivers in an emergency.

In the third quarter of calendar year 2014, we submitted an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for our GEM product candidate. We have completed a Phase 1 clinical trial to assess the pharmacokinetic and pharmacodynamic profiles of BIOD-961, the reconstituted glucagon formulation intended for use in the GEM device. In the Phase 1 clinical trial, the overall pharmacokinetic and pharmacodynamic profiles of BIOD-961 were statistically indistinguishable from the two comparator glucagon formulations marketed by Eli Lilly and Novo Nordisk. In April 2015, we announced results from a formative human factors study of our GEM product candidate in which the GEM device demonstrated a substantial improvement in ease-of-use, frequency of successful administration and reduction in the error rate when compared to the commercially available glucagon kits. Despite these advancements, the timing of the development program for our GEM product candidate is uncertain. Further progress requires at least three registration batches of the fully filled and finished GEM device so that we may conduct the pivotal clinical study, human factors study and stability studies required for an NDA submission to the FDA. Previously, we anticipated that Unilife would deliver the registration batches toward the end of the 2015 calendar year. However, Unilife has informed us that the projected GEM device development timelines were no longer accurate, and discussions with Unilife to resolve a dispute regarding the requirements of our customization and commercial supply contract with them have been unsuccessful. We have initiated formal legal proceedings in Superior Court in the State of Connecticut and with the American Arbitration Association to address Unilife's alleged violation of the Connecticut Unfair Trade Practices Act, or CUTPA, and alleged breaches of contract in connection with the GEM program. Until such time as we are able to resolve these matters, if at all, we will be unable to continue to develop our GEM product candidate. We cannot give any assurance as to the outcome of our legal proceedings with Unilife.

In addition to our GEM product candidate, we are developing ultra-rapid-acting proprietary insulin formulations that are designed to be more rapid-acting than the formulations currently available to Type 1 and Type 2 diabetes patients. BIOD-531, a concentrated ultra-rapid-acting insulin formulation, combines recombinant human insulin, or RHI, with our proprietary combination of excipients to increase the rate of

absorption following subcutaneous injection when compared to other commercially available insulin formulations, including "rapid-acting" mealtime insulin analogs such as Humalog®, marketed by Eli Lilly, NovoLog®, marketed by Novo Nordisk, and Apidra®, marketed by Sanofi. BIOD-531 contains 400 units of RHI per milliliter (instead of the standard 100 units per milliliter), and is formulated with EDTA, citrate and magnesium sulfate. When delivered by subcutaneous injection, BIOD-531 is characterized by a rapid onset of action and a prolonged duration of action, which we believe could address an unmet medical need for a concentrated insulin with an initial rate of absorption superior to that of existing concentrated insulins and prandial/basal premixed insulins and comparable or superior to that of existing rapid-acting insulin analogs.

In addition to our RHI-based ultra-rapid-acting insulin formulations, we have used our proprietary excipients to develop pre-clinical analog-based ultra-rapid-acting insulin formulations using either insulin lispro, the active pharmaceutical ingredient in Humalog®, or insulin aspart, the active pharmaceutical ingredient in NovoLog®.

In December 2015, we announced that our board of directors approved a plan to explore strategic alternatives to further realize value from our pipeline assets while preserving our cash balance to the extent practicable. We intend to retain an advisor to assist us in the process of evaluating our strategic alternatives.

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 expect to continue to incur operating losses as we continue our efforts to develop and commercialize our product candidates. We have financed our operations and internal growth through various financing transactions, including our initial public offering in May 2007 and several subsequent transactions, including, most recently, our April 2015 underwritten public offering. In addition, we raised funds pursuant to our At-the-Market Issuance Sales Agreement, or the sales agreement, with MLV & Co. LLC, or MLV, and our stock purchase agreement with Lincoln Park Capital Fund, LLC, or LPC.

We have devoted substantially all of our efforts to research and development activities, including clinical trials. Our net loss was $18.7 million for the year ended September 30, 2015. As of September 30, 2015 we had an accumulated deficit of $248.3 million.

As of September 30, 2015 we had approximately $40.8 million in cash and cash equivalents compared to $24.6 million in cash and cash equivalents as of September 30, 2014. We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses and capital expenditures at least until the first calendar quarter of 2017. We believe that future cash expenditures will be partially offset by raising additional capital from capital markets, revenues from research grants and proceeds derived from potential collaborations, including, but not limited to, upfront fees, research and development funding, milestone payments and royalties. We can give no assurances that such funding will, in fact, be realized in the time frames we expect, or at all. We may be required to secure alternative financing arrangements or defer or limit some or all of our research, development or clinical projects.

Financial Operations Overview

Revenues

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

Research and Development Expenses

Research and development expenses consist of the 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 intend to focus our research and development efforts on conducting preclinical studies and Phase 1 and Phase 2 clinical trials to determine our preferred development, clinical and regulatory program for our ultra-rapid-acting insulin formulations and our glucagon formulations and presentations. We also intend to conduct a pivotal clinical trial in support of an NDA for our GEM product candidate. If we are able to successfully resolve our dispute with Unilife regarding its contractual obligations to supply the registration batches of our GEM product candidate and, subsequently, the commercial supplies of the injection device intended for use with our GEM product candidate, we anticipate that our research and development expenses for the fiscal year ending September 30, 2016 will increase as compared to the fiscal year ended September 30, 2015, as we may:

- conduct clinical trials with our GEM product candidate, including at least one pivotal clinical trial required for FDA approval of an NDA;
- conduct clinical trials with our BIOD-531 product candidate, including a planned Phase 2, parallel group study in patients with Type 2 diabetes over a six-month treatment period;
- conduct the required stability, preclinical and human factors and user acceptability studies to support the approval of our GEM device and one or more insulin injection devices intended for use with BIOD-531; and
- purchase active pharmaceutical ingredients and other materials in support of our product candidates.

Over the longer term, we anticipate that these expenses will increase further as we:

- prepare and file an NDA for our GEM product candidate; and
- conduct later stage clinical trials of BIOD-531, including, potentially, pivotal clinical trials required for FDA approval of an NDA.

We have used our employee and infrastructure resources across multiple research projects and our drug development programs. A substantial majority of our research and development expenses incurred to date are attributable to our rescue and ultra-rapid-acting insulin programs.

In July and September 2012, we were awarded two National Institutes of Health grants for the development of a concentrated ultra-rapid-acting insulin formulation and a stable glucagon formulation, respectively, for use in an artificial pancreas. The July 2012 award was intended to fund research to develop a proprietary ultra-rapid-insulin product candidate at high concentrations suited to provide sufficient quantities of insulin in an external artificial pancreas pump device that has limited volume capacity. The July 2012 award was for two years and totaled $582 thousand. The September 2012 award was intended to fund research to develop a proprietary glucagon product candidate optimized to algorithmically deliver glucagon as part of a bi-hormonal closed loop system to mitigate hypoglycemic events. The September 2012 award was for two years and totaled $583 thousand. As of September 30, 2014, all grant income was earned and recorded.

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

	Year Ended September 30, 2015	
	2014	2015
	(In thousands)	
Preclinical expenses	$ 4,734	$ 3,872
Manufacturing expenses	3,403	2,794
Clinical/regulatory expenses	6,057	6,699
Total	$ 14,194	$ 13,365

The following table illustrates, for each period presented, our research and development costs by project.

	Year Ended September 30, 2015	
	2014	2015
	(In thousands)	
Ultra-rapid-acting insulin formulations:		
RHI-based	$ 442	$ 71
Insulin analog-based	1,377	156
GEM and stable glucagon	5,569	3,783
BIOD-531 and concentrated RHI-based formulations	3,715	6,101
Other	3,091	3,254
Total	$ 14,194	$ 13,365

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

- the progress, timing or success of our research and development and clinical programs for our product candidates, particularly our GEM and BIOD-531 product candidates;
- our ability to conduct the development work necessary to finalize the formulation and presentation of our GEM product candidate, as well as the preclinical studies, clinical trials, human factor studies and manufacturing activities necessary to support the submission of an NDA to the FDA for that product candidate;
- the ability and willingness of our existing strategic partners, service providers and suppliers, upon which we rely in the advancement of our product candidates, to meet the obligations set forth in our agreements with them, including Unilife, which is responsible for designing and manufacturing the device intended for use with our GEM product candidate, as well as delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA;
- the results of our real-time stability programs for our glucagon-, RHI-, and insulin analog-based product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project long term stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of our product candidates;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- the degree of clinical utility of our product candidates, particularly with regard to our ultra-rapid-acting insulin formulations, which have not yet been shown to be clinically superior to existing rapid-acting insulin analogs;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves;
- our ability to enforce our patents for our product candidates and our ability to secure additional patents for our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies or delivery devices, that could enable a room-temperature rescue product in a portable, easy to use presentation;

- the ability of our contract manufacturing organizations or collaborators to timely and properly produce our products in our final dosage form and in the quantities we may require;

- our ability to secure adequate supplies of active pharmaceutical ingredients to support our product development programs and, if successful, the commercialization one or more product candidates;

- our capabilities and strategies for manufacturing, marketing and commercializing a product candidate; and

- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

A change in the outcome of any of these variables with respect to the development of ultra-rapid-acting insulin formulations or our GEM product candidate, could mean a significant change in the costs and timing associated with product development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for personnel, including stock-based compensation expenses, relating to our internal executive, legal, accounting, finance and information technology departments. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, patent expenses, 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 core expenses in the fiscal year ending September 30, 2016 will remain flat, however, overall general and administrative expenses are subject to ongoing costs of litigation with Unilife. Over the longer term, however, these expenses could increase as we prepare to file an NDA in support of our GEM product candidate and, possibly, commence pre-commercialization activities.

Warrant Liability

In June 2012, we issued warrants to purchase 2,749,469 shares of our common stock at an exercise price of $2.66 per share in connection with our June 2012 private placement. These warrants will expire on June 26, 2017, five years from the original issuance date of June 27, 2012. In May 2011, we issued warrants to purchase 2,256,929 shares of our common stock at an exercise price of $9.92 per share in connection with our May 2011 registered direct offering. These warrants will expire on May 17, 2016, five years from the original issuance date of May 18, 2011. Under the terms of both the 2012 warrants and the 2011 warrants, if we enter into a merger or change of control transaction, the holders of the warrants will be entitled to receive consideration as if they had exercised the warrants immediately prior to such transaction, or they may require us to purchase the unexercised warrants at the Black-Scholes value (as defined in the applicable warrant) of the warrant on the date of such transaction. The holders have up to 30 days following any such transaction to exercise this right. As a result of this provision, we recognize the 2012 and 2011 warrants as liabilities at their fair value on each reporting date.

We use the Black-Scholes valuation model to estimate the fair value of the warrants. The Black-Scholes valuation model takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock, and the risk-free interest rate for the term of the warrant. Using this model, we recorded an initial warrant liability of $4.8 million for the 2012 warrants and $9.4 million for the 2011 warrants, in each case as of the initial warrant issuance date. The significant assumptions for the model used for the 2012 warrants were remaining terms of the warrants, the common stock price of $3.15 per share, the warrant exercise price of $2.66 per share, a risk-free interest rate of 0.63% and an expected volatility rate of 82%. The significant assumptions for the model used for the 2011 warrants were remaining terms of the warrants, the common stock price of $3.15 per share, the warrant exercise price of $9.92 per share, a risk-free interest rate of 0.63% and an expected volatility rate of 77%. The liability for both the 2012 and 2011 warrants is revalued at each reporting period and changes in fair value are recognized currently in the statements of operations under the caption "Adjustments to fair value of common stock warrant liability."

Interest Income

Interest income consists of interest earned on our cash and cash equivalents. In November 2007, our board of directors approved investment policy guidelines, the primary objectives of which are the preservation of capital, the maintenance of liquidity and maintenance of appropriate fiduciary control, subject to our business objectives and tax situation. We have maintained an investment strategy of investing primarily in a premier commercial money market account, which consists primarily of short-term debt securities issued by the U.S. government, Treasury securities and U.S. government agencies. We intend to maintain this conservative strategy in fiscal year ending September 30, 2016.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements that have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and on various assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing at the end of this Annual Report on 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.

Government Grants

Grants received are recognized as grant income when the grants become receivable, provided there is reasonable assurance that we will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. We request cash funding under approved grants as expenses are incurred (not in advance) and report these receipts on the statement of operations as a separate line item entitled "Government Grants." The corresponding expenses are included in research and development expenses. In July and September 2012, we were awarded two National Institutes of Health grants for the development of a concentrated ultra-rapid-acting insulin formulations and a stable glucagon formulation, respectively, for use in an artificial pancreas. Both awards were for two years and totaled approximately $580 thousand each. Work

on the grant for the development of concentrated ultra-rapid-acting insulin formulation started in August 2012 and completed in June 2014. Expenses incurred were $167 thousand during the twelve months ended September 30, 2014. Work on the grant for the development of novel and stable glucagon formulations for closed loop systems started in January 2013 and completed in June 2014. Expenses incurred were $364 thousand during the twelve months ended September 30, 2014. As of September 30, 2014, all grant income was earned and recorded.

Share-Based Compensation

Stock Incentive Plan

In March 2013, our stockholders approved the amended and restated 2010 Stock Incentive Plan (the "2010 Plan"). Up to 3,750,000 shares of common stock may be issued pursuant to awards granted under the 2010 Plan, plus 1,540,739 shares of common stock underlying already outstanding awards under the Company's prior plans. As of September 30, 2015, we had 3,434,597 shares of common stock subject to outstanding awards. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.5 shares for each one share of common stock. We have not made any new awards under any prior equity plans after March 2, 2010, the effective date the 2010 Plan was approved by the stockholders. The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan.

We use the Black-Scholes pricing model to calculate the fair value of stock options. The expected life for these grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110.

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

We base our estimate of expected volatility on the historical volatility of our stock. 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.

We grant restricted stock units, or RSUs, to executive officers and employees pursuant to the 2010 Plan, from time to time. Each RSU represents one share of common stock. There is no direct cost to the recipients of RSUs, except for any applicable taxes. Each award vests in installments on each anniversary of the date of grant, and the costs of the awards are determined as the fair market value of the shares on the date of grant. In all cases, costs are expensed per the vesting schedule outlined in the award. For example, RSUs awarded in December 2010 vest annually over three years, with 50% vesting on the first anniversary of the date of grant and the remainder vesting in two equal installments on each anniversary thereafter, and therefore are expensed 50% in the first year and 25% each year in the next two years. Each year following the annual vesting date, between January 1st and March 15th, we will issue common stock for each vested RSU. During the period when the RSU is vested but not distributed, the RSUs cannot be transferred and the grantee has no voting rights. If we declare a dividend, RSU recipients will receive payment based upon the percentage of RSUs that have vested prior to the date of declaration.

For the year ended September 30, 2015, the share-based compensation expense, including expenses associated with stock options and RSUs, was $0.9 million, of which $0.3 million is reflected in research and development expenses and $0.6 million is reflected in general and administrative expenses. For the year ended September 30, 2014, the share-based compensation expense, including expenses associated with stock options and RSUs, was $0.8 million, of which $0.3 million is reflected in research and development expenses and $0.5 million is reflected in general and administrative expenses.

Income Taxes

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

At September 30, 2014 and 2015, we recorded a 100% valuation allowance against our net deferred tax asset of approximately $62.4 million and $53.3 million, respectively, as our management believes it is uncertain that it will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net deferred tax asset, an adjustment to the deferred tax valuation allowance would increase net income in the period in which we make such a determination.

As of September 30, 2015, we had net operating loss carry-forwards of approximately $31.1 million for U.S. federal tax purposes and $133.5 million for state tax purposes. These loss carry-forwards expire in the period 2025 to 2035. To the extent these net operating loss carry-forwards are available, we intend to use them to reduce the corporate income tax liability associated with our operations. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carry-forwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. Based on a Section 382 analysis review, we determined that an ownership change under Section 382 occurred on December 31, 2013.

We believe that approximately $103.7 million of the $134.8 million federal losses will expire unused as a result of Section 382 limitations. The maximum annual limitation under Section 382 is approximately $0.7 million for 20 years. To the extent our use of net operating loss carry-forwards is limited, future income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carry-forwards, which could result in decreased net income.

We also have state research and development credit carry-forwards of approximately $0.2 million, which expire commencing in fiscal 2022.

Results of Operations

Year Ended September 30, 2015 Compared to Year Ended September 30, 2014

Revenue. We did not recognize any revenue during the years ended September 30, 2015 or 2014.

Research and Development Expenses.

	Year Ended September 30,		Decrease	
	2014	2015	$	%
	In thousands			
Research and Development	$ 14,194	$ 13,365	$ 829	5.8%
Percentage of net loss	100.4%	71.3%		

Research and development expenses were $13.4 million for the year ended September 30, 2015, a decrease of $0.8 million, or approximately 5.8%, from $14.2 million for the year ended September 30, 2014. This decrease was primarily attributable to decreases of $0.6 million in expenses associated with payments to Unilife and other external contract manufacturers for the development of our GEM product candidate, a decrease of $0.5 million in animal studies, a decrease in manufacturing costs, including the purchase of active pharmaceutical ingredients, of $0.4 million offset by an increase of $0.7 million in external expenses associated with our clinical trials.

Research and development expenses for each of the years ended September 30, 2015 and 2014 included $0.3 million in stock-based compensation expense related to options granted to employees.

In July and September 2012, we received two National Institutes of Health awards for the development of a concentrated ultra-rapid-acting insulin formulation and glucagon formulation for use in an artificial pancreas. The July 2012 award was intended to fund research to develop a proprietary ultra-rapid-insulin

product candidate at high concentrations suited to provide sufficient quantities of insulin in an external artificial pancreas pump device that has limited volume capacity. The July award was for two years and totaled $582 thousand. The September 2012 award was intended to fund research to develop a proprietary glucagon product candidate optimized to algorithmically deliver glucagon as part of a bi-hormonal closed loop system to mitigate hypoglycemic events. The September 2012 award was for two years and totaled $583 thousand. For the year ended September 30, 2014, we reported $167 thousand in government grants for the high concentration ultra-rapid-insulin product candidate and $364 thousand for the glucagon formulation work.

General and Administrative Expenses.

	Year Ended September 30,		Increase	
	2014	2015	$	%
	In thousands			
General and Administrative	$ 5,598	$ 6,402	$ 804	14.4%
Percentage of net loss	39.6%	34.2%		

General and administrative expenses were $6.4 million for the year ended September 30, 2015, an increase of $0.8 million, or 14.4%, from $5.6 million for the year ended September 30, 2014. This increase is primarily attributable to an increase in professional fees of $0.9 million.

General and administrative expenses for the years ended September 30, 2015 and 2014 included $0.6 million and $0.5 million, respectively, in stock-based compensation expense related to options granted to employees and non-employee directors.

Interest and Other Income.

	Year Ended September 30,		Increase	
	2014	2015	$	%
	In thousands			
Interest and Other Income	$ 49	$ 52	$ 3	6.1%
Percentage of net loss	0.35%	0.28%		

Interest and other income increased to $52 thousand for the year ended September 30, 2015, from $49 thousand for the year ended September 30, 2014. The increase is primarily due to higher cash balances during the year.

Adjustments to Fair Value of Common Stock Warrant Liability.

	Year Ended September 30,		Decrease	
	2014	2015	$	%
	In thousands			
Adjustments to fair value of common stock warrant liability				
May 2011 Warrants	$ (1,143)	$ (20)	$ 1,123	
June 2012 Warrants	(3,964)	(989)	2,975	
Total	$ (5,107)	$ (1,009)	$ 4,098	80.2%
Percentage of net loss	36.1%	5.4%		

The change in fair value of derivative instruments-warrants of $(5,107) during the year ended September 30, 2014 was primarily a result of the decrease in the price of the common stock from $3.15 per share on September 30, 2013 to $1.67 per share on September 30, 2014. The change in fair value of common stock warrant liability of $(1,009) during the year ended September 30, 2015 was primarily a result of the decrease in the price of the common stock from $1.67 per share at September 30, 2014 to $0.44 per share on September 30, 2015.

Net Loss and Net Loss per Share.

	Year Ended September 30,		Increase	
	2014	2015	$	%
	In thousands, except per share amounts			
Net loss	$ (14,131)	$ (18,737)	$ 4,606	32.6%
Net loss per share	$ (0.66)	$ (0.46)		

Net loss was $18.7 million, or $(0.46) per basic and diluted share, for the year ended September 30, 2015, compared to $14.1 million, or $(0.66) per basic and diluted share, for the year ended September 30, 2014. The increase in net loss was primarily due to a decrease in adjustments to fair value of common stock warrant liability.

Liquidity and Capital Resources

Sources of Liquidity and Cash Flows

As a result of our significant research and development expenditures and the lack of any approved products or other sources of revenue, we have not been profitable and have generated significant operating losses since we were incorporated in 2003. We initially funded our research and development operations through aggregate gross proceeds of $26.6 million from our private financing transactions that we completed prior to our initial public offering. We received an aggregate of approximately $238 million from our initial public offering in May 2007, our follow-on offering in February 2008, our registered direct offerings in August 2010 and May 2011, our private placement in June 2012, our public offering in June 2013, our sales agreement with MLV, purchase agreement with LPC and our public offering in April 2015.

At September 30, 2015, we had cash and cash equivalents totaling approximately $40.8 million. We plan to continue to invest our cash and cash equivalents in accordance with our approved investment policy guidelines.

Net cash used in operating activities was $18.2 million for the year ended September 30, 2015, and $18.7 million for the year ended September 30, 2014. Net cash used in operating activities for the years ended September 30, 2015 and 2014 primarily reflects the net loss for the period, offset in part by depreciation and amortization, share-based compensation and changes in the fair value of the common stock-warrant liability.

Net cash used in/(provided by) investing activities was $(0.01) million for the year ended September 30, 2015 and $0.05 million for the year ended September 30, 2014. Net cash provided by investing activities for the year ended September 30, 2015 reflects the purchase of property and equipment offset by the sale of equipment. Net cash used in investing activities for the year ended September 30, 2014 reflects the purchase of property and equipment.

Net cash provided by financing activities was $34.5 million for the year ended September 30, 2015 and $3.6 million for the year ended September 30, 2014. Net cash provided by financing activities for the year ended September 30, 2015 primarily reflects proceeds from the sale of securities through our April 2015 public offering, our sales agreement with MLV, our purchase agreement with LPC, and through our employee stock purchase plan. Net cash provided by financing activities for the year ended September 30, 2014 primarily reflects proceeds from the sale of securities through our sales agreement with MLV, our purchase agreement with LPC, and through our employee stock purchase plan.

On April 20, 2015, we completed an underwritten public offering of 37,500,000 shares of our common stock, which included the full exercise of the underwriter's option to purchase 4,891,304 shares to cover overallotments, at a price to the public of $0.92 per share. We received net proceeds from this offering, after deducting underwriting discounts, commissions and expenses of $32.1 million.

On July 25, 2014, we entered into the purchase agreement with LPC. Under the terms, and subject to the conditions of the purchase agreement, we had the right to sell to LPC, and LPC was obligated to purchase, up to $15 million in shares of our common stock, subject to certain limitations, from time to time over the 36-month period commencing on the date that a registration statement, which we filed with the SEC, was

declared effective by the SEC and a final prospectus in connection therewith was filed. As of September 30, 2015 we sold an aggregate of 750,000 shares of common stock pursuant to this agreement and received proceeds, net of sales commissions, of $1.2 million. In April 2015, we terminated the purchase agreement with LPC.

In May 2013, we entered into the sales agreement with MLV, under which we may initially issue and sell up to $14 million in shares of our common stock from time to time through MLV as our sales agent. On July 2, 2014 we began selling shares pursuant to this agreement. As of September 30, 2015 we sold an aggregate of 2,607,535 shares of common stock pursuant to the sales agreement and received proceeds, net of sales commissions, of $4.7 million.

Funding Requirements

We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses and capital expenditures at least until the first calendar quarter of 2017. We have based this estimate upon assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect. Our existing capital resources are not sufficient to complete our clinical development program for an ultra-rapid-acting insulin product candidate. 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 exploration of various strategic alternatives with the assistance of an advisor, and possible execution of one such alternative;
- the progress, timing or success of our research and development and clinical programs for our product candidates, particularly our GEM and BIOD-531 product candidates;
- our ability to conduct the development work necessary to finalize the formulation and presentation of our GEM product candidate, as well as the preclinical studies, clinical trials, human factor studies and manufacturing activities necessary to support the submission of an NDA to the FDA for that product candidate;
- the ability and willingness of our existing strategic partners, service providers and suppliers, upon which we rely in the advancement of our product candidates, to meet the obligations set forth in our agreements with them, including Unilife, which is responsible for designing and manufacturing the device intended for use with our GEM product candidate, as well as delivering three registration lots of the filled and finished GEM device required for submitting an NDA to the FDA;
- the results of our real-time stability programs for our glucagon-, RHI-, and insulin analog-based product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project long term stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of our product candidates;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- the degree of clinical utility of our product candidates, particularly with regard to our ultra-rapid-acting insulin formulations, which have not yet been shown to be clinically superior to existing rapid-acting insulin analogs;
- our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves;
- our ability to enforce our patents for our product candidates and our ability to secure additional patents for our product candidates;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;

- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies or delivery devices, that could enable a room-temperature rescue product in a portable, easy to use presentation;

- the ability of our contract manufacturing organizations or collaborators to timely and properly produce our products in our final dosage form and in the quantities we may require;

- our ability to secure adequate supplies of active pharmaceutical ingredients to support our product development programs and, if successful, the commercialization one or more product candidates;

- our capabilities and strategies for manufacturing, marketing and commercializing a product candidate; and

- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

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

We may receive additional proceeds from the exercise of the warrants that we issued in connection with our May 2011 registered direct offering and our June 2012 private placement, if any of those warrants are exercised for cash. Whether the warrants are exercised for cash will depend on decisions made by the warrant holders and on whether the market price of our common stock exceeds the $9.92 per share warrant exercise price of the May 2011 warrants or the $2.66 per share warrant exercise price of the June 2012 warrants. The May 2011 warrants and the June 2012 warrants will expire on May 17, 2016 and June 26, 2017, respectively.

While we continue to pursue cost saving initiatives to reduce operating expenses, we will also need to raise additional funds and periodically explore sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, debt financings, bank borrowings or other sources. However, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs. The accompanying financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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 excess funds are invested in a premium commercial money market fund with one major financial institution. We do not hedge interest rate exposure. A portion of our investments may be subject to interest rate risk and could fall in value if interest rates were to increase.

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 below.

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

Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Management's Evaluation of Disclosure Controls and Procedures

We are required to maintain disclosure controls and procedures designed to ensure that material information related to us is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015 and, based on this evaluation, our chief executive officer and chief financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of September 30, 2015. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013).

Based on our assessment, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2015, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended September 30, 2015 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 2016 annual meeting of stockholders, or proxy statement, and the information included in the proxy statement is incorporated herein by reference.

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

Certain information required by this Item is contained under the heading "Executive Officers of the Registrant" in Part I of this Annual Report on Form 10-K. Other information required by this Item will appear in our proxy statement and is 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 Capital 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 in our proxy statement and is 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 RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this Item will appear in our proxy statement and is incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this Item will appear in our proxy statement and is incorporated herein by reference.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

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

(2) Financial Statement Schedules: Not applicable.

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

SIGNATURES

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

BIODEL INC.

By: /s/ Errol De Souza
Dr. Errol De Souza
President and Chief Executive Officer
Date: December 22, 2015

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

Signature	Title	Date
/s/ Errol De Souza Errol De Souza	President and Chief Executive Officer (Principal Executive Officer), Director	December 22, 2015
/s/ Gary G. Gemignani Gary G. Gemignani	Chief Financial Officer (Principal Financial and Accounting Officer)	December 22, 2015
/s/ Julia R. Brown Julia R. Brown	Director	December 22, 2015
/s/ Barry H. Ginsberg Barry H. Ginsberg	Director	December 22, 2015
/s/ Ira W. Lieberman Ira W. Lieberman	Director	December 22, 2015
/s/ Daniel Lorber Daniel Lorber	Director	December 22, 2015
/s/ Arlene M. Morris Arlene M. Morris	Director	December 22, 2015
/s/ Davey S. Scoon Davey S. Scoon	Director	December 22, 2015

Exhibits Index

Exhibit Number	Description of Document
3.1	Registrant's Second Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (333-140504) filed on February 7, 2007).
3.2	Certificate of Designation of Series A Convertible Preferred Stock of the Registrant (Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed on May 19, 2011).
3.3	Certificate of Amendment to Registrant's Second Amended and Restated Certificate of Incorporation, as amended (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 11, 2012).
3.4	Certificate of Designation of Series B Convertible Preferred Stock of the Registrant (Incorporated by reference to Exhibit 4.8 to the Registrant's Current Report on Form 8-K filed on June 27, 2012).
3.5	Certificate of Amendment of Registrant's Second Amended and Restated Certificate of Incorporation, as amended (Incorporated by reference to Exhibit 3.5 to the Registrant's Annual Report on Form 10-K filed on December 21, 2012).
3.6	Registrant's Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.6 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
3.7	Certificate of Amendment of Registrant's Second Amended and Restated Certificate of Incorporation, as amended (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2015).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
4.2	Form of Warrant to Purchase Shares of Common Stock issued in the Registrant's May 2011 registered direct offering (Incorporated by reference to Exhibit 4.7 to the Registrant's Current Report on Form 8-K filed on May 13, 2011).
4.3	Form of Warrant issued in the Registrant's June 2012 private placement (Incorporated by reference to Exhibit 4.9 to the Registrant's Current Report on Form 8-K filed on June 22, 2012).
10.1*	2010 Stock Incentive Plan, as amended March 8, 2012 (Incorporated by reference to Exhibit A of the Registrant's Definitive Proxy Statement on Schedule 14A filed on January 26, 2012).
10.2*	2010 Incentive Stock Option Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.3*	2010 Non Statutory Stock Option Agreement (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.4*	2010 Restricted Stock Unit Agreement (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.5*	Form of Indemnification Agreement entered into between the Registrant and its directors and certain of its executive officers (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (333-140504) filed on February 7, 2007).
10.6*	Amended and Restated 2004 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).

Exhibit Number	Description of Document
10.7*	2005 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
10.8*	2005 Non-Employee Directors' Stock Option Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
10.9*	Employment Agreement, dated March 26, 2010, between the Registrant and Errol B. De Souza (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 1, 2010).
10.10*	Change of Control Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (333-140504) filed on February 7, 2007).
10.11*	Executive Severance Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (333-140504) filed on February 7, 2007).
10.12	Commercial Lease, dated February 2, 2004, by and between the Registrant and Mulvaney Properties, LLC and an amendment thereto dated September 29, 2006 (for the premises located at 6 Christopher Columbus Avenue, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
10.13	Commercial Lease, dated October 19, 2006, by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 8 Christopher Columbus Avenue, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, Amendment No. 1 (333-140504), filed on May 10, 2007).
10.14	Amendment to Commercial Lease, dated July 23, 2007 by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 6 Christopher Columbus Avenue, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.15	Amendment to Commercial Lease, dated July 23, 2007 by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 8 Christopher Columbus Avenue, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.16	Commercial Lease, dated July 23, 2007, by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 100 Saw Mill Road, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.1 the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.17	Lease Amendment, dated October 1, 2007, to Commercial Lease, dated July 23, 2007, by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 100 Saw Mill Road, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 4, 2007).
10.18	Option to Renew, dated as of November 6, 2013, to Commercial Lease, dated as of July 23, 2007, as amended, by and between the Registrant and Mulvaney Properties, LLC (for the premises located at 100 Saw Mill Road, Danbury, CT 06810) (Incorporated by reference to Exhibit 10.15 to Registrant's Annual Report on Form 10-K filed on December 20, 2013).
10.19*	Form of Incentive Stock Option Agreement for 2004 Amended and Restated Stock Incentive Plan (Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).

Exhibit Number	Description of Document
10.20*	Form of Option Agreement for 2005 Non-Employee Directors' Stock Option Plan (Incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).
10.21	At-the-Market Issuance Sales Agreement, dated May 13, 2013, between the Registrant and MLV & Co. LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 13, 2013).
10.22	Underwriting Agreement, dated April 14, 2015, among the Registrant and the several Underwriters named therein (Incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on April 15, 2015).
10.23	Purchase Agreement, dated as of July 25, 2014, by and between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 28, 2014).
10.24	Registration Rights Agreement, dated as of July 25, 2014, by and between the Registrant and Lincoln Park Capital Fund, LLC (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 28, 2014).
10.25*	Employment Agreement, dated August 21, 2014, by and between the Registrant and Gary G. Gemignani (Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed on August 27, 2014).
10.26†	Commercial Supply Agreement for Glucagon, dated July 17, 2012, among Bachem Americas, Inc., Bachem AG and the Registrant (Incorporated by reference to Exhibit 10.25 to Registrant's Annual Report on Form 10-K filed on December 20, 2013).
10.27†	Customization and Commercial Supply Agreement, effective April 8, 2013, between Unilife Medical Solutions, Inc. and the Registrant (Incorporated by reference to Exhibit 10.26 to Registrant's Annual Report on Form 10-K filed on December 20, 2013).
10.28	Securities Purchase Agreement, dated as of June 21, 2012, among the Registrant and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 22, 2012).
21.1	Subsidiaries of the Registrant.
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
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.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.LAB	XBRL Taxonomy Label Linkbase Document.
101.PRE	XBRL Taxonomy Presentation Linkbase Document.

Exhibit Number	Description of Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.

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

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

* Indicates a management contract or compensatory plan or arrangement.

Attached as Exhibit 101 to this are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets; (ii) Statements of Operations, (iii) Statements of Stockholders' Equity; (iv) Statements of Comprehensive Loss; (v) Statements of Cash Flows; and (vi) Notes to Financial Statements.

BIODEL INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We have audited the accompanying consolidated balance sheets of Biodel Inc. as of September 30, 2015 and 2014 and the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 audits 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Biodel Inc. as of September 30, 2015 and 2014, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

/s/ BDO USA, LLP

New York, New York
December 22, 2015

Biodel Inc.

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

	September 30, 2014	September 30, 2015
ASSETS		
Current:		
Cash and cash equivalents	$ 24,588	$ 40,845
Prepaid and other assets	316	262
Total current assets	24,904	41,107
Property and equipment, net	481	280
Intellectual property, net	40	37
Total assets	$ 25,425	$ 41,424
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current:		
Accounts payable	$ 172	$ 421
Accrued expenses:		
Clinical trial expenses	214	1
Payroll and related	958	863
Accounting and legal fees	131	289
Other	141	234
Total current liabilities	1,616	1,808
Common stock warrant liability	1,014	5
Other long term liabilities	-	54
Total liabilities	2,630	1,867
Commitments		
Stockholders' equity:		
Convertible preferred stock, $.01 par value; 50,000,000 shares authorized, 1,950,000 and 1,909,410 issued and outstanding	19	19
Common stock, $.01 par value; 200,000,000 shares authorized; 23,079,543 and 62,151,202 issued and outstanding, respectively	231	622
Additional paid-in capital	252,104	287,212
Accumulated deficit	(229,559)	(248,296)
Total stockholders' equity	22,795	39,557
Total liabilities and stockholders' equity	$ 25,425	$ 41,424

See accompanying notes to financial statements.

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

	September 30,	
	2014	2015
Revenue	$ —	$ —
Operating expenses:		
Research and development	14,194	13,365
Government grants	(531)	—
General and administrative	5,598	6,402
Total operating expenses	19,261	19,767
Other expense/(income):		
Interest and other income	(49)	(52)
Adjustments to fair value of common stock warrant liability	(5,107)	(1,009)
Loss on fixed asset	—	2
Loss before tax provision	(14,105)	(18,708)
Tax provision	26	29
Net loss	$ (14,131)	$ (18,737)
Net loss per share — basic and diluted	$ (0.66)	$ (0.46)
Weighted average shares outstanding — basic and diluted	21,404,258	41,017,855

See accompanying notes to financial statements.

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

	Common Stock $.01 Par Value		Series B Preferred stock $.01 Par Value		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, September 30, 2013	21,070,824	$ 211	1,950,000	$ 19	$ 247,761	$ (215,428)	$ 32,563
Proceeds from ATM facility	1,564,821	16	—	—	3,010	—	3,026
Proceeds from equity line	395,000	4	—	—	486	—	490
Stock-based compensation	—	—	—	—	784	—	784
Proceeds from the sale of stock — ESPP	8,189	—	—	—	15	—	15
Stock options exercised	19,241	—	—	—	48	—	48
RSUs converted to common stock	21,468	—	—	—	—	—	—
Net loss	—	—	—	—	—	(14,131)	(14,131)
Balance, September 30, 2014	23,079,543	$ 231	1,950,000	$ 19	$ 252,104	$ (229,559)	$ 22,795
Proceeds from ATM facility	1,042,714	10	—	—	1,581	—	1,591
Proceeds from equity line	450,000	5	—	—	667	—	672
Proceeds from April 2015 Public Offering.....	37,500,000	375	—	—	31,774	—	32,149
Conversion of Series B preferred stock.....	40,590	—	(40,590)	—	—	—	—
Stock-based compensation	—	—	—	—	868	—	868
Proceeds from the sale of stock — ESPP	38,355	1	—	—	40	—	41
Accrued bonus liability settled with RSU's	—	—	—	—	178	—	178
Net loss	—	—	—	—	—	(18,737)	(18,737)
Balance, September 30, 2015	62,151,202	$ 622	1,909,410	$ 19	$ 287,212	$ (248,296)	$ 39,557

See accompanying notes to financial statements.

Consolidated Statements of Cash Flows
(In thousands)

	September 30, 2014	September 30, 2015
Cash flows from operating activities:		
Net loss	$ (14,131)	$ (18,737)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	603	197
Stock-based compensation for employees and directors	784	868
Adjustment to fair value of common stock warrant liability	(5,107)	(1,009)
(Increase) decrease in:		
Prepaid expenses and other assets	(47)	51
Income taxes receivable	1	3
Grant receivable	26	—
Increase (decrease) in:		
Accounts payable	(74)	249
Income tax payable	(75)	—
Accrued expenses and other liabilities	(703)	175
Total adjustments	(4,592)	534
Net cash used in operating activities	(18,723)	(18,203)
Cash flows from investing activities:		
Purchase/sale of property and equipment	(49)	7
Net cash used in/provided by investing activities	(49)	7
Cash flows from financing activities:		
Options exercised	48	—
Net proceeds from employee stock purchase plan	15	41
Net proceeds from ATM facility	3,026	1,591
Net proceeds from equity line	490	672
Net proceeds from sale of common stock	—	32,149
Net cash provided by financing activities	3,579	34,453
Net increase (decrease) in cash and cash equivalents	(15,193)	16,257
Cash and cash equivalents, beginning of period	39,781	24,588
Cash and cash equivalents, end of period	$ 24,588	$ 40,845
Cash paid for interest and income taxes:		
Interest	$ —	$ —
Income taxes	25	26
Non-cash financing and investing activities		
Conversion of convertible preferred stock to common stock	—	—
Issuance of restricted stock units to settle bonus accrual	—	178

See accompanying notes to financial statements.

1. Business

Biodel Inc. and its wholly owned subsidiary (collectively, "Biodel" or the "Company", and formerly Global Positioning Group Ltd.) is a 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 formed a wholly owned subsidiary in the United Kingdom in October 2011 ("Biodel UK Limited"). This subsidiary has been inactive since its inception.

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 $14,194, and $13,365 for the years ended September 30, 2014 and 2015, respectively.

Government Grants

Grants received are recognized as grant income when the grants become receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The Company requests cash funding under approved grants as expenses are incurred (not in advance) and report these receipts on the statement of operations as a separate line item entitled "Government Grants". The corresponding expenses are included in research and development expenses. In July and September 2012, the Company was awarded two National Institutes of Health grants for the development of a concentrated ultra-rapid-acting insulin formulation and a stable glucagon formulation for use in an artificial pancreas, in the amounts of $582 and $583, respectively. Each award was for two years.

Work on the grant for the development of concentrated ultra-rapid-acting insulin formulation started in August 2012 and completed in June 2014. Expenses incurred and grant income were $167 and $0, for the years ended September 30, 2014 and 2015, respectively.

Work on the grant for the stable glucagon formulation started in January 2013 and completed in June 2014. Expenses incurred and grant income were $364 and $0 for the years ended September 30, 2014 and 2015, respectively.

The Company reported grant income of $531 and $0, for the years ended September 30, 2014 and 2015, 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, forfeiture rate used in the computation of share-based compensation, deferred tax assets, and warrant liability estimated at fair value. 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. As of

September 30, 2014 and 2015, the Company had cash and cash equivalents of $24,588 and $40,845, respectively, which are primarily held in a premium commercial money market account.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents and accounts payable, approximate their fair values due to their short term maturities. Warrant liability is recorded at fair value.

Pre-Launch Inventory

Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit. If the probability of future commercial use and future economic benefit cannot be reasonably determined, then pre-launch inventory costs associated with such product candidates are expensed as research and development expense during the period the costs are incurred. Because all of its product candidates are in early stages of preclinical or clinical development, the Company currently expenses all purchases of pre-launch inventory as research and development, and expects to continue to do so until it can determine the probability of regulatory approval for the applicable product candidate.

For the years ended September 30, 2014 and 2015, the Company expensed $3 and $103, respectively, of costs associated with the purchase of RHI and glucagon as research and development expense after such materials passed quality control inspection by the Company and transfer of title occurred.

Intellectual Property

Intangible assets consist primarily of capitalized costs associated with the Company's ultra-rapid-acting insulin patents and the purchase of two domain addresses. They are amortized using the straight-line method over twenty years. If the Company determines that a patent will not result in future revenues, the cost related to such patent will be expensed in full on the date of that determination. Intellectual property amortization expense was $3 for each of the years ended September 30, 2014 and 2015.

Property and Equipment

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

Impairment of Long-Lived Assets

Whenever events or changes in circumstances indicate that the carrying amounts of a long-lived asset may not be recoverable, the Company reviews these assets for impairment and determines whether adjustments are needed to carrying values. There were no adjustments to the carrying value of long-lived assets at September 30, 2014 and 2015.

Warrant Liability

The Company applies the provisions of Accounting Standards Codification Topic 480 ("ASC 480") (formerly FASB Staff Position 150-5 (FSP 15-5)), Issuers Accounting under FASB Statement No. 150 for Freestanding Warrants and other Similar Instruments on Shares that are Redeemable or Distinguishing Liabilities from Equities. Pursuant to ASC 480, a freestanding financial instrument (other than outstanding share) that, at inception, embodies an obligation to repurchase the issuer's shares and "requires or may require" the obligation to be settled by transferring assets, qualifies as a liability (if the obligation is conditional, the number of conditions is irrelevant).

The Company issued warrants in May 2011 and June 2012 and recorded a liability determined by the Black-Scholes valuation model. The Black-Scholes valuation model was used because the warrants do not contain a repricing provision. The Black-Scholes valuation model takes into account, as of the valuation date, factors including the current exercise price, the expected life of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock, and the risk-free interest rate for the term of the warrant. These warrants will be revalued at each reporting period and changes in fair value are recognized currently in the statements of operations under the caption "Adjustments to fair value of common stock warrant liability."

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, 2015, the Company had a deficit accumulated of $248,296. 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 an ultra-rapid-acting insulin or a glucagon rescue product, launch and commercialize the product if it receives regulatory approval, and continue research and development programs. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

The Company is currently developing its first product candidates and has no products that have received regulatory approval. Any products developed by the Company will require approval from the 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

(In thousands, except share and per share amounts)

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.

Stock-Based Compensation

In March 2013, the stockholders of the Company approved the amended and restated 2010 Stock Incentive Plan (the "2010 Plan"). Up to 3,750,000 shares of the Company's common stock may be issued pursuant to awards granted under the 2010 Plan, plus 1,540,739 shares of common stock underlying already outstanding awards under the Company's prior plans. As of September 30, 2015, the Company had a total of 3,434,597 shares of common stock subject to outstanding awards from prior and current plans. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.5 shares for each one share of common stock. The Company has not made any new awards under any prior equity plans after March 2, 2010, the effective date the 2010 Plan was approved by the Company's stockholders. The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan.

The Company uses the Black-Scholes pricing model to calculate the fair value of stock options. The expected life for grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110. The Company bases its estimates of expected volatility on the Company's historical volatility.

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.

The Company expenses ratably over the vesting period the cost of the stock options granted to employees and directors. The total compensation cost for the years ended September 30, 2014, and 2015 was $784, and $868 respectively. At September 30, 2015, the total compensation cost related to non-vested options not yet recognized was $1,386, which will be recognized over the next three years assuming the employees complete their service period for vesting of the options. The Black-Scholes valuation model assumptions are as follows and were determined as discussed above:

	Year Ended September 30,	
	2014	**2015**
Expected life (in years)	3.77-4.75	3.77-4.75
Expected volatility	70-83%	61-82%
Expected dividend yield	0%	0%
Risk-free interest rate	0.58-1.63%	0.87-1.62%
Weighted-average grant date fair value	$2.35	$1.38

Participating Securities

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

(In thousands, except share and per share amounts)

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

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

3. Fair Value Measurement

ASC Topic 820 ("ASC 820"), originally issued as SFAS No. 157, Fair Value Measurements, applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, ASC 820 does not require any new fair value measurements. The fair value framework requires the categorization of assets and liabilities into three levels based upon the assumptions (inputs) used to price the assets or liabilities. The three levels of inputs used are as follows:

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

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

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

As of September 30, 2014 and 2015, the Company had assets and liabilities that fell under the scope of ASC 820. The fair value of the Company's warrant liability was determined by the Black-Scholes valuation model for the warrants issued in connection with the Company's May 2011 and June 2012 financings. Accordingly, the Company's fair value measurements of its warrant liability is classified as a Level 3 input.

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

Description	Fair Value at September 30, 2015	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Market Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 40,845	$ 40,845	—	—
Subtotal	40,845	40,845	—	—
Liabilities:				
Common stock warrant liability	(5)	—	—	(5)
Subtotal	(5)	—	—	(5)
Total	$ 40,840	$ 40,845	$ —	$ (5)

(In thousands, except share and per share amounts)

Description	Fair Value at September 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Market Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 24,588	$ 24,588	$ —	$ —
Subtotal	24,588	24,588	—	—
Liabilities:				
Common stock warrant liability	(1,014)	—	—	(1,014)
Subtotal	(1,014)	—	—	(1,014)
Total	$ 23,574	$ 24,588	$ —	$ (1,014)

The Company recognizes transfers into and out of the levels indicated above on the actual date of the event or change in circumstances that caused the transfer of change. All changes within Level 3 can be found in the following Level 3 reconciliation table:

Balance at September 30, 2013	$ (6,121)
Decrease in fair value	5,107
Balance at September 30, 2014	(1,014)
Decrease in fair value	1,009
Balance at September 30, 2015	$ (5)

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

Fair Value Assumptions Used in Accounting for Warrant Liability

The Company has determined its warrant liability to be a Level 3 fair value measurement and used the Black Scholes valuation model to calculate the fair value for the fiscal year ended September 30, 2014 and 2015.

At the measurement date, the Company estimated the fair value for the June 2012 warrants using the Black-Scholes valuation model using the following assumptions:

	September 30, 2014	September 30, 2015
June 2012 Financing		
Stock price	$ 1.67	$0.44
Exercise price	$ 2.66	$2.66
Risk-free interest rate	1.07%	0.64%
Expected remaining term	2.74 years	1.74 years
Expected volatility	61%	57%
Dividend yield	0%	0%

(In thousands, except share and per share amounts)

Warrants outstanding June 2012 financing	2,749,469	2,749,469

The Company estimated the fair value for the May 2011 warrants using the Black-Scholes valuation model at the measurement dates of September 30, 2014 and 2015, respectively using the following assumptions:

	September 30, 2014	September 30, 2015
May 2011 Financing		
Stock price	$1.67	$0.44
Exercise price	$9.92	$9.92
Risk-free interest rate	0.58%	0.08%
Expected remaining term	1.63 years	0.63 years
Expected volatility	62%	74%
Dividend yield	0%	0%
Warrants outstanding May 2011 financing	2,256,929	2,256,929

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

Expected Remaining Term. This is the remaining contractual life of the warrant.

Expected Volatility. This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. Since the Company's stock has been traded for the expected remaining term of the warrants, the Company uses its own historic volatility over the retrospective period corresponding to the expected remaining term of the warrants on the measurement date. An increase in the expected volatility will increase the fair value and the associated derivative liability.

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

4. Net Loss per Share

Net loss per share information is determined using the two-class method, which includes the weighted-average number of common shares outstanding during the period and other securities that participate in dividends ("participating securities"). The Company considers the outstanding warrants participating securities because they include rights to participate in dividends with the common stock on a one-for-one basis. In applying the two-class method, earnings are allocated to both common stock shares and warrants based on their respective weighted-average shares outstanding for the period. Since losses are not allocated to the participating securities, the two-class method results in the same loss per common share calculated using the basic method for the periods presented in these financial statements.

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

The amount of options, warrants, shares of preferred stock and restricted stock units excluded are as follows:

(In thousands, except share and per share amounts)

	Year Ended September 30,	
	2014	2015
Common shares issuable upon conversion of Series B Preferred Stock	1,950,000	1,909,410
Common shares underlying warrants issued for common stock	5,006,398	5,006,398
Stock options	2,643,523	3,434,597
Restricted stock units	—	131,128

5. Property and Equipment

Property and equipment consists of the following:

	September 30,	
	2014	2015
Furniture and fixtures	$ 324	$ 324
Leasehold improvements	1,548	1,548
Laboratory equipment	2,112	2,105
Manufacturing equipment	655	655
Facility equipment	65	65
Computer equipment and other	1,308	1,308
Sub-Total	6,012	6,005
Less: Accumulated depreciation and amortization	5,531	5,725
Total	$ 481	$ 280

Depreciation expense for the years ended September 30, 2014, and 2015 was $599, and $197, respectively.

6. Commitments

Change in Control and Severance Agreements

Certain employees have agreements which provide for payouts in the event that the Company consummates a change in control. At September 30, 2015, the amount of compensation due as a result of this event is approximately $3,091, as set forth in the agreements. These employees are also entitled to full vesting of their outstanding equity awards. These agreements also provide for routine severance compensation. As of September 30, 2015 and September 30, 2014, no amounts have been accrued.

Leases

As of September 30, 2015, the Company leased three facilities in Danbury, Connecticut.

The Company renewed its lease for laboratory space for one year on October 10, 2014. This lease provides for annual basic lease payments from February 1, 2015 through January 31, 2016 of $68, plus the annual Consumers Price Index ("CPI") increase for October, not to exceed 6%, plus operating expenses.

The Company renewed its lease agreement for additional office space adjacent to its laboratory space for one year on October 10, 2014. This lease provides for annual basic lease payments from February 1, 2015 through January 31, 2016 of $3, plus the annual CPI increase for October, not to exceed 6%, plus operating expenses.

The Company renewed its lease for its corporate office for five years on November 6, 2013. This lease provides for annual basic lease payments from August 1, 2014 through July 31, 2019 of $388, plus the annual CPI increase for May, not to exceed 6%, plus operating expenses. Escalations shall be on an annual basis

(In thousands, except share and per share amounts)

from August 1, 2015 through July 31, 2019, and will be calculated using the preceding year's basic lease payment, plus the annual CPI increase for May, not to exceed 6%.

Lease expense for the years ended September 30, 2014, and 2015 was $627, and $666, respectively.

Minimum lease payments under these agreements as of September 30, 2015, as well as equipment leases subsequently entered into, are as follows:

Years Ending September 30,	
2016	598
2017	558
2018	564
2019	480
Total	$ 2,200

Purchase Commitments

Commercial Supply Agreement with Bachem Americas

The Company has entered into a commercial supply agreement for the supply of glucagon with Bachem Americas, a supplier of glucagon. The Company is obligated to purchase certain quantities of glucagon pursuant to a rolling forecast submitted by the Company under this agreement. At this time, no forecast has been provided and there is no obligation to purchase.

Customization and Commercial Supply Agreement with Unilife Medical Solutions, Inc.

The Company has entered into a customization and commercial supply agreement with Unilife Medical Solutions, Inc. ("Unilife"), a wholly owned subsidiary of Unilife Corporation, a company which designs, develops and manufactures advanced drug delivery devices. The agreement obligates Unilife to develop and supply dual-chamber reconstitution devices to be used with the Company's glucagon rescue product candidate. The Company is obligated to make payments to Unilife on the achievement of certain development milestones, including a payment of $750 upon the delivery of registration batches for the Company's glucagon rescue product candidate. On September 11, 2015, the Company filed a complaint in Superior Court in the State of Connecticut against Unilife. The Complaint contains two counts. The First Count seeks injunctive relief pending arbitration of certain contract claims relating to the Company's GEM program. The Second Count seeks compensatory and punitive damages from Unilife based on its alleged violation of the Connecticut Unfair Trade Practices Act in connection with the GEM program. As of September 30, 2015, no additional milestones have been achieved and no additional payments have been made.

Manufacturing Agreement with Cangene bioPharma

The Company has entered into a manufacturing agreement with Cangene bioPharma Inc., doing business as Emergent BioSolutions, or Emergent, under which Emergent will fill and finish the GEM device, using lyophilized glucagon and an aqueous diluent. During the term of the agreement following validation of the manufacturing process, the Company is required to purchase, and Emergent is obligated to deliver to the Company, one manufactured lot of the GEM device every quarter beginning in the third quarter of fiscal year 2017. The Company expects to reserve and commit to additional manufacturing capacity with Emergent following the commercial launch of our GEM product candidate, if successful. Either party may terminate the agreement without cause upon thirty-six months prior written notice. At this time there is no obligation to purchase.

Agreement with Aegis Therapeutics

In June 2012, the Company entered into an agreement with Aegis Therapeutics, LLC, or Aegis, to acquire an exclusive, sublicensable, worldwide license to the protein stabilization technology that it is using in

(In thousands, except share and per share amounts)

the development of liquid glucagon formulations. Under the terms of the agreement, Aegis will prepare, file, prosecute and maintain patents and patent applications that are specific to the Company's liquid glucagon formulations in jurisdictions that the Company may designate from time to time. In October 2014, the Company amended this agreement to require the Company to pay Aegis $25 quarterly, beginning June 2015, subject to certain terms and conditions. Aegis has agreed to waive the quarterly payments due from the Company, and the Company did not make any payments to Aegis during fiscal year 2015. The agreement with Aegis was terminated in July 2015.

Other Commitments

The Company has entered into certain licensing and collaboration agreements for products currently under development. The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory, and approval milestones. The specific timing of such milestones cannot be predicted and depend upon future discretionary research and clinical developments, as well as, regulatory agency actions. Further, under the terms of certain agreements the Company may be obligated to pay commercial milestones contingent upon the realization of sales revenues and sublicense revenues. Due to the long range nature of such commercial milestones, they are neither probable at this time nor predictable, and consequently are not considered contingent milestone payment amounts.

7. Income Taxes

The Company files its tax returns on a fiscal year basis. For the years ended September 30, 2014 and 2015, the Company paid only state taxes.

The provision for income taxes is as follows:

	Year Ended September 30,	
	2014	**2015**
Current expense		
Federal	$ —	$ —
State	26	29
Tax provision	$ 26	$ 29

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

	Year Ended September 30,	
	2014	**2015**
Federal statutory rate	34.00%	34.00%
Federal taxes at statutory rate	$ (4,796)	$ (6,353)
Tax expense on permanent differences (a)	(1,475)	(56)
State taxes, net of federal tax effect	17	19
Valuation allowance increase (b)	6,316	6,419
Other	(36)	—
Actual tax provision	$ 26	$ 29

(a) Permanent differences were derived from share based compensation and adjustments to common stock warrant liability.

(b) Net of the Section 382 Adjustment.

(In thousands, except share and per share amounts)

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

	Year Ended September 30,	
	2014	2015
Balance, beginning of year	$ 75	$ —
Decrease related to prior year's tax position	(75)	—
Balance, at end of year	$ —	$ —

The Company files U.S. federal and state tax returns and has determined that its major tax jurisdictions are the United States and Connecticut. The tax years through 2015 remain open due to net operating loss carry-forwards and are subject to examination by the appropriate governmental agencies in the United States and Connecticut.

As of September 30, 2015, the Company had net operating loss ("NOL") carry-forwards of approximately $31,076 (net of Section 382 limitation discussed below) for U.S. federal tax purposes and $133,461 for state tax purposes. These loss carry-forwards expire between 2025 and 2035. To the extent these net operating loss carry-forwards are available, the Company intends to use them to reduce the corporate income tax liability associated with its operations.

The ability of the Company to utilize its NOL carry-forwards to reduce future taxable income is subject to various limitations under Internal Revenue Code Section 382 ("Section 382"). The utilization of such carry-forwards may be limited upon the occurrence of certain ownership changes, including the purchase or sale of stock by 5% shareholders and the offering of stock by the Company during any three-year period resulting in an aggregate change of more than 50% in the beneficial ownership of the Company. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of a Company's taxable income that can be offset by these carry-forwards. As of September 30, 2015, the Company completed a study of the impact of Section 382 limitation on future payments and determined that the statutory provisions limited the Company's ability to realize future tax benefits. Accordingly, the Company decreased federal net operating loss carry-forwards by approximately $47,827.

The Company also has state research and development credit carry-forwards of approximately $211, which expire commencing in fiscal 2022.The major components of deferred tax assets and valuation allowances and deferred tax liabilities at September 30, 2014 and 2015 are as follows:

	September 30,	
	2014	2015
Deferred Tax Assets		
Net operating losses	$ 30,706	$ 17,172
Capitalized expense	30,762	35,381
Research and development credits	230	140
Depreciation of fixed assets	467	364
Other	196	225
Total deferred tax asset	62,361	53,282
Valuation Allowance	(62,361)	(53,282)
Net Deferred Tax Assets	$ —	$ —

A valuation allowance for the full amount of the deferred tax assets has been established as of September 30, 2014 and 2015.

8. Stockholders' Equity

Common Stock

The Company's authorized common stock consists of 200,000,000 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.

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.

Financings

April 2015 Underwritten Public Offering

On April 20, 2015, the Company completed an underwritten public offering of 37,500,000 shares of its common stock, which included the full exercise of the underwriter's option to purchase 4,891,304 shares to cover overallotments, at a price to the public of $0.92 per share. The Company received net proceeds from this offering, after deducting underwriting discounts, commissions and expenses of $32.1 million.

July 2014 Purchase Agreement

On July 25, 2014, the Company entered into a purchase agreement (the "Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("LPC"). Under the terms, and subject to the conditions of the Purchase Agreement, the Company had the right to sell to LPC, and LPC was obligated to purchase, up to $15 million in shares of common stock, subject to certain limitations, from time to time over the 36-month period commencing on the date that a registration statement, which the Company agreed to file with the SEC pursuant to the Registration Rights Agreement, was declared effective by the SEC and a final prospectus in connection therewith was filed. The Company's registration statement was declared effective on September 2, 2014. The Company was obligated, within twenty (20) calendar days, to file with the SEC an initial Registration Statement covering the maximum number of Registrable Securities as shall be permitted to be included thereon in accordance with applicable SEC rules, regulations and interpretations so as to permit the resale of such Registrable Securities by the Investor under Rule 415 under the Securities Act at then prevailing market prices (and not fixed prices), as mutually determined by both the Company and LPC in consultation with their respective legal counsel. The Company shall use its commercially reasonable efforts to keep the Registration Statement effective pursuant to Rule 415 promulgated under the Securities Act and available for the resale by the Investor of all of the Registrable Securities covered thereby at all times until the date on which LPC shall have resold all the Registrable Securities covered thereby and no Available Amount remains under the Purchase Agreement. The Company could direct LPC, at its sole discretion and subject to certain conditions, to purchase up to 150,000 shares of common stock in any business day, increasing to amounts of up to 250,000 shares, depending upon the closing sale price of the common stock. The purchase price of shares of common stock purchased under the Purchase Agreement were based on the prevailing market prices of such shares at the time of sales, but in no event was the Company able to sell shares to LPC on a day when the closing sale price of the common stock was less than a floor price of $1.50 per share (subject to adjustment). As consideration for LPC's

commitment to purchase shares of common stock pursuant to the Purchase Agreement, the Company issued to LPC 95,000 shares of Common Stock as commitment shares, with a fair market value of $189, which is recorded as the cost of capital in additional paid in capital. The Company sold 750,000 shares of common stock pursuant to the Purchase Agreement, and received proceeds, net of expenses, of $1.2 million.

The Company terminated the Purchase Agreement, effective April 16, 2015, pursuant to its terms and no further sales may be made thereunder.

May 2013 At-the-Market Issuance Sales Agreement

In May 2013, the Company entered into an At-the-Market Issuance Sales Agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV"), under which the Company may initially issue and sell shares of common stock having aggregate sales proceeds of up to $14 million from time to time through MLV as the Company's sales agent. To date, the Company has sold an aggregate of 2,607,535 shares of common stock pursuant to the Sales Agreement and received proceeds, net of sales agent commissions and expenses, of $4.7 million.

June 2012 Private Placement

On June 27, 2012 the Company completed a private placement (the "2012 Private Placement") of an aggregate of 4,250,020 shares of common stock, 3,605,607 shares of Series B preferred stock and warrants to purchase 2,749,469 shares of common stock at an exercise price of $2.66 per share. For each unit consisting of either, a share of common stock or Series B preferred stock and a warrant to purchase 0.35 of a share of common stock, the purchasers in the June 2012 Private Placement paid a negotiated price of $2.355. The warrants are immediately exercisable and will expire on June 26, 2017, five years from the original issuance date of June 27, 2012.

Each share of Series B preferred stock is convertible into one share of the Company's common stock at any time at the option of the holder, except that the securities purchase agreement that the Company entered into in connection with the 2012 Private Placement (the "Securities Purchase Agreement") provides that a holder will be prohibited from converting shares of Series B preferred stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of common stock then issued and outstanding. In the event of the Company's liquidation, dissolution or winding up, holders of the Series B preferred stock will receive a payment equal to $0.01 per share of Series B preferred stock before any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock specifically ranking by its terms senior to the Series B preferred stock, holders of Series B preferred stock and holders of the Company's Series A preferred stock will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of capital stock that participates with the common stock in such distributions. Shares of Series B preferred stock will generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding Series B preferred stock will be required to amend the terms of the Series B preferred stock. Holders of Series B preferred stock are entitled to receive, and the Company is required to pay, dividends on shares of the Series B preferred stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

As required by the Securities Purchase Agreement, the Company filed a Registration Statement on Form S-3 (the "Registration Statement") with the Securities and Exchange Commission (the "SEC") on July 27, 2012, which was within 30 days after the closing of the 2012 Private Placement. The Registration Statement, which was declared effective on August 13, 2012, registers the resale of the shares of common stock and Series B preferred stock issued and sold in the 2012 Private Placement, the shares of common stock issuable upon conversion of the Series B preferred stock issued and sold in the 2012 Private Placement, and the shares of common stock issuable upon exercise of the warrants issued and sold in the 2012 Private Placement. Pursuant to the terms of the Securities Purchase Agreement, the Company agreed to pay liquidated damages to

the purchasers in the 2012 Private Placement if, after effectiveness of the Registration Statement and subject to certain specified exceptions, the Company suspends the use of the Registration Statement or the Registration Statement ceases to remain continuously effective as to all the securities for which it is required to be effective (each such event, a "Registration Default"). Subject to specified exceptions, for each 30-day period or portion thereof during which a Registration Default remains uncured, the Company is obligated to pay liquidated damages to each purchaser in cash in an amount equal to 1.0% of the aggregate purchase price paid by each such purchaser in the 2012 Private Placement, up to a maximum of 8.0% of such aggregate purchase price. As of the date of these financial statements, the Company does not believe that it is probable that it will be obligated to pay any such liquidated damages. Accordingly, the Company has not established an accrual for liquidated damages.

The Company received net proceeds, after deducting placement agent fees and other offering expenses of approximately $17,100 from this financing. In June 2013, 176,964 shares of the Company's Series B preferred stock were converted into an equal number of shares of common stock. In September 2013, 1,478,643 shares of the Company's Series B preferred stock were converted into an equal number of shares of common stock. In January 2015, 40,590 shares of the Company's Series B preferred stock were converted into an equal number of shares of common stock. As of September 30, 2015, the Company had 1,909,410 shares of the Series B preferred stock outstanding. In October 2015, all 1,909,410 remaining outstanding shares, of the Company's Series B preferred stock were converted into an equal number of shares of common stock.

In the event that the Company enters into a merger or change of control transaction, the holders of the warrants issued in the 2012 Private Placement will be entitled to receive consideration as if they had exercised the warrants immediately prior to such transaction, or they may require the Company to purchase the unexercised warrants at the Black-Scholes value (as defined in the warrant) of the warrant on the date of such transaction. The holders have up to 30 days following any such transaction to exercise this right. As a result of this provision, the Company recognizes the warrants as liabilities at their fair value on each reporting date.

May 2011 Registered Direct Offering

On May 12, 2011, the Company completed a registered direct offering of an aggregate of 3,018,736 shares of common stock, 1,813,044 shares of Series A preferred stock to one investor and warrants to purchase 2,256,929 shares of common stock at an exercise price of $9.92 per share. The investor who purchased Series A preferred stock units received units consisting of one share of Series A preferred stock and a warrant to purchase 0.1625 of a share of common stock. No fractional warrants were issued. Each unit was sold at a price of $8.84 per unit.

Each share of Series A preferred stock was convertible into 0.25 of a share of the Company's common stock at any time at the option of the holder, provided that the holder would be prohibited from converting the shares of
Series A preferred stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of the Company's common stock then issued and outstanding. In the event of the Company's liquidation, dissolution or winding up, holders of the Series A preferred stock would receive a payment equal to $0.01 per share of Series A preferred stock before any proceeds are distributed to the holders of the Company's common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock specifically ranking by its terms senior to the Series A preferred stock, holders of Series A preferred stock and holders of the Company's Series B preferred stock will participate ratably in the distribution of any remaining assets with the Company's common stock and any other class or series of capital stock that participates with the common stock in such distributions. Shares of Series A preferred stock generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding Series A preferred stock will be required to amend the terms of the Series A preferred stock. The Series A preferred stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors.

The Company received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $28,000 from this financing. As of September 2013, all of the Company's Series A preferred stock was converted into 453,483 shares of common stock.

In the event that the Company enters into a merger or change of control transaction, the holders of the warrants issued in the May 2011 financing will be entitled to receive consideration as if they had exercised the warrant immediately prior to such transaction, or they may require the Company to purchase the unexercised warrants at the Black-Scholes value (as defined in the warrant) of the warrant on the date of such transaction. As per the terms of the warrants, the holders have up to 30 days following any such transaction to exercise this right. As a result of this provision, the Company recognizes the warrants as liabilities at their fair value on each reporting date.

The Company's warrant liability is marked-to-market each reporting period with the change in fair value recorded as a gain or loss within Other (Income) Expense ("Adjustments to fair value of common stock warrant liability"), until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified as an equity instrument.

2004 Stock Incentive Plan

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

The Plan is 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.

2010 Stock Incentive Plan

In March 2013, the stockholders of the Company approved the amended and restated 2010 Stock Incentive Plan (the "2010 Plan"). Up to 3,750,000 shares of the Company's common stock may be issued pursuant to awards granted under the 2010 Plan, plus 1,540,739 shares of common stock underlying already outstanding awards under the Company's prior plans. As of September 30, 2015, the Company had 3,434,597 shares of common stock subject to outstanding awards. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.5 shares for each one share of common stock. The Company has not made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by the Company's stockholders. The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan. The total compensation cost related to options for the years ended September 30, 2014 and 2015 was $756 and $648 respectively.

(In thousands, except share and per share amounts)

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 for the purchase of common stock under the Purchase Plan. The employee's purchase price is equal to the lower of: 85% of the fair market value per share on the start date of the offering period in which the employee is enrolled or 85% of the fair market value per share on the semi-annual purchase date. The Purchase Plan imposes a limitation upon a participant's right to acquire common stock if immediately after the purchase, the employee would own 5% or more of the total combined voting power or value of the Company's common stock or of any of its affiliates not eligible to participate in the Purchase Plan. The Purchase Plan provides for an automatic rollover when the purchase price for a new offering period is lower than previously established purchase price(s). The Purchase Plan also provides for a one-time election that allows an employee the opportunity to enroll into a new offering period when the new offering is higher than their current offering price. This election must be made within 30 days from the start of a new offering period. Offering periods are twenty-seven months in length. The compensation cost in connection with the plan for the years ended September 30, 2014 and 2015 was $4 and $16 respectively.

An aggregate of 525,000 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 25,000 shares. As of September 30, 2014 and 2015, a total of 383,737 and 370,382 shares, respectively, were reserved and available for issuance under this plan. For the years ended September 30, 2014 and 2015, the Company issued a total of 116,263, and 154,618 shares, respectively, under the Purchase Plan.

2005 Non-Employee Directors' Stock Option Plan

The Company's 2005 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") was adopted by its Board of Directors and approved by its stockholders on March 20, 2007 and subsequently replaced with the 2010 Stock Incentive Plan. The Directors' Plan became effective upon the closing of the Company's initial public offering. An aggregate of 125,000 shares of common stock were 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 6,250 shares of common stock. Upon appointment, non-employee directors receive a one-time grant of an option to purchase 6,250 shares of common stock. Annually, non-employee directors receive an option to purchase 5,000 shares of common stock. Effective March 3, 2009, these shares vest pro rata over one year. However, in the event a non-employee director has not served since the date of the preceding annual meeting of stockholders, that director will receive an annual grant that has been reduced pro rata for each full quarter prior to the date of grant during which such person did not serve as a non-employee director.

The following table summarizes all stock option activity through September 30, 2015:

Options	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding balance September 30, 2013	1,920,051	$ 22.31	4	$ 445
Granted	1,427,000	2.35	6	—
Exercised	(19,241)	2.48	5	10

(In thousands, except share and per share amounts)

Options	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Forfeited, expired	(684,287)	16.48		—
Outstanding balance September 30, 2014	2,643,523	$ 13.15	5	—
Granted	916,750	1.38	6	—
Forfeited, expired	(125,676)	47.11		—
Outstanding balance September 30, 2015	3,434,597	$ 8.61	5	—
Exercisable shares, September 30, 2015	1,534,147	$ 16.99	3	—

Restricted Stock Units

The Company grants restricted stock units ("RSUs") to executive officers and employees pursuant to the 2010 Plan from time to time. There is no direct cost to the recipients of RSUs, except for any applicable taxes.

Each RSU award represents one share of common stock and each award vests annually over three years, with fifty percent vesting on the first anniversary of the date of grant and the remainder vesting in two equal installments on each anniversary thereafter. Each year following the annual vesting date, between January 1st and March 15th, the Company will issue common stock for each vested RSU. During the period when the RSU is vested but not distributed, the RSUs cannot be transferred and the grantee has no voting rights. If the Company declares a dividend, RSU recipients will receive payment based upon the percentage of RSUs that have vested prior to the date of declaration. The costs of the awards, determined as the fair market value of the shares on the grant date, are expensed per the vesting schedule outlined in the award. Based on historical experience of option cancellations, the Company has estimated an annualized forfeiture rate of 10% for all employee options and RSUs. Forfeiture rates will be adjusted over the requisite service period when actual forfeitures differ, or are expected to differ, from the estimate. As of September 30, 2015, the executives, the board of directors and employees had 418,295 vested and distributed RSUs and 131,128 vested but not yet distributed RSUs.

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

	September 30,	
	2014	2015
Stock compensation expense — RSUs	$ 54	$ 206

The following table summarizes RSU activity from October 1, 2013 through September 30, 2015:

	Shares	Weighted Average Grant-Date Fair Value
Non-vested and outstanding balance at September 30, 2013	31,296	10.48
Changes during the period:		
Shares granted	—	—
Shares vested and issued	31,296	10.48
Non-vested and outstanding balance at September 30, 2014	—	—
Changes during the period:		

Shares granted	131,128	1.57
Issued and distributed	—	—
Subtotal	131,128	1.57
Vested and not distributed	131,128	1.57
Non-vested and outstanding balance at September 30, 2015	—	—

Shares Reserved for Future Issuance

As of September 30, 2015, the Company reserved shares of common stock for future issuance as follows:

2010 stock incentive plan	5,043,510
2005 employee stock purchase plan	525,000
Common stock issuable upon conversion of Series B Preferred Stock	1,909,410
Warrants issued in connection with May 2011 registered direct offering	2,256,929
Warrants issued in connection with June 2012 private placement	2,749,469
Total	12,484,318

9. 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. For the years ended September 30, 2014 and 2015, the Company had not elected to make any contributions to the plan.

10. Subsequent Event

In December 2015, the Company announced that its board of directors approved a plan to explore strategic alternatives to further realize value from the Company's pipeline assets while preserving its cash balance to the extent practicable. The Company intends to retain an advisor to assist in the process of evaluating its strategic alternatives. As part of this plan, patient enrollment in BIOD-531 Study 3-157 and Study 3-250 is suspended.

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Exhibit 21.1

Subsidiaries of the Registrant

Biodel UK Limited (domiciled in the United Kingdom)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-182877 and 333-188576) and the Registration Statements on Form S-8 (Nos. 333-144407, 333-168903 and 333-180409) of Biodel Inc. of our report dated December 22, 2015, relating to the consolidated financial statements, which appears in this Form 10-K for the year ended September 30, 2015.

/s/BDO USA, LLP

New York, New York

December 22, 2015

Exhibit 31.01

CERTIFICATION

I, Errol De Souza, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Errol De Souza

Errol De Souza
President and Chief
Executive Officer
Date: December 22, 2015

Exhibit 31.02

CERTIFICATION

I, Gary G. Gemignani, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ Gary G. Gemignani
Gary G. Gemignani
Chief Financial Officer
Date: December 22, 2015

Exhibit 32.01

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

In connection with the Annual Report on Form 10-K of Biodel Inc. (the "Company") for the year ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Errol De Souza, President and Chief Executive Officer of the Company and Gary G. Gemignani, Chief Financial Officer of the Company, each hereby certifies that: (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Errol De Souza
Errol De Souza,
President and
Chief Executive Officer
Dated: December 22, 2015

/s/ Gary G. Gemignani
Gary G. Gemignani
Chief Financial Officer
Dated: December 22, 2015