BIODEL INC

FORM 10-K
(Annual Report)

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Address	100 SAW MILL ROAD
	DANBURY, CT 06810
Telephone	203-796-5000
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Industry	Biotechnology & Drugs
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Fiscal Year	09/30

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, 2012

or

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

Commission File Number 001-33451

BIODEL INC.

(Exact Name of Registrant as Specified in Its Charter)

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

Registrant's telephone number, including area code
(203) 796-5000
Securities registered pursuant to Section 12(b) of the Act:

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

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☐ Smaller reporting company ☑

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock of the registrant held by non-affiliates was $23 million based on the last sales price at which the common stock was last sold on the NASDAQ Capital Market on March 31, 2012.

The number of shares outstanding of the registrant’s common stock, as of November 30, 2012 was 14,177,220.

Documents Incorporated by Reference

Portions of the registrant’s definitive Proxy Statement, or the 2013 Proxy Statement, which will be filed with the Securities and Exchange Commission not later than 120 days after September 30, 2012, for its 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report. With the exception of the portions of the 2013 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Annual Report on Form 10-K.

BIODEL INC.
INDEX TO REPORT ON FORM 10-K

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- the progress, timing or success of our research and development and clinical programs for our product candidates, including the resulting data from clinical trials of an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;
- our ability to complete our Phase 2 clinical trial of BIOD-123, our lead candidate for an ultra-rapid-acting insulin formulation, in a timely manner and the outcome of that trial;
- the success of our formulation development work to improve the stability, pharmacokinetic and pharmacodynamic characteristics of our ultra-rapid-acting insulin analog-based formulations;
- our ability to conduct the development work necessary to select a lead formulation for our liquid glucagon product candidate for the rescue treatment of severe hypoglycemia and commence clinical trials of that formulation;
- the results of our real-time stability programs for our insulin and glucagon product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project real-time stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges we may face in the development of a glucagon rescue product candidate;
- our ability to secure approval by the U.S. Food and Drug Administration, or FDA, for our product candidates under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FFDCA;
- our ability to conduct pivotal clinical trials and other tests or analyses required by the FDA to secure approval to commercialize an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;
- 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 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;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies that could enable a room-temperature rescue product in a portable, easy to use presentation;
- the ability of our major suppliers to produce our products in our final dosage form;

- our commercialization, marketing and manufacturing capabilities and strategies; and

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

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

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

PART I

ITEM 1: *BUSINESS*

Overview

We are a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. We develop our product candidates by applying our proprietary formulation technologies to existing drugs in order to improve their therapeutic profiles. Our most advanced program involves developing proprietary formulations of injectable recombinant human insulin, or RHI, designed to be more rapid-acting than the “rapid-acting” mealtime insulin analogs currently used to treat patients with Type 1 and Type 2 diabetes. We, therefore, refer to these formulations as our “ultra-rapid-acting” insulin formulations. In addition to our RHI-based formulations, we are using our formulation technologies to develop new ultra-rapid-acting formulations of insulin analogs. These insulin analog-based formulations generally use the same or similar excipients as our RHI-based formulations and are designed to be more rapid-acting than the “rapid-acting” mealtime insulin analogs, but they may present characteristics that are different from those offered by our RHI-based formulations. We are also developing liquid glucagon formulations for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia.

An earlier RHI-based formulation known as Linjeta ™ (and previously referred to as VIAject®) was the subject of a New Drug Application, or NDA, that we submitted to the FDA in December 2009. In October 2010, the FDA issued a complete response letter stating that the NDA for Linjeta ™ could not be approved in its submitted form and that we should conduct two new Phase 3 clinical trials using our preferred commercial formulation of Linjeta ™ prior to re-submitting the NDA. Based upon the complete response letter and subsequent feedback that the FDA provided to us at a meeting in January 2011, we decided to study newer RHI-based formulations in earlier stage clinical trials. The objective of these clinical trials was to identify an RHI-based formulation with pharmacokinetic and pharmacodynamic profiles similar to the Linjeta ™ formulation, but with improved injection site toleration characteristics. These earlier stage clinical trials evaluated the pharmacokinetic, pharmacodynamic and injection site toleration profiles of our product candidates relative to Humalog®, a rapid-acting insulin analog.

In September 2011, we announced that two newer formulations, BIOD-105 and BIOD-107, did not demonstrate our target profile in Phase 1 clinical trials. We subsequently conducted a Phase 1 clinical trial of two additional formulations, BIOD-123 and BIOD-125, and announced top line results from that trial in April 2012. Both BIOD-123 and BIOD-125 achieved our target pharmacokinetic, pharmacodynamic and toleration profiles. Based on our assessment of these two formulations, we selected BIOD-123 as our lead RHI-based product candidate, and in the third calendar quarter of 2012, we began enrolling patients in a Phase 2 clinical trial of BIOD-123. This Phase 2 clinical trial is designed to assess the clinical impact of BIOD-123 relative to Humalog®. The trial is being conducted at investigative centers in the United States and is expected to enroll approximately 130 randomized patients with Type 1 diabetes. We expect to announce top-line results from this Phase 2 clinical trial in the third calendar quarter of 2013.

In May 2012, we selected two insulin analog-based formulations, BIOD-238 and BIOD-250, to evaluate in a Phase 1 clinical trial. BIOD-238 and BIOD-250 generally use the same or similar excipients as BIOD-123 and are intended to be optimized for rapid absorption and injection site toleration. We began enrolling patients in the Phase 1 clinical trial in the third calendar quarter of 2012. This trial, which is being conducted in Australia, is designed to compare the pharmacokinetic and injection site toleration profiles of these formulations relative to a rapid-acting mealtime insulin analog. We expect to announce top-line results from this clinical trial in the first calendar quarter of 2013. In parallel with the Phase 1 clinical trial of BIOD-238 and BIOD-250, we are continuing our formulation development work to improve the stability characteristics of our ultra-rapid-

acting insulin analog-based formulations.

In addition to our ultra-rapid-acting insulin formulation program, we are developing a liquid glucagon formulation for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia, or very low concentrations of blood glucose. To date, we have not selected a lead formulation to advance into clinical trials. We are continuing to conduct preclinical testing to develop formulations that achieve a combination of

pharmacokinetic, pharmacodynamic and stability characteristics that we believe would be required for a glucagon rescue treatment product to be commercially successful.

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, that 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 approximately 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 oral medications. These oral medications act, in part, by increasing the amount of insulin produced by the pancreas, by increasing the sensitivity of insulin-responsive cells, by reducing the glucose output of the liver or by some combination of these mechanisms. These treatments are limited in their ability to manage the disease effectively and generally have significant side effects, such as weight gain. Because of the limitations of non-insulin treatments, many patients with Type 2 diabetes deteriorate over time and eventually require insulin therapy to support their metabolism.

Insulin therapy has been used for more than 80 years to treat diabetes. This therapy usually involves administering several injections of insulin each day. These injections consist of administering a long-acting

basal injection one or two times per day and an injection of a rapid-acting insulin at mealtime. Although this treatment regimen is accepted as effective, it has limitations. First, patients generally dislike injecting themselves with insulin due to the inconvenience and pain of needles. As a result, patients tend not to comply adequately with the prescribed treatment regimens and are often inadequately medicated.

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

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

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. To administer glucagon with this kit, the liquid solution must first be injected into the vial with the dry powder and then 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 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.

Clinical Trials of Linjeta ™

We have conducted Phase 1, Phase 2 and Phase 3 clinical trials comparing the performance of our Linjeta ™ formulation of RHI to either Humulin® R, which is a branded formulation of RHI, or Humalog®,

which is one of the largest selling rapid-acting insulin analogs in the United States. In our Phase 1 and Phase 2 clinical trials, we observed that the Linjeta ™ formulation was more rapidly absorbed than Humulin® R or Humalog®. Accordingly, we believe that our ultra-rapid acting formulations better simulate the natural first-phase insulin release in response to a meal that would be typical of healthy individuals.

We completed our two pivotal Phase 3 clinical trials of Linjeta ™ in July 2008. Our pivotal Phase 3 clinical trials were open-label, parallel group, randomized trials conducted at centers in the United States, Germany and India. The trials were designed to compare the efficacy and safety of Linjeta ™ to Humulin® R. One of the trials tested Linjeta ™ in patients with Type 1 diabetes and the other in patients with Type 2 diabetes. We enrolled more than 400 patients in each trial for a six month treatment period. Approximately one-half of the patients in each trial were treated with Linjeta ™ and the remainder with Humulin® R. The primary objective of the trials was to determine if Linjeta ™ was not inferior to Humulin® in

the management of blood glucose levels, as measured by the mean change in patients' glycosylated hemoglobin, or HbA1c, levels from baseline to the end of the trial. HbA1c levels are a measure of patients' average blood glucose levels over a period of approximately 3 months. HbA1c is the FDA's preferred endpoint for diabetes trials. Predefined secondary endpoints in the trials included rates of mild and moderate and severe hypoglycemic events, and changes in body weight. Approximately 400 patients with Type 1 and Type 2 diabetes who completed the pivotal Phase 3 clinical trials elected to participate in a long term safety extension trial in which all patients were treated with Linjeta ™ as their mealtime insulin. The last patient visit in the extension trial was in February 2010.

In 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 requesting additional information regarding our NDA for Linjeta ™ . 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.

Development of Additional RHI- and Insulin Analog-Based Formulations

Based upon the complete response letter and subsequent feedback that the FDA provided to us at a meeting in January 2011, we decided to study newer RHI-based formulations in earlier stage clinical trials. After reviewing the results of a Phase 1 clinical trial of two newer formulations, BIOD-105 and BIOD-107, we determined that the overall pharmacokinetic and pharmacodynamic profiles of these formulations did not demonstrate our target product profile. We subsequently conducted a Phase 1 clinical trial of two additional formulations, BIOD-123 and BIOD-125, and announced top-line results from that trial in April 2012. We determined that both formulations achieved our target pharmacokinetic, pharmacodynamic and toleration profiles.

The Phase 1 clinical trial of BIOD-123 and BIOD-125 evaluated the pharmacokinetic, pharmacodynamic and injection site toleration profiles of these product candidates relative to Humalog®, a rapid-acting insulin analog. The objective of the clinical trial was to identify an RHI-based formulation with pharmacokinetic and pharmacodynamic profiles similar to the Linjeta ™ formulation, but with improved injection site toleration characteristics. The clinical trial was a single-center, randomized, double-blind, three-period crossover trial in 12 patients with Type 1 diabetes. Each study drug was administered subcutaneously on separate days with a washout period between injections. In the Phase 1 clinical trial, absorption rates of BIOD-123 and BIOD-125 were significantly faster than that of Humalog® as indicated by 64% and 54% reductions, respectively, in mean times to half maximal insulin concentrations ($p < 0.001$ for both BIOD-123 and BIOD-125 compared to Humalog®). Both RHI-based formulations and Humalog® were well tolerated, with injection site toleration generally perceived by patients to be similar to that of their usual mealtime injections used at home. As measured on a 100 mm visual analog scale, or VAS, in which 100 mm is defined as the worst possible injection discomfort, local toleration was not significantly different for BIOD-123 compared to Humalog® (BIOD-123 mean VAS 3.6 ± 2.1 mm, Humalog® 1.8 ± 1.1 mm, p=NS). The VAS score for BIOD-125 was slightly higher as compared to Humalog® (mean VAS 6.8 ± 2.9 mm, $p < 0.05$).

In the third calendar quarter of 2012 we began enrolling patients in a Phase 2 clinical trial of BIOD-123. This Phase 2 clinical trial is designed to assess the clinical impact of BIOD-123 relative to Humalog®. The

trial is being conducted at investigative centers in the United States and is expected to enroll approximately 130 randomized patients with Type 1 diabetes. We expect to announce top-line results from this Phase 2 clinical trial in the third calendar quarter of 2013.

In May 2012, we selected two insulin analog-based formulations, BIOD-238 and BIOD-250, to evaluate in a Phase 1 clinical trial. We formulated BIOD-238 and BIOD-250 by adding our proprietary combination of excipients to a marketed presentation of a rapid-acting insulin analog. BIOD-238 and BIOD-250 generally use the same or similar excipients as BIOD-123 and are intended to be optimized for rapid absorption and injection site toleration. We began enrolling patients in the Phase 1 clinical trial of BIOD-238 and BIOD-250 in the third calendar quarter of 2012. This trial, which is being conducted in Australia, is designed to compare the pharmacokinetic and injection site toleration profiles of BIOD-238 and BIOD-250 relative to the rapid-acting insulin analog on which the formulations were based. The trial is a single-center, randomized, double-blind, three-period crossover trial in approximately 12 patients with Type 1 diabetes.

We expect to announce top-line results from the Phase 1 clinical trial of BIOD-238 and BIOD-250 in the first calendar quarter of 2013. Even if the results of this trial are positive, we do not expect to study these formulations in additional clinical trials, including multiple injection Phase 2 clinical trials, because they were formulated by adding our proprietary excipients to a marketed presentation of an insulin analog and because they do not demonstrate stability characteristics consistent with our target product profile. Accordingly, in parallel with the Phase 1 clinical trial of BIOD-238 and BIOD-250, we are continuing our formulation development work to improve the stability characteristics of our ultra-rapid-acting insulin analog-based formulations. We are also developing formulations using the active pharmaceutical ingredient, rather than a marketed presentation, of an insulin analog.

Our Development of a Liquid Glucagon Formulation

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. We also believe that the development of a more stable form of liquid glucagon can overcome the limitations resulting from the rescue kits containing a dry powder of

glucagon. Accordingly, we are using our formulation technologies to develop a liquid glucagon formulation that does not require reconstitution and could, therefore, be administered using a pre-filled syringe in an autoinjector or similar device.

To date, we have not selected a lead formulation to advance into clinical trials. We are continuing to conduct preclinical testing to develop formulations that achieve a combination of pharmacokinetic, pharmacodynamic and stability characteristics that we believe would be required for a glucagon rescue product to be commercially successful.

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. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent institutional review board, or IRB, 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 applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA. 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, the primary competition for our ultra-rapid-acting insulin formulations will be rapid-acting mealtime injectable insulins such as Humalog®, which is marketed by Eli Lilly, NovoLog®, which is marketed by Novo Nordisk, and Apidra®, which is marketed by Sanofi-Aventis. These rapid-acting insulin analogs provide improvement over regular forms of 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.

In addition, other development stage insulin formulations may be approved and compete with ours. Halozyme Therapeutics, Inc. has conducted a Phase 1 and multiple Phase 2 clinical trials of RHI, lispro (the insulin analog in Humalog®) and aspart (the insulin analog in NovoLog®) in combination with a recombinant

human hyaluronidase enzyme and has reported that in each case the combination yielded pharmacokinetics and glucodynamics that better mimicked physiologic mealtime insulin release and activity than RHI, Humalog® or NovoLog® alone. Novo Nordisk has reported that they have initiated clinical development of an insulin analog intended to provide faster onset of action than the currently available rapid-acting insulin analogs and that a candidate formulation will enter Phase 3 clinical trials either in late 2012 or early 2013.

Several companies are also developing alternative insulin systems for diabetes, including MannKind Corporation, which submitted an NDA in early 2009 for an inhalable insulin product candidate. Mannkind's product candidate was not approved by the FDA and MannKind is currently conducting two additional Phase 3 clinical trials. MannKind has announced that it plans to resubmit a revised NDA in the third quarter of 2013. Approval of an inhaled insulin could reduce the overall market for injectable mealtime insulin.

A liquid glucagon formulation for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia would also face significant competition if it were to be commercialized. Eli Lilly and Novo Nordisk currently market injectable glucagon rescue kit products. We are aware of several glucagon rescue product candidates in early stage development, such as an auto-injector device that integrates glucagon powder and a diluent into a dual chamber cartridge within that device and an auto-injector utilizing a concentrated, non-aqueous glucagon formulation. In addition, other companies with expertise in protein stabilization have announced that they have developed a stable liquid glucagon formulation using FDA-approved injectable ingredients. We believe that at least one of these formulations of glucagon is being studied in one or more clinical trials. All of these programs utilize the same active ingredient as the liquid glucagon formulations that we are developing and offer, or may offer, presentations allowing for room temperature storage. In addition, Eli Lilly is developing a glucagon analog, which may also offer advantages over our liquid glucagon formulations.

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, EP2319500 and EP2106790, have been allowed. 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.

In June 2012, we entered into an agreement with Aegis Therapeutics, LLC, or Aegis, to acquire an exclusive, sublicensable, worldwide license to the protein stabilization technology that we are using in the development of our liquid glucagon formulations. Under the terms of the agreement, Aegis will prepare, file, prosecute and maintain patents and patent applications that are specific to our liquid glucagon formulations in jurisdictions

that we may designate from time to time.

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 contracted with N.V. Organon, a global producer of insulin, to supply us with all of the insulin that we will need for the testing and manufacturing of our RHI-based formulations. Our agreement with N.V. Organon will terminate in June 2018. We believe that our current supplies of insulin, together with the quantities of insulin called for under our existing supply agreement, will be sufficient to allow us to complete our current and anticipated future clinical trials of our proprietary RHI-based formulations, as well as support the commercial launch of the product if approved by the FDA.

With regard to our insulin analog-based formulations, we have entered into an agreement with a pharmaceutical company to acquire a limited supply of an insulin analog for use as the active pharmaceutical ingredient in our proprietary formulations. In addition, we have conducted some development work and all of our clinical trials of our insulin analog-based formulations by combining our proprietary excipients with a marketed presentation of an insulin analog.

We have entered into a commercial supply agreement with a third party for the supply of the glucagon that we intend to use in the manufacture of our liquid glucagon formulations.

Sales and Marketing

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

Employees

At September 30, 2012 we had 36 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, 2012:

Name	Age	Position
Dr. Errol B. De Souza	59	President and Chief Executive Officer
Gerard Michel	49	Chief Financial Officer
Dr. Alan Krasner	49	Chief Medical Officer

Paul Bavier	40	General Counsel and Secretary
Erik Steiner	46	Vice President, Operations

Dr. 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 received his postdoctoral fellowship in neuroscience from The Johns Hopkins University School of Medicine.

Mr. Gerard Michel joined our company in November 2007 as Chief Financial Officer, Vice President of Corporate Development and Treasurer. From October 2003 to November 2007, Mr. Michel served as Chief Financial Officer and from April 2006 to November 2007, Vice President, Corporate Development of NPS Pharmaceuticals, a publicly traded biopharmaceutical company. From June 1995 to July 2002, Mr. Michel served as a Principal of the consulting firm Booz-Allen & Hamilton. From 1988 to 1995, Mr. Michel held various licensing, sales and product management roles at Lederele Labs and Wyeth. Mr. Michel received an MBA and B.S. from The University of Rochester, and an M.S., in Microbiology from The University of Rochester School of Medicine and Dentistry.

Dr. Alan Krasner joined our company in May 2008 as Chief Medical Officer. From 2002 to 2008, Dr. Krasner served as Director in the Department of Clinical Research Metabolic Diseases at Pfizer Global Research and Development where he was responsible for the design, execution, clinical analysis, and reporting of multiple, global clinical trials supporting registration of late stage drug candidates. Dr. Krasner currently serves as a consulting physician at the Joslin Diabetes and Endocrinology Center of the Lawrence and Memorial Hospital in New London, Connecticut. Dr. Krasner holds a B.S. from the Medical Education Honors Program at Northwestern University and an M.D. from Northwestern University Medical School. He completed his residency at Johns Hopkins Hospital in internal medicine and subsequently completed his fellowship at Johns Hopkins Hospital in endocrinology and metabolism.

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

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

ITEM 1A. *RISK FACTORS*

Risks Related to Our Financial Position and Need for Additional Capital

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

Since our inception in December 2003, we have incurred significant operating losses. Our net losses were approximately $20.7 million for the fiscal year ended September 30, 2012. As of September 30, 2012, we had a deficit accumulated during the development stage of approximately $196.1 million. We have invested a significant portion of our efforts and financial resources in the development of our ultra-rapid-acting RHI-based insulin product candidates, including our prior Linjeta ™ formulation and our current lead formulation, BIOD-123. More recently, we have begun to invest an increasing portion of our efforts and financial resources in the development of our ultra-rapid-acting insulin analog-based formulations, including BIOD-238 and BIOD-250, and our liquid glucagon formulations.

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

- conduct clinical trials to study formulations of RHI- and insulin analog-based ultra-rapid-acting formulations that may be associated with less injection site discomfort than the Linjeta ™ formulation;
- conduct additional formulation development work to improve the stability, pharmacokinetic, and pharmacodynamic properties of our ultra-rapid-acting insulin analog-based formulations and our liquid glucagon formulations, or purchase rights related to proprietary technologies that are compatible with our formulations;

- conduct later stage clinical trials of our ultra-rapid-acting insulin formulations and a liquid glucagon formulation, including one or more pivotal clinical trials required for FDA approval of the NDAs;
- produce validation batches of our product candidates to support one or more NDAs;
- conduct additional work necessary to support an NDA for a liquid glucagon formulation, including conducting toxicology studies and human factor studies using the intended commercial presentation;
- conduct the required stability, preclinical and human factors and user acceptability studies to support the approval of one or more insulin pen and glucagon auto-injector devices intended for use with our product candidates;
- purchase active pharmaceutical ingredients and other materials consistent with our existing contractual obligations; and
- conduct clinical development of our other product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities, including developing proprietary insulin and glucagon formulations 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 a development stage company with no commercial products. All of our product candidates are in early 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 liquid glucagon formulation, we may 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 until the second calendar quarter of 2014. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Our future capital requirements will depend on many factors, including:

- the progress, timing or success of our research and development and clinical programs for our product candidates, including the resulting data from clinical trials of an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;
- our ability to complete our Phase 2 clinical trial of BIOD-123 in a timely manner and the outcome of that trial;
- the success of our formulation development work to improve the stability, pharmacokinetic and pharmacodynamic characteristics of our ultra-rapid-acting insulin analog-based formulations;
- our ability to conduct the development work necessary to select a lead formulation for our liquid glucagon product candidate for the rescue treatment of severe hypoglycemia and commence clinical trials of that formulation;
- the results of our real-time stability programs for our insulin and glucagon product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project real-time stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of a glucagon rescue product candidate;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- our ability to conduct pivotal clinical trials and other tests or analyses required by the FDA to secure approval to commercialize an ultra-rapid-

acting insulin formulation or a liquid glucagon formulation;

- 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 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;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies that could enable a room-temperature rescue product in a portable, easy to use presentation;
- the ability of our major suppliers to produce our products in our final dosage form;
- our commercialization, marketing and manufacturing capabilities and strategies; and

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

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 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 ultra-rapid-acting mealtime insulin development program.

We have invested a significant portion of our efforts and financial resources in the development of our ultra-rapid-acting insulin product candidates. The FDA concluded that the results from our completed pivotal Phase 3 clinical trials of Linjeta ™ were not sufficient to obtain marketing approval for the Linjeta ™ formulation, and we chose to advance new formulations into the clinic. Clinical trials of our first two new formulations, BIOD-105 and BIOD-107, did not achieve satisfactory results. If we are not able to develop alternative RHI- or insulin-analog based formulations with desirable pharmacokinetic, pharmacodynamic, stability and injection site toleration characteristics, or experience significant delays in doing so, then our business may be materially harmed. For example, while BIOD-123, our lead candidate for an ultra-rapid-acting RHI-based formulation, demonstrated pharmacokinetic, pharmacodynamic and injection site toleration characteristics consistent with our target product profile in a Phase 1 clinical trial, we have generated limited real-time stability data with this formulation.

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, in parallel with the Phase 1 clinical trial of BIOD-238 and BIOD-250 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 a marketed presentation of an insulin analog, are currently 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.

We have limited experience with developing pharmaceutical preparations of glucagon.

Our experience with the manufacture, testing and analysis of pharmaceutical preparations of glucagon in preclinical studies is limited, and we have not yet conducted any clinical trials using glucagon as an active pharmaceutical ingredient. In addition, we have limited experience with some of the technologies we use to stabilize our liquid glucagon formulations. Because of our limited experience, we may be unable to accurately anticipate the technical challenges that we may face in the development of a glucagon rescue product. For example, we previously expected to complete the necessary development work for a liquid glucagon formulation to allow us to file an NDA for a glucagon rescue product by the end of the second calendar quarter of 2014. However, we have not, to date, selected a lead liquid glucagon formulation to advance into clinical trials, because we have not yet achieved in the preclinical studies of our prototype formulations a combination of pharmacokinetic, pharmacodynamic and stability characteristics that we believe would be required for a glucagon rescue product to be commercially successful. As a result, we intend to continue our development work with our liquid glucagon formulations into the first calendar quarter of 2013. We cannot forecast when we will have, and we may never have, sufficient clinical and stability data to select a lead formulation to advance into clinical trials.

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

We have completed and released the results of our two pivotal Phase 3 clinical trials of Linjeta ™ . 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 decided to advance alternate formulations, including BIOD-105, BIOD-107, BIOD-123 and BIOD-125 into the clinic and discontinued development of earlier formulations of Linjeta ™ . The outcomes of preclinical testing and clinical trials of prior formulations of Linjeta ™ may not be predictive of the success of clinical trials with current or future formulations of our RHI- or insulin analog-based formulations. 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 RHI- or insulin analog-based formulations will ultimately be successful. New information regarding the safety, efficacy, toleration and stability of our RHI- or insulin analog-based formulations may arise that may be less favorable than the data observed to date. Furthermore, much of the clinical data we have generated to date has compared one or more of our ultra-rapid-acting formulations to recombinant human insulin, which is known to have a slower onset of action than the currently marketed rapid acting insulin analogs. In the future, we plan to conduct all of our clinical trials using an insulin analog as the comparator. We have limited ability to predict how our RHI- or insulin analog-based formulations will perform when compared to an insulin analog.

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 an RHI- or insulin analog based-formulation, the formulation is well-tolerated in chronic use;
- establishing that, with regard to a liquid glucagon formulation for use as a rescue product, 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 and toleration profiles of the products following approval.

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

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

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

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

- be delayed in obtaining 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. 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 stable liquid glucagon formulations. If these formulations are easier to use than any product that we may develop, such as by allowing for room temperature storage, our products, 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.

Our ultra-rapid-acting insulin analog-based formulations and our liquid glucagon formulations are at early stages of development. In order for us to meet our projected milestones for these programs, we must obtain reliable sources of active pharmaceutical ingredients and other related materials and supplies. Our leading candidate for a liquid glucagon formulation uses proprietary stabilization technology supplied by a third party pursuant to a license agreement. If we do not maintain a commercial license to this technology, our efforts to commercialize a glucagon rescue product may be materially harmed. We may also continue to study additional third-party proprietary stabilization technologies for use in these programs. Even if these studies are successful, we cannot assure you that we will be able to license any third-party technologies on terms that would be acceptable to us.

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; we cannot commercialize our insulin analog-based formulations until all

applicable third-party patents have expired.

A broad base of physicians, including primary care physicians, internists and endocrinologists, treat patients with diabetes. A large sales force may be required to educate and support these physicians. In addition, we cannot commercialize on our own any insulin analog-based formulation in the United States until 2014 at the earliest, when the patents covering the currently marketed insulin analogs first begin to expire. Therefore, 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 revenues and prospects for profitability will suffer.

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

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

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

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

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 global 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. 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-Aventis. These rapid-acting insulin analogs provide improvement over regular forms of 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.

In addition, other development stage insulin formulations may be approved and compete with ours. Halozyme Therapeutics, Inc. has conducted a Phase 1 and multiple Phase 2 clinical trials of RHI, lispro (the insulin analog in Humalog®) and aspart (the insulin analog in NovoLog®) in combination with a recombinant human hyaluronidase enzyme and has reported that in each case the combination yielded pharmacokinetics and glucodynamics that better mimicked physiologic mealtime insulin release and activity than RHI, Humalog® or NovoLog® alone. Novo Nordisk has reported that they have initiated clinical development of an insulin analog intended to provide faster onset of action than the currently available rapid-acting insulin analogs and that a candidate formulation will enter Phase 3 clinical trials either in late 2012 or early 2013.

Several companies are also developing alternative insulin systems for diabetes, including MannKind Corporation, which submitted an NDA in early 2009 for an inhalable insulin product candidate. Mannkind's product candidate was not approved by the FDA and MannKind is currently conducting two additional Phase 3 clinical trials. MannKind has announced that it plans to resubmit a revised NDA in the third quarter of 2013. Approval of an inhaled insulin could reduce the overall market for injectable mealtime insulin.

A liquid glucagon formulation for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia would also face significant competition if it were to be commercialized. Eli Lilly and Novo Nordisk currently market injectable glucagon rescue kit products. We are aware of several glucagon rescue product candidates in early stage development, such an auto-injector device that integrates glucagon powder and a diluent into a dual chamber cartridge within that device and an auto-injector utilizing a concentrated, non-aqueous glucagon formulation. In addition, other companies with expertise in protein stabilization have announced that they have developed a stable liquid glucagon formulation using FDA-approved injectable ingredients. We believe that at least one of these formulations of glucagon is being studied in one or more clinical trials. All of these programs utilize the same active ingredient as the liquid glucagon formulations that we are developing and offer, or may offer, presentations allowing for room temperature storage. In addition, Eli Lilly is developing a glucagon analog, which may also offer advantages over our liquid glucagon formulations.

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

We do not currently own or operate manufacturing facilities for commercial production of our product candidates. We have limited experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. Our current strategy is to outsource to third parties all of the manufacturing required for our product candidates. We also expect to rely upon third parties to produce materials required for the commercial production of our product candidates if we succeed in obtaining necessary regulatory approvals. We have recently relied on the University of Iowa to manufacture our product candidates, but we do not have any commercial manufacturing agreements in place with third parties.

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 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 ultra-rapid acting insulin formulations or our liquid glucagon formulation 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, pre-filled 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 an agreement with our existing RHI supplier from which we obtain all of the RHI that we use for testing and manufacturing our RHI-based formulations. In July 2011, we amended our agreement with this insulin supplier so that the agreement will terminate in June 2018.

We believe that our current supplies of RHI, together with the quantities of RHI called for under our existing supply agreement, will be sufficient to allow us to complete the full development program required by the FDA in order to receive approval to market an RHI-based formulation if we are successful in developing one. If we are unable to procure sufficient quantities of insulin from our current or any future supplier, if supply of RHI 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 an ultra-rapid-acting insulin, 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.

We have entered into a commercial supply agreement with a third party for the supply of glucagon that we intend to use in the manufacture of our glucagon rescue product candidate. However, we have not purchased significant quantities of glucagon from this third-party supplier and we do not anticipate doing so prior to the manufacture of validation batches of a proposed commercial product. Additionally, we have agreed to purchase an excipient used to stabilize one of our glucagon rescue candidate formulations from a third-party that has licensed its proprietary stabilization

technologies to us. If this third-party is unable to supply us with sufficient quantities of the stabilizing excipient, our development program for a liquid glucagon formulation may be materially harmed.

We have not entered into any long-term agreements for the supply of one or more insulin analogs, vials, cartridges, pre-filled syringes or injection devices, some or all of which we would need to procure in significant quantities if we were to commercialize any of our product candidates.

Risks Related to Our Intellectual Property

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

The following factors are important to our success:

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

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors.

In June 2012 we entered into an agreement with Aegis to acquire an exclusive, sublicensable, worldwide license to the protein stabilization technology that we are using in the development of our liquid glucagon formulations. Under the terms of the agreement, Aegis will prepare, file, prosecute and maintain patents and patent applications that are specific to our liquid glucagon formulations in jurisdictions that we may designate from time to time.

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 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 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. 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 liquid glucagon formulation 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 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 RHI- or insulin analog-based 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, Gerard Michel, our Chief Financial Officer and Dr. Alan Krasner, our Chief Medical Officer. The loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experiences required to develop, gain regulatory approval of and commercialize our product candidates successfully. We generally do not maintain key person life insurance to cover the loss of any of our employees.

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

than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

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

Risks Related to Our Common Stock

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

Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

Among others, these provisions:

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

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

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

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

- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;

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

Our outstanding warrants may be exercised, 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 A convertible preferred stock that are convertible into 453,486 shares of common stock and shares of Series B preferred

stock that are convertible into 3,605,607 shares of common stock. The exercise of these warrants for, or the conversion of shares of Series A preferred stock or 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 capital stock and we do not anticipate paying any cash dividends in the foreseeable future.

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

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

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

Risks Related to our June 2012 Private Placement

The number of shares of our common stock outstanding has increased substantially as a result of our June 2012 private placement, and some of the purchasers in the private placement beneficially own significant blocks of our common stock; the securities that we issued in the private placement will be generally available for resale in the public market upon registration under the Securities Act of 1933, as amended, or the Securities Act.

In June 2012, we completed our 2012 private placement of an aggregate of 4,250,020 shares of our common stock, 3,605,607 shares of our Series B preferred stock and warrants to purchase an aggregate of 2,749,469 shares of our common stock. The issuance of these shares and warrants resulted in substantial dilution to stockholders who held our common stock prior to the 2012 private placement. Some of the purchasers in the private placement will have significant influence over the outcome of any stockholder vote, including the election of directors and the approval of mergers or other business combination transactions.

Pursuant to the securities purchase agreement that we entered into with the purchasers in the 2012 private placement, we filed with the Securities and Exchange, or the SEC, a registration statement to register the resale of the shares of common stock and Series B preferred stock issued and sold in the private placement, the shares of common stock issuable upon conversion of the Series B preferred stock issued and sold in the private placement, and the shares of common stock issuable upon exercise of the warrants issued and sold in the private placement. Upon the effectiveness of the registration statement, these securities became generally available for resale in the public market. The market price of our common stock could fall as a result of an increase in the number of shares available for sale in the public market.

If we do not maintain effectiveness of the registration statement, we will be required to pay certain liquidated damages, which could be material in amount.

Pursuant to the terms of the securities purchase agreement that we entered into with the purchasers in the 2012 private placement, we have agreed to pay liquidated damages to such purchasers if the registration

statement we filed with the SEC, which was declared effective on August 13, 2012, is suspended or ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to such an event as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each purchaser in cash in an amount equal to 1% of the aggregate purchase price paid by each such purchaser in the private placement, up to a maximum of 8% of such aggregate purchase price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

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 this office space expires July 31, 2014, subject to our right to renew the lease under the same terms and conditions for an additional seven year term. Our laboratory 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 expire in January 2013. We expect to renew these leases before they expire. Our laboratory facilities are fully equipped to perform our current drug delivery and related research and development activities.

ITEM 3. ***LEGAL PROCEEDINGS***

We currently are not involved in any material legal proceedings. However, from time to time, we may have certain contingent liabilities that arise in the ordinary course of our business activities. Our management believes that the resolution of such matters will not have a material adverse effect on our financial position, results of operations or cash flows.

In February 2012, we brought action against one of our vendors, before the American Arbitration Association in New York relating to disputed fees charged to us for inventory storage. As part of an arbitration stipulation, we established a $1.5 million escrow account and recorded an accrual of $0.7 million towards this claim. During the quarter ended June 30, 2012, we paid $0.5 million from the escrow account to the vendor. On July 30, 2012, we received a judgment from the arbitrator stating that we were required to only pay the vendor a balance of $55 thousand, after deducting legal fees. During the quarter ended September 30, 2012, the remaining escrow balance of $1.0 million was transferred to cash and the remaining accrual of $0.2 million was reversed and recorded in research and development expense.

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

Not applicable.

PART II-OTHER INFORMATION

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 applicable exchange in each of the quarters within our two most recent fiscal years. All prices shown in the table reflect the one-for-four reverse split of our outstanding common stock that we effected on June 11, 2012.

Fiscal Quarter Ended	High	Low
December 31, 2010	$21.28	$6.00
March 31, 2011	$11.88	$7.28
June 30, 2011	$10.36	$5.96
September 30, 2011	$ 8.52	$2.04
December 31, 2011	$ 3.48	$2.04
March 31, 2012	$ 2.96	$2.24
June 30, 2012	$ 4.00	$2.00
September 30, 2012	$ 3.82	$2.41

The closing price of our common stock, as reported on the NASDAQ Capital Market, was $2.58 on December 14, 2012.

Holders

As of November 30, 2012, the number of holders of record of our common stock was 51.

Dividends

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

Equity Compensation Plan Information

Information relating to compensation plans under which our equity securities are authorized for issuance will be set forth under "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for our 2013 Annual Meeting of Stockholders.

Issuer Purchases of Equity Securities

The following table sets forth the information relating to repurchases of our equity securities during the three months ended September 30, 2012:

Period	(a) Total number of shares (or units) purchased	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
July 1, 2012 to July 31, 2012	—	$ —	—	$ —
August 1, 2012 to August 31, 2012	—	—	—	—
September 1, 2012 to September 30, 2012	82,470	2.87	—	—
Total	82,470	$ 2.87	—	$ —

(a) These shares were not purchased as part of publicly announced plans or programs. They represent the surrender of shares to us to satisfy employee withholding tax obligations related to the vesting of stock-based compensation awards.

ITEM 6. *SELECTED FINANCIAL DATA*

You should read the following selected financial data together with our financial statements and the related notes which are included elsewhere in this Annual Report and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report. We have derived the statement of operations data set forth below for the three-year period ended September 30, 2012 and the balance sheet data as of September 30, 2011 and 2012 set forth below from our audited financial statements which are included in this Annual Report. We have derived the statement of operations data set forth below for the years ended September 30, 2008 and 2009 and the balance sheet data as of September 30, 2008, 2009 and 2010 set forth below from our audited financial statements, which are not included in this Annual Report. Historical results for any prior period are not necessarily indicative of results to be expected in any future period. All share and per share amounts set forth below reflect the one-for-four reverse split of our outstanding common stock that we effected on June 11, 2012.

	Year Ended September 30,				
	2008	2009	2010	2011	2012
	(In thousands, except share and per share amounts)				
Statement of operations data:					
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
Research and development	32,554	32,325	26,177	13,901	12,571
Government grants	—	—	—	—	(88)
General and administrative	14,800	10,994	10,980	9,321	6,816
Total operating expenses	47,354	43,319	37,157	23,222	19,299
Other (income) and expense:					
Interest and other income	(3,010)	(386)	(17)	(60)	(80)
Adjustment to fair value of common stock warrant liability	—	—	1,254	(12,611)	1,510
Loss before tax provision (benefit)	(44,344)	(42,933)	(38,394)	(10,551)	(20,729)
Tax provision (benefit)	(983)	337	(104)	41	18
Net loss	(43,361)	(43,270)	(38,290)	(10,592)	(20,747)
Net loss applicable to common stockholders	$ (43,361)	$ (43,270)	$ (38,290)	$ (10,592)	$ (20,747)
Net loss per share — basic and diluted*	$ (7.76)	$ (7.28)	$ (6.34)	$ (1.36)	$ (1.91)
Weighted average shares outstanding — basic and diluted*	5,597,609	5,936,650	6,040,467	7,788,741	10,882,688

	As of September 30,				
	2008	2009	2010	2011	2012
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents, and marketable securities	$ 90,283	$ 54,640	$ 28,923	$ 38,701	$ 39,050
Working capital	84,377	46,787	25,178	35,907	36,756
Total assets	97,511	59,625	32,616	41,505	41,134
Deficit accumulated during the development stage	(83,194)	(126,464)	(164,754)	(175,346)	(196,093)
Total stockholders' equity	88,487	50,538	24,060	37,078	31,016

* Restated for a one for four (1:4) reverse stock split effective on June 11, 2012.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements

and the related notes 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 proprietary formulation technologies to existing drugs in order to improve their therapeutic profiles. Our most advanced program involves developing proprietary formulations of injectable recombinant human insulin, or RHI, designed to be more rapid-acting than the "rapid-acting" mealtime insulin analogs currently used to treat patients with Type 1 and Type 2 diabetes. We, therefore, refer to these formulations as our "ultra-rapid-acting" insulin formulations. In addition to our RHI-based formulations, we are using our formulation technologies to develop new ultra-rapid-acting formulations of insulin analogs. These insulin analog-based formulations generally use the same or similar excipients as our RHI-based formulations and are designed to be more rapid-acting than the "rapid-acting" mealtime insulin analogs, but they may present characteristics that are different from those offered by our RHI-based formulations. We are also developing liquid glucagon formulations for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia.

An earlier RHI-based formulation known as Linjeta ™ (and previously referred to as VIAject®) was the subject of a New Drug Application, or NDA, that we submitted to the FDA in December 2009. In October 2010, the FDA issued a complete response letter stating that the NDA for Linjeta ™ could not be approved in its submitted form and that we should conduct two new Phase 3 clinical trials using our preferred commercial formulation of Linjeta ™ prior to re-submitting the NDA. Based upon the complete response letter and subsequent feedback that the FDA provided to us at a meeting in January 2011, we decided to study newer RHI-based formulations in earlier stage clinical trials. The objective of these clinical trials was to identify an RHI-based formulation with pharmacokinetic and pharmacodynamic profiles similar to the Linjeta ™ formulation, but with improved injection site toleration characteristics. These earlier stage clinical trials evaluated the pharmacokinetic, pharmacodynamic and injection site toleration profiles of our product candidates relative to Humalog®, a rapid-acting insulin analog.

In September 2011, we announced that two newer formulations, BIOD-105 and BIOD-107, did not demonstrate our target profile in Phase 1 clinical trials. We subsequently conducted a Phase 1 clinical trial of two additional formulations, BIOD-123 and BIOD-125, and announced top line results from that trial in April 2012. Both BIOD-123 and BIOD-125 achieved our target pharmacokinetic, pharmacodynamic and toleration profiles. Based on our assessment of these two formulations, we selected BIOD-123 as our lead RHI-based product candidate, and in the third calendar quarter of 2012, we began enrolling patients in a Phase 2 clinical trial of BIOD-123. This Phase 2 clinical trial is designed to assess the clinical impact of BIOD-123 relative to Humalog®. The trial is being conducted at investigative centers in the United States and is expected to enroll approximately 130 randomized patients with Type 1 diabetes. We expect to announce top-line results from this Phase 2 clinical trial in the third calendar quarter of 2013.

In May 2012, we selected two insulin analog-based formulations, BIOD-238 and BIOD-250, to evaluate in a Phase 1 clinical trial. BIOD-238 and BIOD-250 generally use the same or similar excipients as BIOD-123 and are intended to be optimized for rapid absorption and injection site toleration. We began enrolling patients in the Phase 1 clinical trial in the third calendar quarter of 2012. This trial, which is being conducted in Australia, is designed to compare the pharmacokinetic and injection site toleration profiles of these formulations relative to a rapid-acting mealtime insulin analog. We expect to announce top-line results from

this clinical trial in the first calendar quarter of 2013. In parallel with the Phase 1 clinical trial of BIOD-238 and BIOD-250, we are continuing our formulation development work to improve the stability characteristics of our ultra-rapid-acting insulin analog-based formulations.

In addition to our ultra-rapid-acting insulin formulation program, we are developing a liquid glucagon formulation for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia, or very low concentrations of blood glucose. To date, we have not selected a lead formulation to advance into clinical trials. We are continuing to conduct preclinical testing to develop formulations that achieve a combination of pharmacokinetic, pharmacodynamic and stability characteristics that we believe would be required for a glucagon rescue treatment product to be commercially successful.

We are a development stage company. We were incorporated in December 2003 and commenced active operations in January 2004. To date, we have generated no revenues and have incurred significant losses. We 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 June 2012 private placement. We have devoted substantially all of our efforts to research and development activities, including clinical trials. Our net loss was $20.7 million for the year ended September 30, 2012. As of September 30, 2012, we had a deficit accumulated during the development stage of $196.1 million. Research and development and general and administrative expenses, as a percentage of net loss applicable to common stockholders, represent approximately 73% and 33%, respectively, of the expenses that we have incurred since our inception.

As of September 30, 2012, we had approximately $39.1 million in cash and cash equivalents compared to $38.7 million in cash and cash

equivalents as of September 30, 2011. 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 until the second calendar quarter of 2014. We believe that future cash expenditures will be partially offset by raising additional capital from research grants, capital markets, proceeds derived from collaborations, including, but not limited to, upfront fees, research and development funding, milestone payments and royalties. We can give no assurances that such funding will, in fact, be realized in the time frames we expect, or at all. We may be required to secure alternative financing arrangements 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 liquid glucagon formulations. We anticipate that our research and development expenses for the fiscal year ending September 30, 2013 will increase as compared to the fiscal year ended September 30, 2012, as we continue to:

- study BIOD-123 in a Phase 2 clinical trial;
- study our ultra-rapid-acting insulin analog-based formulations in early stage clinical trials and conduct additional formulation development work to improve the stability, pharmacokinetic, and pharmacodynamic properties of our ultra-rapid-acting insulin analog-based formulations; and
- conduct the development work necessary to select a lead formulation for our liquid glucagon rescue product candidate and commence clinical trials of that formulation.

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

- conduct later stage clinical trials of our ultra-rapid-acting insulin formulations and a liquid glucagon formulation, including one or more pivotal clinical trials required for FDA approval of NDAs for these product candidates; and
- purchase active pharmaceutical ingredients and other materials to support our research and development activities.

We have used our employee and infrastructure resources across multiple research projects and our drug development programs for our ultra-rapid-acting insulin formulations, including BIOD-123, BIOD-238 and BIOD-250, and our liquid glucagon formulations. To date, we have not tracked expenses related to our product development activities on a project or program basis. Accordingly, we cannot reasonably estimate the amount of research and development expenses that we incurred with respect to each of our clinical and preclinical product candidates. However, substantially all of our research and development expenses incurred to date are attributable to our ultra-rapid-acting insulin program.

In July and September 2012, we received two National Institutes of Health (NIH) awards for the development of concentrated ultra-rapid-acting insulin formulation and glucagon formulation for use in an artificial pancreas. The July 2012 award is 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 is for two years and totals $582 thousand. The September 2012 award is intended to fund research to develop a proprietary glucagon product candidate optimized to algorithmically deliver glucagon as part of a bihormonal closed loop system to mitigate hypoglycemic events. The September 2012 award is for two years and totals $583 thousand.

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

	Year Ended September 30,			December 3, 2003 (Inception) to September 30, 2012
	2010	2011	2012	
	(In thousands)			
Research and development expenses:				
Preclinical expenses	$ 2,746	$ 3,665	$ 3,974	$ 22,639
Manufacturing expenses	8,894	5,332	2,644	38,931
Clinical/regulatory expenses	14,537	4,904	5,953	81,130
Total	$26,177	$13,901	$12,571	$142,700

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

- our ability to complete our Phase 2 clinical trial of BIOD-123 in a timely manner and the outcome of that trial;

- the success of our formulation development work to improve the stability, pharmacokinetic and pharmacodynamic characteristics of our ultra-rapid-acting insulin analog-based formulations;
- our ability to conduct the development work necessary to select a lead formulation for our liquid glucagon product candidate for the rescue treatment of severe hypoglycemia and commence clinical trials of that formulation;
- the results of our real-time stability programs for our insulin and glucagon product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project real-time stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of a glucagon rescue product candidate;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- our ability to conduct pivotal clinical trials and other tests or analyses required by the FDA to secure approval to commercialize an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;
- 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 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;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies that could enable a room-temperature rescue product in a portable, easy to use presentation;
- the ability of our major suppliers to produce our products in our final dosage form;
- our commercialization, marketing and manufacturing capabilities and strategies; and
- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

A change in the outcome of any of these variables with respect to the development of ultra-rapid-acting insulin formulations or our liquid glucagon formulation, 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, in our executive, legal, accounting, finance and information technology functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, travel expenses, costs associated with industry conventions and professional fees, such as legal and accounting fees and consulting costs.

We anticipate that our general and administrative expenses in the fiscal year ending September 30, 2013 will remain substantially the same as in the fiscal year ended September 30, 2012 as we continue to focus our efforts on product formulation activities and earlier stage clinical trials. Over the longer term, however, these expenses could increase if we are successful in advancing our product candidates into later stage clinical trials, including Phase 3 pivotal trials.

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 $2.97 per share, the warrant exercise price of $2.66 per share, a risk-free interest rate of 0.62% and an expected volatility rate of 98%. The significant assumptions for the model used for the 2011 warrants were remaining terms of the warrants, the common stock price of $2.97 per share, the warrant exercise price of $9.92 per share, a risk-free interest rate of 0.31% and an expected volatility rate of 82%. 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 “Adjustment to fair value of common stock warrant liability.”

In August 2010, we issued warrants to purchase 599,550 shares of our common stock in connection with our August 2010 registered direct offering. On December 1, 2011, the unexercised warrants to purchase 589,000 shares of common stock expired. We revalued the liability from September 30, 2011 through the date of expiration and there was no impact on the statement of operations. The common stock warrant liability associated with these warrants no longer exists.

In addition to the 2012 and 2011 warrants, as of June 30, 2012, we had outstanding warrants to purchase 10,415 shares of our common stock at an exercise price of $5.64. These warrants expired unexercised in July 2012.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents and marketable securities. 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 2013.

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 concentrated ultra-rapid-acting insulin formulations and liquid glucagon formulations, respectively, for use in an artificial pancreas. Both awards are for two years and total approximately $580 thousand each. Work on the grant for the development of concentrated ultra-rapid-acting insulin formulation started in August 2012 and expenses incurred were $88 thousand during the twelve months ended September 30, 2012 and corresponding income and a receivable were recorded.

Share-Based Compensation

Stock Incentive Plan

In March 2010, our shareholders approved our 2010 Stock Incentive Plan, which we refer to as the 2010 Plan. Up to 1,350,000 shares of our common stock may be issued pursuant to awards granted under the 2010 Plan, plus 851,908 shares of common stock underlying already outstanding awards under our prior plans. In addition, on March 8, 2012, our stockholders approved an amendment to the 2010 Plan to increase the number of shares of common stock authorized for issuance under the plan solely for the purpose of allowing us to issue an aggregate of 274,192 RSUs to certain of our employees in place of discretionary cash bonuses in connection with the fiscal year ended September 30, 2011.

The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a “fungible share” concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.6 shares for each one share of common stock. We have not

made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by our stockholders. We will continue to use the Black-Scholes pricing model to assist in the calculation of fair value. The expected life for these grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110. The simplified method was chosen due to our limited history. Until we have adequate history, we will continue to

utilize the simplified method.

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

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

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

For options granted to non-employees and non-directors, primarily consultants who served on our Scientific Advisory Board, we measure fair value of the equity instruments utilizing the Black-Scholes valuation model, if that value is more reliably measurable than the fair value of the consideration or service received. The fair value of these equity investments were periodically revalued as the options were vesting and were recognized as expense over the related period of service or the vesting period, whichever was longer. We have not granted options to non-employees and non-directors since the year ending September 30, 2008. Prior to September 30, 2008, we issued to these non-employees options to purchase an aggregate of 94,278 shares of our common stock. All of these options are currently vested. For the years ended September 30, 2010, 2011 and 2012, the share-based compensation expense (income) related to these options was ($0.01) million, ($0.04) million and $0, respectively.

We grant 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. Except as set forth below with regard to RSUs awarded to employees in place of discretionary cash bonuses, 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. Except as set forth below with regard to RSUs awarded to employees in place of discretionary cash bonuses, each year following the annual vesting date, between January 1 st 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.

In March 2012, we granted RSUs to our employees in place of the discretionary cash bonuses that were established in connection with the fiscal year ended September 30, 2011. The cost of these awards was

determined to be the value of the discretionary cash bonuses. These RSUs vested, and the underlying shares were distributed, on September 30, 2012. At that time, the value of the discretionary cash bonuses exceeded the fair market value of the corresponding RSUs.

For the year ended September 30, 2012, the share-based compensation expense, including expenses associated with stock options and RSUs, was $1.8 million, of which $0.7 million is reflected in research and development expenses and $1.1 million is reflected in general and administrative expenses. For the year ended September 30, 2011, the share-based compensation expense, including expenses associated with stock options and RSUs, was $5.0 million, of which $2.0 million is reflected in research and development expenses and $3.0 million is reflected in general and administrative expenses. For the year ended September 30, 2010, the share-based compensation expense was $5.6 million, of which $2.0 million is reflected in research and development expenses and $3.6 million is reflected in general and administrative expenses.

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, 2011 and 2012, we recorded a 100% valuation allowance against our net deferred tax asset of approximately $42.2 million and $47.9 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, 2012, we had net operating loss carry-forwards of approximately $54 million for U.S. federal and $110.2 million for state tax purposes. These loss carry-forwards expire between 2024 and 2032. 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. We updated the Section 382 analysis, performed in fiscal year 2010, to incorporate the registered direct offering that we completed in May 2011. As of September 30, 2010, we performed a preliminary Section 382 analysis in connection with the registered direct offering that we completed in August 2010 and believed that an ownership change had occurred. We updated this analysis to take into account the registered direct offering that we completed in May 2011. Based on this further review, we determined that an ownership change under Section 382 occurred on May 12, 2011. We believe that approximately $55.9 million of the $106.9 million federal losses will expire unused as a result of Section 382 limitations. The maximum annual limitation under Section 382 is approximately $2.5 million for 20 years. As of September 30, 2012, we have determined that ownership change, under Section 382, occurred as a result of the June 2012 financing and, therefore, the ability to utilize our current NOLs is further limited. 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 $0.5 million, which expire commencing in fiscal 2022.

Results of Operations

Year Ended September 30, 2012 Compared to Year Ended September 30, 2011

Revenue. We did not recognize any revenue during the years ended September 30, 2012 or 2011.

Research and Development Expenses.

	Year Ended September 30,		Decrease	
	2011	2012	$	%
	In thousands, except per share amounts			
Research and Development	$13,901	$12,571	$1,330	10%
Percentage of net loss	131.2%	60.6%		

Research and development expenses were $12.5 million for the year ended September 30, 2012, a decrease of $1.3 million or 10%, from $13.9 million for the year ended September 30, 2011. This decrease was primarily attributable to reductions of $2.6 million in manufacturing expenses and $0.4 million in regulatory expenses. These decreases were offset in part by an increase of $1.4 million in clinical expenses related primarily to our Phase 1 clinical trial of BIOD-123 and BIOD-125 and a net increase of $0.3 million in research and development expenses related to an increase in the number of preclinical animal studies we conducted and a licensing fee paid to Aegis.

The reductions in manufacturing expenses are attributable to savings of $2.2 million as a result of renegotiating the terms of our supply agreement for RHI and $0.4 million in reduced personnel costs. The $0.4 million reduction in regulatory expenses resulted from lower professional fees for the year ended September 30, 2012, as compared to 2011, and lower stock-based compensation costs.

The research and development expenses for the twelve months ended September 30, 2011 were reduced by our receipt in January 2011 of $1.2 million in research grants under the Internal Revenue Services therapeutic tax credit program and were increased by a $1.4 million severance charge resulting from the retirement of our former Chief Scientific Officer.

Research and development expenses for the year ended September 30, 2012 include $0.7 million in stock-based compensation expense related to options granted to employees. We did not record any stock-based compensation expense for the year ended September 30, 2012 for options granted to non-employees.

In July and September 2012, we received two National Institutes of Health (NIH) awards for the development of concentrated ultra-rapid-acting insulin formulation and glucagon formulation for use in an artificial pancreas. The July 2012 award is 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 is for two years and totals $582 thousand. The September 2012 award is intended to fund research to develop a proprietary glucagon product candidate optimized to algorithmically deliver glucagon as part of a bihormonal closed loop system to mitigate hypoglycemic events. The September 2012 award is for two years and totals $583 thousand. For the quarter ended September 30, 2012, we reported $88 thousand in government grants for the high concentration ultra-rapid-insulin product candidate and did not start the glucagon formulation work.

General and Administrative Expenses.

	Year Ended September 30,		Decrease	
	2011	2012	$	%
	In thousands, except per share amounts			
General and Administrative	$9,321	$6,816	$2,505	27%
Percentage of net loss	88.0%	32.9%		

General and administrative expenses were $6.8 million for the year ended September 30, 2012, a decrease of $2.5 million, or 27%, from $9.3 million for the year ended September 30, 2011. This decrease is attributable to reductions of $0.2 million in depreciation expense due primarily to fully depreciating our accounting software, $1.9 million in employee and non-employee director stock-based compensation expenses, and other expenses of $0.4 million. General and administrative expenses for the year ended September 30, 2012 include $1.1 million in stock-based compensation expense related to options granted to employees and non-employee directors.

Interest and Other Income.

	Year Ended September 30,		Increase	
	2011	2012	$	%
	In thousands, except per share amounts			
Interest and Other Income	$ 60	$ 80	$20	33%
Percentage of net loss	0.57%	0.39%		

Interest and other income increased to $0.08 million for the year ended September 30, 2012 from $0.06 million for the year ended September 30, 2011. The increase resulted primarily from interest on the higher cash balances generated by our June 2012 private placement.

Interest Expense. For the years ended September 30, 2012 and 2011, we had no interest expense.

Adjustments to Fair Value of Common Stock Warrant Liability.

	Year Ended September 30,		Decrease	
	2011	2012	$	%
	In thousands, except per share amounts			
Adjustments to fair value of common stock warrant liability	$(12,611)	$1,510	$14,121	112%
Percentage of net loss	119%	7%		

Change in Warrant Valuation.

	Year Ended September 30,		
	2011	2012	Net change
Warrant:			
August 2011	$ (4,169)	$ —	$ 4,169
May 2011	(8,442)	709	9,151
June 2012	—	801	801
Total	$(12,611)	$1,510	$14,121

The change in fair value of derivative instruments-warrants of $(12,611) during the year ended September 30, 2011 was primarily a result of the decrease in the price of the common stock from $5.30 per share at September 30, 2010 to $2.16 per share at September 30, 2011. The change in fair value of derivative instruments-warrants of $1,510 during the year ended September 30, 2012 was a result of the increase in the price of the common stock from $2.16 per share at September 30, 2011 to $2.97 per share at September 30, 2012.

Net Loss and Net Loss per Share.

	Year Ended September 30,		Increase	
	2011	2012	$	%
	In thousands, except per share amounts			
Net loss	$(10,592)	$(20,747)	$10,155	96%
Net loss per share	$ (1.36)	$ (1.91)		

Net loss was $20.7 million, or $(1.91) per share, for the year ended September 30, 2012, compared to $10.6 million, or $(1.36) per share, for the year ended September 30, 2011. The increase in net loss was primarily due to an increase in adjustments to fair value of common stock warrant liability, as noted above.

Year Ended September 30, 2011 Compared to Year Ended September 30, 2010

Revenue. We did not recognize any revenue during the years ended September 30, 2011 or 2010.

Research and Development Expenses.

	Year Ended September 30,		Decrease	
	2010	2011	$	%
	In thousands, except per share amounts			
Research and Development	$26,177	$13,901	$12,276	46.9%
Percentage of net loss	68.4%	131.2%		

Research and development expenses were $13.9 million for the year ended September 30, 2011, a decrease of $12.3 million or 46.9%, from $26.2 million for the year ended September 30, 2010. This decrease was primarily attributable to reductions of $6.0 million in clinical expenses, $3.5 million in manufacturing and device development expenses and $3.5 million in regulatory expenses. These decreases were offset in part by an increase of $0.7 million in expenses related to our discovery activities as we increased our preclinical studies in the year ended September 30, 2011. Research and development expenses for the year ended September 30, 2011 were reduced by our receipt in January 2011 of $1.2 million in research grants under the Internal Revenue Service's therapeutic tax credit program and were increased by a $1.4 million severance charge resulting from the retirement of our former Chief Scientific Officer.

The reductions in clinical expenses reflect reduced expenses of $4.3 million because we conducted two Phase 1 clinical trials during the year ended September 30, 2011, as compared to two 18-month safety extension trials, two tolerability studies and a pump study during the year ended September 30, 2010. In addition, the reductions in clinical expenses reflect reduced professional fees of $1.4 million and reduced personnel costs of $0.3 million as a result of our implementation of cost-saving initiatives. The reductions in manufacturing and device development expenses are attributable to savings of $2.1 million as a result of renegotiating the terms of our recombinant human insulin supply agreement; the completion of our insulin pen development in the year ended September 30, 2010, which resulted in 2010 expenses of $0.7 million that did not recur in the year ended September 30, 2011; and reduced personnel and professional costs of $0.7 million. The $3.5 million reduction in regulatory expenses resulted from lower professional fees in the year ended September 30, 2011 as compared to 2010 because the year ended September 30, 2010 included the filing of our NDA and a 120 day update with the FDA.

Research and development expenses for the year ended September 30, 2011 include $2.0 million in stock-based compensation expense related to options granted to employees. We also recorded a credit of $42 thousand in stock-based compensation income for the year ended September 30, 2011 for options granted to non-employees, which we must revalue for accounting purposes each reporting period.

General and Administrative Expenses.

	Year Ended September 30,		Decrease	
	2010	2011	$	%
	In thousands, except per share amounts			
General and Administrative	$10,980	$9,321	$1,659	15%
Percentage of net loss	28.7%	88%		

General and administrative expenses were $9.3 million for the year ended September 30, 2011, a decrease of $1.7 million, or 15%, from $11.0 million for the year ended September 30, 2010. This decrease is attributable to a decrease of $0.9 million in professional fees, $0.2 million in personnel and employee stock-based compensation expenses, $0.1 million in non-employee director stock-based compensation expense and other expenses of $0.4 million. General and administrative expenses for the year ended September 30, 2011 include $3.0 million in stock-based compensation expense related to options granted to employees and non-employee directors. We also recorded a credit of $2 thousand in stock-based compensation income for the year ended September 30, 2011 for options granted to non-employees, which we must revalue for accounting purposes each reporting period.

Interest and Other Income.

	Year Ended September 30,		Increase	
	2010	2011	$	%
	In thousands, except per share amounts			
Interest and Other Income	$ 17	$ 60	$43	253%
Percentage of net loss	0.04%	0.57%		

Interest and other income increased to $0.06 million for the year ended September 30, 2011 from $0.02 million for the year ended September 30, 2010. The increase resulted primarily from interest on the higher cash balances generated by our May 2011 financing and by moving our cash to a premium money market fund which eliminated investment fees and yielded a higher return.

Interest Expense. For the years ended September 30, 2011 and 2010, we had no interest expense.

Adjustments to Fair Value of Common Stock Warrant Liability.

	Year Ended September 30,		Increase	
	2010	2011	$	%
	In thousands, except per share amounts			
Adjustments to fair value of common stock warrant liability	$1,254	$(12,611)	$13,865	1,106%
Percentage of net loss	3.3%	119%		

Adjustments to fair value of common stock warrant liability decreased to $(12.6) million for the year ended September 30, 2011 from $1.3 million for the year ended September 30, 2010. The September 30, 2011 adjustment to fair value of common stock warrant liability of $12.6 million is comprised of decreases in the value of the May 2011 and August 2010 warrants of $8.4 million and $4.1 million, respectively. The decrease from the prior year was primarily attributable to the closing price of our common stock on September 30, 2011 of $2.16 per share being lower than the September 30, 2010 closing price of our common stock of $21.20 per share, for the August 2010 warrants, and the May 18, 2011 closing price of our common stock of $8.24 for the May 2011 warrants. We use the Black-Scholes valuation method to calculate the fair value for the May 2011 warrants and the Monte Carlo simulation method for the August 2010 warrants. As a result, the fair value for the May 2011 and August 2010 warrant liability decreased. The August 2010 warrants expired on December 1, 2011. The May 2011 warrants will be revalued each reporting period.

Net Loss and Net Loss per Share.

	Year Ended September 30,		Decrease	
	2010	2011	$	%
	In thousands, except per share amounts			
Net loss	$(38,290)	$(10,592)	$27,698	72.3%
Net loss per share	$ (6.34)	$ (1.36)		

Net loss was $10.6 million, or $(1.36) per share, for the year ended September 30, 2011, compared to $38.3 million, or $(6.34) per share, for the year ended September 30, 2010. The decrease in net loss was primarily due to reduced expenses and adjustments to fair value of common stock warrant liability as noted above.

Liquidity and Capital Resources

Sources of Liquidity and Cash Flows

As a result of our significant research and development expenditures and the lack of any approved products or other sources of revenue, we have not been profitable and have generated significant operating losses since we were incorporated in 2003. We initially funded our research and development operations through 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 $184 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 and our private placement in June 2012.

At September 30, 2012, we had cash and cash equivalents totaling approximately $39.1 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 $16.7 million for the year ended September 30, 2012, $18.3 million for the year ended September 30, 2011 and $34.4 million for the year ended September 30, 2010. Net cash used in operating activities for the years ended September 30, 2012, 2011 and 2010 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 provided by (used in) investing activities was $(0.1) million for the year ended September 30, 2012, $5.8 million for the year ended September 30, 2011 and $(6.3) million for the year ended September 30, 2010. Net cash used in investing activities for the year ended September 30, 2012 reflects the purchase of property and equipment. Net cash provided by investing activities for the year ended September 30, 2011 primarily reflects the sale of marketable securities, offset by the purchase of property and equipment. Net cash used in investing activities for the year ended September 30, 2010 primarily reflects the purchase of marketable securities and of property and equipment.

Net cash provided by financing activities was $17.1 million for the year ended September 30, 2012, $28.2 million for the year ended September 30, 2011 and $9.0 million for the year ended September 30, 2010. Net cash provided by financing activities for the year ended September 30, 2012 primarily reflects proceeds from the sale of our securities in our private placement offering in June 2012 and through our employee stock purchase plan. Net cash provided by financing activities in 2011 primarily reflects proceeds from the sale our securities in our registered direct offering in May 2011 and through our employee stock purchase plan. Net cash provided by financing activities in 2010 primarily reflects proceeds from the sale of our securities in our registered direct offering in August 2010 and through our employee purchase plan.

In June 2012, we completed a private placement of securities in which we issued 4,250,020 shares of our common stock, 3,605,607 shares of our Series B preferred stock and warrants to purchase 2,749,469 shares of our common stock. We received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $17.1 million from this financing.

In May 2011, we completed a registered direct offering of an aggregate of 12,074,945 shares of our common stock, 1,813,944 shares of our Series A Preferred Stock and warrants to purchase 9,027,772 shares of our common stock at an exercise price of $2.48 per share. The warrants will expire on May 17, 2016. We received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $28.0 million from this financing.

In August 2010, we completed a registered direct offering of an aggregate of 599,550 shares of our common stock and warrants to purchase an additional 559,550 shares of our common stock at an initial exercise price of $18.86 per share. We received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $8.7 million from this financing. In December 2010, the exercise price of the warrants was reset to $6.24 per share and in May 2011, the exercise price of the warrants was reset to $4.70 per share. In August 2011, warrants for a total of 10,550 shares were exercised and we received proceeds of approximately $50 thousand. The remaining warrants for 589,000 shares expired unexercised on December 1, 2011.

Funding Requirements

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 until the second calendar quarter of 2014. 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 or a liquid glucagon formulation. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and to the extent that we may or may not enter into collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current anticipated clinical trials.

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

- the progress, timing or success of our research and development and clinical programs for our product candidates, including the resulting data

from clinical trials of an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;

- our ability to complete our Phase 2 clinical trial of BIOD-123 in a timely manner and the outcome of that trial;
- the success of our formulation development work to improve the stability, pharmacokinetic and pharmacodynamic characteristics of our ultra-rapid-acting insulin analog-based formulations;
- our ability to conduct the formulation development work necessary to select a commercial candidate formulation for our glucagon rescue product for the treatment of severe hypoglycemia and commence clinical trials of that formulation;
- the results of our real-time stability programs for our insulin and glucagon product candidates, including the reproducibility of earlier, smaller scale, stability studies and our ability to accurately project real-time stability on the basis of accelerated testing;
- our ability to accurately anticipate technical challenges that we may face in the development of a glucagon rescue product candidate;
- our ability to secure approval by the FDA for our product candidates under Section 505(b)(2) of the FFDCA;
- our ability to conduct pivotal clinical trials and other tests or analyses required by the FDA to secure approval to commercialize an ultra-rapid-acting insulin formulation or a liquid glucagon formulation;
- 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 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;
- the emergence of competing technologies and products and other adverse market developments, such as advancements in glucagon stabilization technologies that could enable a room-temperature rescue product in a portable, easy to use presentation;
- the ability of our major suppliers to produce our products in our final dosage form;
- our commercialization, marketing and manufacturing capabilities and strategies; and
- our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing.

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

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.

We have implemented cost saving initiatives to reduce operating expenses, including reducing the number of employees, and we continue to seek additional areas for cost reductions. However, 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.

Adopted Accounting Pronouncements

Comprehensive Income

In June 2011, the FASB, issued ASU 2011-05 Presentation of Comprehensive Income, or ASU 2011-05. ASU 2011-05 allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While ASU 2011-05 changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. In December 2011, the FASB issued ASU 2011-12 Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05, or ASU 2011-12. ASU 2011-12 deferred certain aspects of ASU 2011-05 pertaining only to the presentation of reclassification adjustments out of accumulated other comprehensive income and reinstates the previous requirements to present reclassification adjustments either on the face of the statement in which other comprehensive income is reported or to disclose them in a note to the financial statements. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We adopted this guidance in the first quarter of the fiscal year ended September 30, 2012. The adoption of ASU 2011-05 and the deferrals in ASU 2011-12 had no impact on our consolidated financial statements.

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

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, as permitted by the terms of our investment policy guidelines. Currently, our 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.

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, 2012 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, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of September 30, 2012, 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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file a definitive proxy statement within 120 days after the end of our fiscal year for our 2013 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 RELATIONSHIP 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, 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 21, 2012

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 21, 2012
/s/ Gerard J. Michel Gerard J. Michel	Chief Financial Officer, Vice President, Corporate Development and Treasurer (Principal Financial and Accounting Officer)	December 21, 2012
/s/ Julia R. Brown Julia R. Brown	Director	December 21, 2012
/s/ Barry H. Ginsberg Barry H. Ginsberg	Director	December 21, 2012
/s/ Ira W. Lieberman Ira W. Lieberman	Director	December 21, 2012
/s/ Daniel Lorber Daniel Lorber	Director	December 21, 2012
/s/ Brian J.G. Pereira Brian J.G. Pereira	Director	December 21, 2012
/s/ Davey S. Scoon	Director	December 21, 2012

Exhibits Index

Exhibit Number	Description of Document
3.1	Registrant's Second Amended and Restated Certificate of Incorporation (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
3.2	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.
3.6	Registrant's Amended and Restated Bylaws (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.1	Specimen Common Stock Certificate (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
4.2	Form of Warrant 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 21, 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 the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.3	2010 Non Statutory Stock Option Agreement (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.4	2010 Restricted Stock Unit Agreement (Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2010).
10.5	Form of Indemnity Agreement entered into between the Registrant and its directors and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.6	Amended and Restated 2004 Stock Incentive Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.7	2005 Employee Stock Purchase Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.8	2005 Non-Employee Directors' Stock Option Plan (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.9	Employment Agreement, dated March 26, 2010, between the Registrant and Errol B. De Souza (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on April 1, 2010).

Exhibit Number	Description of Document
10.10	Change of Control Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.11	Executive Severance Agreement entered into between the Registrant and certain of its executive officers (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.12	Lease Agreement, dated February 2, 2004, between the Registrant and Mulvaney Properties, LLC and amendment thereto dated September 29, 2006 (Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (333-140504)).
10.13	Commercial Lease, dated July 23, 2007, by and between the Registrant and Mulvaney Properties LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 27, 2007).
10.14	Lease Amendment, dated October 1, 2007, between the Registrant and Mulvaney Properties LLC (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on October 4, 2007).
10.15	Amendment to Lease Agreement, dated February 2, 2004, as amended, by and between the Registrant and Mulvaney Properties LLC. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 27, 2007).

10.16	Offer Letter, dated November 12, 2007, by and between the Registrant and Gerard J. Michel. (Incorporated by reference to the Registrant's Current Report on Form 8-K filed on November 14, 2007).
10.17	Form of Incentive Stock Option Agreement for 2004 Amended and Restated Stock Incentive Plan. (Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).
10.18	Form of Option Agreement for 2005 Non-Employee Directors' Stock Option Plan. (Incorporated by reference to the Registrant's Annual Report on Form 10-K filed on December 21, 2007).
10.19	Base salaries of Executive Officers of the Registrant.
10.20	Summary of the Registrant's Non-Employee Director Compensation.
10.21†	Supply Agreement, dated July 7, 2008, between the Registrant and N.V. Organon (Incorporated by reference to exhibit 10.3 the Registrant's Quarterly Report on Form 10-Q filed on August 11, 2008).
10.22†	Letter Agreement, dated November 12, 2009, between the Registrant and N.V. Organon, amending the Supply Agreement, dated July 7, 2008, between the parties. (Incorporated by reference to exhibit 10.22 to Registrant's Annual Report on Form 10-K filed on December 14, 2009).
10.23†	Letter Agreement, dated July 25, 2011, between the Registrant and N.V. Organon amending the Supply Agreement dated July 7, 2008 (Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended September 30, 2011 filed on December 15, 2011).
10.24†	License Agreement, effective as of June 8, 2012, between Aegis Therapeutics, LLC and the Registrant (Incorporated by reference to Exhibit 10.01 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 filed on August 14, 2012).
10.25	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 21, 2012).
21.1	Subsidiaries of the Registrant.

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

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

* submitted electronically herewith

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.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Biodel Inc.
Danbury, Connecticut

We have audited the accompanying balance sheets of Biodel Inc. (a development stage company) as of September 30, 2012 and 2011 and the related statements of operations, stockholders' equity, cash flows and comprehensive loss for each of the three years in the period ended September 30, 2012 and the statements of operations, stockholders' equity and cash flows for the period from December 3, 2003 (inception) to September 30, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our 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 financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Biodel Inc. at September 30, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2012, and for the period from December 3, 2003 (inception) to September 30, 2012, in conformity with accounting principles generally accepted in the United States.

/s/ BDO USA, LLP

New York, New York
December 21, 2012

Biodel Inc.
(A Development Stage Company)

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

	September 30, 2011	September 30, 2012
ASSETS		
Current:		
Cash and cash equivalents	$ 38,701	$ 39,050
Restricted cash	60	60

Taxes receivable	35	34
Grant receivable	—	88
Other receivable	1	9
Prepaid and other assets	399	295
Total current assets	39,196	39,536
Property and equipment, net	2,253	1,552
Intellectual property, net	49	46
Long term other assets	7	—
Total assets	$ 41,505	$ 41,134
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current:		
Accounts payable	$ 222	$ 285
Accrued expenses:		
Clinical trial expenses	763	488
Payroll and related	1,118	1,248
Accounting and legal fees	191	244
Severance	688	141
Other	204	273
Income taxes payable	103	101
Total current liabilities	3,289	2,780
Common stock warrant liability	996	7,338
Severance payable, long term portion	142	—
Total liabilities	4,427	10,118
Commitments		
Stockholders' equity:		
Convertible preferred stock, $.01 par value; 50,000,000 shares authorized, 1,813,944 and 5,419,551 issued and outstanding	18	54
Common stock, $.01 par value; 25,000,000 shares authorized; 9,661,868 and 14,174,545 issued and outstanding	96	142
Additional paid-in capital	212,310	226,913
Deficit accumulated during the development stage	(175,346)	(196,093)
Total stockholders' equity	37,078	31,016
Total liabilities and stockholders' equity	$ 41,505	$ 41,134

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

	Year Ended September 30,			
	2010	2011	2012	December 3, 2003 (Inception) to September 30, 2012
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	26,177	13,901	12,571	142,700
Government grants	—	—	(88)	(88)
General and administrative	10,980	9,321	6,816	63,762
Total operating expenses	37,157	23,222	19,299	206,374
Other (income) and expense:				

Interest and other income	(17)	(60)	(80)	(5,646)
Interest expense	—	—	—	78
Adjustments to fair value of common stock warrant liability	1,254	(12,611)	1,510	(9,847)
Loss on settlement of debt	—	—	—	627
Loss before tax provision (benefit)	(38,394)	(10,551)	(20,729)	(191,586)
Tax provision (benefit)	(104)	41	18	(553)
Net loss	(38,290)	(10,592)	(20,747)	(191,033)
Charge for accretion of beneficial conversion rights	—	—	—	(603)
Deemed dividend — warrants	—	—	—	(4,457)
Net loss applicable to common stockholders	$ (38,290)	$ (10,592)	$ (20,747)	$(196,093)
Net loss per share — basic and diluted*	$ (6.34)	$ (1.36)	$ (1.91)	
Weighted average shares outstanding — basic and diluted*	6,040,467	7,788,741	10,882,688	

* Restated for a one for four (1:4) reverse stock split effective on June 11, 2012.

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

	Common Stock $01 Par Value		Series A Preferred stock $.01 Par Value		Series B Preferred stock $.01 Par Value					
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid in Capital	Accumulated Other Comprehensive Income (loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance at Inception (December 3, 2003)	—	$ —	—	$ —	—	$ —	$ —	$ —	$ —	$ —
Shares issued to employees	183,126	2	—	—	—	—	(2)	—	—	—
January 2004 Proceeds from sale of common stock	1,145,306	11	—	—	—	—	1,343	—	—	1,354
Net loss	—	—	—	—	—	—	—	—	(774)	(774)
Balance, September 30, 2004	1,328,432	$ 13	—	$ —	—	$ —	$ 1,341	$ —	$ (774)	$ 580
Additional stockholder contributions	—	—	—	—	—	—	514	—	—	514
Stock-based compensatio	—	—	—	—	—	—	353	—	—	353
Shares issued to employees and directors for services	10,658	—	—	—	—	—	61	—	—	61
July 2005 Private placement — Sale of Series A preferred stock, net of issuance costs of $379	—	—	569,000	6	—	—	2,460	—	—	2,466
Founder's										

compensation contributed to capital	—	—	—	—	—	—	63	—	—	63
Net loss	—	—	—	—	—	—	—	—	(3,383)	(3,383)
Balance, September 30, 2005	1,339,090	$ 13	569,000	$ 6	—	$ —	$ 4,792	$ —	$ (4,157)	$ 654
Stock-based compensation	—	—	—	—	—	—	1,132	—	—	1,132
July 2006 Private placement — Sale of Series B preferred stock, net of issuance costs of $1,795	—	—	—	—	5,380,711	54	19,351	—	—	19,405
July 2006 — Series B preferred stock units issued July 2006 to settle debt	—	—	—	—	817,468	8	3,194	—	—	3,202
Shares issued to employees and directors for services	988	—	—	—	—	—	23	—	—	23
Accretion of fair value of beneficial conversion charge	—	—	—	—	—	—	603	—	(603)	—
Net loss	—	—	—	—	—	—	—	—	(8,068)	(8,068)
Balance, September 30, 2006	1,340,078	$ 13	569,000	$ 6	6,198,179	$ 62	$ 29,095	$ —	$ (12,828)	$ 16,348
May 2007 Proceeds from sale of common stock	1,437,500	14	—	—	—	—	78,741	—	—	78,755
Conversion of preferred stock on May 16, 2007	1,601,749	16	(569,000)	(6)	(6,198,179)	(62)	52	—	—	—
Stock-based compensation	—	—	—	—	—	—	4,224	—	—	4,224
Shares issued to employees, non-employees and directors for services	732	—	—	—	—	—	16	—	—	16
Stock options exercised	885	—	—	—	—	—	5	—	—	5
March 2007 Warrants exercised	659,226	7	—	—	—	—	416	—	—	423
Deemed dividend — warrants	—	—	—	—	—	—	4,457	—	(4,457)	—
Net loss	—	—	—	—	—	—	—	—	(22,548)	(22,548)
Balance, September 30, 2007	5,040,170	$ 50	—	$ —	—	$ —	$117,006	$ —	$ (39,833)	$ 77,223
Proceeds from sale of common stock	815,000	8	—	—	—	—	46,809	—	—	46,817
Issuance of restricted stock	2,428	—	—	—	—	—	172	—	—	172
Stock-based compensation	—	—	—	—	—	—	6,503	—	—	6,503
Stock options exercised	43,600	1	—	—	—	—	901	—	—	902
Warrants exercised	19,802	—	—	—	—	—	112	—	—	112
Net unrealized loss on Marketable Securities	—	—	—	—	—	—	—	(62)	—	(62)
Proceeds from sale of stock — ESPP	3,596	—	—	—	—	—	181	—	—	181

Net loss	—	—	—	—	—	—	—	—	(43,361)	(43,361)
Balance, September 30, 2008	5,924,596	$ 59	—	$ —	—	—	$171,684	$ (62)	$ (83,194)	$ 88,487
Stock-based compensation	—	—	—	—	—	—	5,064	—	—	5,064
Stock options exercised	4,413	—	—	—	—	—	25	—	—	25
Net unrealized gain on Marketable Securities	—	—	—	—	—	—	—	62	—	62
Proceeds from the sale of stock — ESPP	21,863	—	—	—	—	—	170	—	—	170
Net loss									(43,270)	(43,270)
Balance, September 30, 2009	5,950,872	$ 59	—	$ —	—	$ —	$176,943	$ —	$ (126,464)	$ 50,538
Registered direct financing	599,550	6	—	—	—	—	8,706	—	—	8,712
Initial value of warrants issued in a registered direct	—	—	—	—	—	—	(2,915)	—	—	(2,915)
Stock-based compensation	—	—	—	—	—	—	5,621	—	—	5,621
Stock options exercised	8,076	—	—	—	—	—	68	—	—	68
Net unrealized gain on marketable securities	—	—	—	—	—	—	—	1	—	1
Proceeds from the sale of stock — ESPP	41,393	1	—	—	—	—	324	—	—	325
Net loss	—	—	—	—	—	—	—	—	(38,290)	(38,290)

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

	Common Stock $01 Par Value		Series A Preferred stock $.01 Par Value		Series B Preferred stock $.01 Par Value					
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid in Capital**	**Accumulated Other Comprehensive Income (loss)**	**Deficit Accumulated During the Development Stage**	**Total Stockholders' Equity**
Balance, September 30, 2010	6,599,891	$ 66	—	$ —	—	$ —	$188,747	$ 1	$ (164,754)	$ 24,060
Registered direct financing	3,018,736	30	1,813,944	18	—	—	27,913	—	—	27,961
Initial value of warrants issued in a registered direct offering	—	—	—	—	—	—	(9,438)	—	—	(9,438)
Stock-based compensation	—	—	—	—	—	—	4,920	—	—	4,920
Stock options exercised	104	—	—	—	—	—	—	—	—	—
Warrants exercised	10,549	—	—	—	—	—	50	—	—	50
RSU's										

granted	15,537	—	—	—	—	—	—	—	—	—
Net unrealized loss on marketable securities	—	—	—	—	—	—	—	(1)	—	(1)
Proceeds from the sale of stock — ESPP	17,051	—	—	—	—	—	118	—	—	118
Net loss	—	—	—	—	—	—	—	—	(10,592)	(10,592)
Balance, September 30, 2011	9,661,868	$ 96	1,813,944	$ 18	—	$ —	$212,310	$ —	$ (175,346)	$ 37,078
Proceeds from the sale of unregistered securities	4,250,020	43	—	—	3,605,607	36	16,999	—	—	17,078
Initial value of warrants issued in private placement financing	—	—	—	—	—	—	(4,832)	—	—	(4,832)
Stock-based compensation	—	—	—	—	—	—	1,828	—	—	1,828
Proceeds from the sale of stock — ESPP	10,776	—	—	—	—	—	27	—	—	27
RSUs issued to settle bonus liability	191,719	2	—	—	—	—	582	—	—	584
RSUs granted	60,409	1	—	—	—	—	(1)	—	—	—
Net loss	—	—	—	—	—	—	—	—	(20,747)	(20,747)
Company re-purchase of fractional shares from the reverse stock split	(247)	—	—	—	—	—	—	—	—	—
Balance, Septermber 30, 2012	14,174,545	$ 142	1,813,944	$ 18	3,605,607	$ 36	$226,913	$ —	$ (196,093)	$ 31,016

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

Statements of Comprehensive Loss
(In thousands)

	Year Ended September 30,		
	2010	**2011**	**2012**
Net loss	$(38,290)	$(10,592)	$(20,747)
Unrealized holding gains arising during the period	1	—	—
Comprehensive loss	$(38,289)	$(10,592)	$(20,747)

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

	Year Ended September 30,			
	2010	2011	2012	December 3, 2003 (Inception) to September 30, 2012
Cash flows from operating activities:				
Net loss	$(38,290)	$(10,592)	$(20,747)	$(191,033)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	991	938	725	4,803
Founder's compensation contributed to capital	—	—	—	271
Share-based compensation for employees and directors	5,628	4,964	1,828	27,624
Share-based compensation for non-employees	(7)	(44)	—	2,274
Loss on settlement of debt	—	—	—	627
Write-off of capitalized patent expense	—	—	38	246
Write-off of loan to related party	—	—	—	41
Adjustment to fair value of common stock warrant liability	1,254	(12,611)	1,510	(9,847)
(Increase) decrease in:				
Prepaid expenses and other assets	117	(41)	111	(295)
Income taxes receivable	636	81	1	(34)
Grant receivable	—	—	88	88
Other receivable	(11)	10	(8)	(9)
Increase (decrease) in:				
Accounts payable	982	(1,767)	63	285
Income tax payable	(120)	58	(2)	101
Accrued expenses and other liabilities	(5,561)	753	(128)	3,199
Total adjustments	3,909	(7,659)	4,052	29,198
Net cash used in operating activities	(34,381)	(18,251)	(16,695)	(161,835)
Cash flows from investing activities:				
Purchase of property and equipment	(292)	(189)	(59)	(6,349)
Purchase of marketable securities	(6,000)	—	—	(31,614)
Sale of marketable securities	—	6,000	—	31,614
Capitalized intellectual properties	—	—	—	(298)
Loan to related party	—	—	—	(41)
Net cash (used in) provided by investing activities	(6,292)	5,811	(59)	(6,688)
Cash flows from financing activities:				
Restricted cash	(150)	90	—	(60)
Options exercised	68	—	—	1,000
Warrants exercised	—	50	—	585
Net proceeds from employee stock purchase plan	325	118	27	821
Deferred public offering costs	—	—	—	(1,458)
Stockholder contribution	—	—	—	1,660
Net proceeds from sale of Series A preferred stock 2005	—	—	—	2,466
Net proceeds from sale of Series A preferred stock 2011	—	2,685	—	2,685
Net proceeds from sale of common stock	8,712	25,276	—	161,018
Proceeds from bridge financing	—	—	—	2,575
Net proceeds from sale of Series B preferred stock 2006	—	—	—	19,205
Net proceeds from sale of Series B preferred stock 2012	—	—	8,491	8,491
Net proceeds from sale of unregistered common stock — private placement	—	—	8,585	8,585
Net cash provided by financing activities	8,955	28,219	17,103	207,573
Net (decrease) increase in cash and cash equivalents	(31,718)	15,779	349	39,050
Cash and cash equivalents, beginning of period	54,640	22,922	38,701	—
Cash and cash equivalents, end of period	$ 22,922	$ 38,701	$ 39,050	$ 39,050
Cash paid for interest and income taxes was:				

Interest	$ —	$ —	$ —	$ 9
Income taxes	60	—	20	326

See accompanying notes to financial statements.

	Year Ended September 30,			
	2010	2011	2012	December 3, 2003 (Inception) to September 30, 2012
Non-cash financing and investing activities:				
Warrants issued in connection with registered direct offering	$2,915	$9,438	$ —	$12,353
Warrants issued in connection with unregistered common stock — private placement	—	—	4,832	4,832
Settlement of debt with Series B preferred stock	—	—	—	3,202
Accrued expenses settled with Series B preferred stock	—	—	—	150
Deemed dividend — warrants	—	—	—	4,457
Accretion of fair value of beneficial charge on preferred stock	—	—	—	603
Conversion of convertible preferred stock to common stock	—	—	—	68
Issuance of restricted stock units to settle accrued bonus	—	—	584	584

See accompanying notes to financial statements.

Biodel Inc.
(A Development Stage Company)

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

1. Business and Basis of Presentation

Business

Biodel Inc. and its wholly owned subsidiary (collectively, "Biodel" or the "Company", and formerly Global Positioning Group Ltd.) is a development stage specialty pharmaceutical company located in Danbury, Connecticut. The Company was incorporated in the State of Delaware on December 3, 2003 and commenced operations in January 2004. The Company formed a wholly owned subsidiary in the United Kingdom in October 2011 ("Biodel UK Limited"). This subsidiary has been inactive since its inception.

The Company focuses on the development and commercialization of innovative treatments for diabetes that may be safer, more effective and more convenient for patients. The Company's most advanced program involves developing proprietary formulations of injectable recombinant human insulin ("RHI") designed to be more rapid-acting than the "rapid-acting" mealtime insulin analogs presently used to treat patients with Type 1 and Type 2 diabetes. The Company, therefore, refers to these formulations as its "ultra-rapid-acting" insulin formulations. In addition to the Company's RHI-based formulations, the Company is using its formulation technologies to develop new ultra-rapid-acting formulations of insulin analogs. These insulin analog-based formulations generally use the same or similar excipients as the Company's RHI-based formulations and are designed to be more rapid-acting than the "rapid-acting" mealtime insulin analogs, but they may present characteristics that are different from those offered by the Company's RHI-based formulations.

In April 2012, the Company announced top-line results from a Phase 1 clinical trial of two RHI-based formulations, BIOD-123 and BIOD-125. In this clinical trial, BIOD-123 and BIOD-125 achieved the Company's target pharmacokinetic, pharmacodynamic and toleration profiles. In May 2012, the Company selected two insulin analog-based formulations, BIOD-238 and BIOD-250, to study in a Phase 1 clinical trial. Based on its assessment of these two formulations, the Company selected BIOD-123 as its lead RHI-based product candidate, and in the third calendar quarter of 2012, the Company began enrolling patients in a Phase 2 clinical trial of BIOD-123. This Phase 2 clinical trial is designed to assess the clinical impact of BIOD-123 relative to Humalog®. The trial is being conducted at investigative centers in the United States and is expected to enroll approximately 130 randomized patients with Type 1 diabetes. We expect to announce top-line results from this Phase 2 clinical trial in the third calendar quarter of 2013.

In May 2012, we selected two insulin analog-based formulations, BIOD-238 and BIOD-250, to evaluate in a Phase 1 clinical trial. BIOD-238 and BIOD-250 generally use the same or similar excipients as BIOD-123 and are intended to be optimized for rapid absorption and injection site toleration. We began enrolling patients in the Phase 1 clinical trial in the third calendar quarter of 2012. This trial is designed to compare the pharmacokinetic and injection site toleration profiles of these formulations relative to a rapid-acting mealtime insulin analog. We expect to announce top-line results from this clinical trial in the first calendar quarter of 2013. In parallel with the Phase 1 clinical trial of BIOD-238 and BIOD-250, we have continued our formulation development work to improve the stability characteristics of our ultra-rapid-acting insulin analog-based formulations.

In addition to our ultra-rapid-acting insulin formulation program, we are developing a liquid glucagon formulation for use as a rescue treatment for diabetes patients experiencing severe hypoglycemia, or very low concentrations of blood glucose. To date, we have not selected a lead formulation to advance into clinical trials. We are continuing to conduct preclinical testing to develop formulations that achieve a combination of pharmacokinetic, pharmacodynamic and stability characteristics that we believe would be required for a glucagon rescue treatment product to be commercially successful.

Basis of Presentation

The Company is in the development stage, as defined by Financial Accounting Standards Board ("FASB") ASC 915 (prior authoritative literature: Statement of Financial Accounting Standards No. 7),

"Accounting and Reporting by Development Stage Enterprises", as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning and raising capital.

On June 11, 2012, the Company effected a one-for-four reverse split of its outstanding common stock. All references in these financial statements and accompanying notes to units of common stock or per share amounts are reflective of the reverse split for all periods reported. (See Note 13.)

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 $26,177, $13,901 and $12,483 for the years ended September 30, 2010, 2011 and 2012, 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" with the corresponding expenses are included in research and development. In July and September 2012, the Company was awarded two National Institutes of Health grants for the development of concentrated ultra-rapid-acting insulin formulation and glucagon formulation, respectively, for use in an artificial pancreas. Both awards are for two years and total approximately $580 each. Work on the grant for the development of concentrated ultra-rapid-acting insulin formulation started in August 2012 and expenses incurred were $88 during the twelve months ended September 30, 2012, and corresponding income and a receivable were recorded. In January 2011, the Company received $1,200 in tax credits under the Internal Revenue Service's therapeutic tax credit program which was recorded as a credit to reduce our research and development expenses.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers currency on hand, demand deposits and all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash and cash equivalents. As of September 30, 2011 and 2012, the Company had cash and cash equivalents of $38,701 and $39,050, respectively, and they are primarily held in a premium commercial money market account.

Restricted Cash

Restricted cash was $60 as of September 30, 2011 and 2012. This amount was held in a money market account with a bank to secure a credit card purchasing agreement utilized to facilitate employee travel and certain ordinary purchases.

In February 2012, the Company brought action against one of its vendors before the American Arbitration Association in New York relating to disputed fees charged to the Company for inventory storage. As part of the arbitration stipulation, the Company established a $1,500 escrow account and recorded an accrual of $741 toward this claim. During the quarter ended June 30, 2012, the Company paid $500 from the escrow account. On July 30, 2012, the Company received a judgment from the arbitrator stating the Company's final amount due was $55. The remaining escrow balance of $945 was removed from the escrow account and transferred to cash. The remaining accrual of $186 was reversed and recorded in research and development expense during the quarter ended September 30, 2012.

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.

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, 2011 and 2012, the Company expensed $2,409 and $170, 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 for the years ended September 30, 2010, 2011 and 2012 was $3, $4 and $3, respectively.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation or amortization. Major improvements are capitalized, while maintenance and repairs are expensed in the period the cost is incurred. Property and equipment are depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are amortized using the straight-line method over their estimated useful lives, or the remaining term of the lease, whichever is 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, 2011 and 2012.

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 June 2012 and recorded a liability determined by the Black-Scholes valuation model. The Black-Scholes valuation model was used because the June 2012 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 "Adjustment to fair value of common stock warrant liability."

The Company issued warrants in May 2011 and recorded a liability determined by the Black-Scholes valuation model. The Black-Scholes valuation model was used because the May 2011 warrants do not contain a repricing provision. 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 "Adjustment to fair value of common stock warrant liability."

The Company issued warrants in August 2010 and recorded a liability determined by the Monte Carlo simulation method, which was used because the August 2010 warrants contain a re-pricing provision. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of future expected stock prices of the Company and its peer group and minimize standard error.

On December 2, 2011, the unexercised warrants to purchase 589,000 shares of common stock expired. The Company revalued the liability associated with these warrants from September 30, 2011 through the date of expiration and there was no material impact on the statement of operations. The common stock warrant liability associated with these warrants no longer exists.

Comprehensive Loss

Comprehensive Loss is comprised of net loss and changes in equity for unrealized holding gains on marketable securities during the period.

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, 2012, the Company had a deficit accumulated during the development stage of $196,093. 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 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 2010, the stockholders of the Company approved a new 2010 Stock Incentive Plan (the "2010 Plan"). The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan. In addition, on March 8, 2012, the Company's stockholders approved an amendment to the 2010 Plan to increase the number of shares of common stock authorized for issuance thereunder solely for the purpose of allowing the Company to issue an aggregate of 274,192 restricted stock units to certain of the Company's employees in place of an aggregate of $823 in discretionary cash bonuses in connection with the fiscal year ended September 30, 2011 (the "2011 Bonus RSUs"). The Company will continue to use the Black-Scholes pricing model to assist in the calculation of fair value. The expected life for grants was calculated in accordance with the simplified method described in the Securities and Exchange Commission Staff Accounting Bulletin (SAB) Topic 14.D.2 in accordance with SAB No. 110. The simplified method was

chosen due to limited Company history. Until the Company has adequate history, it will continue to utilize the simplified method (see Note 11).

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

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

For stock options granted to non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes valuation model, if that value is more reliably measurable than the fair value of the consideration or service received. The fair value of these instruments is periodically revalued as the options vest, and is recognized as expense over the related period of service or vesting period, whichever is longer. The total cost expensed (credited) for options granted to non-employees for the years ended September 30, 2010, 2011 and 2012 was $(7), $(44) and $0, respectively.

The Company expenses ratably over the vesting period the cost of the stock options granted to employees and directors. The total compensation

(In thousands, except share and per share amounts)

cost for the years ended September 30, 2010, 2011 and 2012 was $5,628, $4,964 and $1,828, respectively. At September 30, 2012, the total compensation cost related to non-vested options not yet recognized was $1,637, 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,		
	2010	2011	2012
Expected life (in years)	2.72 – 5.25	3.77 – 5.25	3.0 – 4.75
Expected volatility	64 – 77%	65 – 72%	58 – 76%
Expected dividend yield	0%	0%	0%
Risk-free interest rate	0.77 – 2.69%	0.75 – 1.97%	0.39 – 0.91%
Weighted-average grant date fair value	$ 16.37	$ 6.36	$ 2.54

Participating Securities

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

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

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

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU 2011-05 Presentation of Comprehensive Income ("ASU 2011-05"). ASU 2011-05 allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While ASU 2011-05 changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. In December 2011, the FASB issued ASU 2011-12 Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 ("ASU 2011-12"). ASU 2011-12 deferred certain aspects of ASU 2011-05 pertaining only to the presentation of reclassification adjustments out of accumulated other comprehensive income and reinstates the previous requirements to present reclassification adjustments either on the face of the statement in which other comprehensive income is reported or to disclose them in a note to the financial statements. The new guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this guidance in the first quarter of the fiscal year ending September 30, 2012. The adoption of ASU 2011-05 and the deferrals in ASU 2011-12 had no impact on the Company's consolidated financial statements.

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:

(In thousands, except share and per share amounts)

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, 2011 and 2012, 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 Monte Carlo simulation method for the warrants issued in connection with the Company's August 2010 financing and by the Black-Scholes valuation model for the warrants issued in connection with the Company's May 2011 and June 2012 financings. The Monte Carlo simulation method is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of future expected stock prices of the Company and its peer group and minimize standard error. 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. Accordingly, the Company's fair value measurements of its marketable securities are classified as a Level 1 input, and 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, 2012	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	$39,050	$ 39,050	$ —	$ —
Restricted cash	60	60	—	—
Subtotal	39,110	39,110	—	—
Liabilities:				
Common stock warrant liability	(7,338)	—	—	(7,338)
Subtotal	(7,338)	—	—	(7,338)
Total	$31,772	$ 39,110	$ —	$(7,338)

Description	Fair Value at September 30, 2011	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	$38,701	$ 38,701	$ —	$ —
Restricted cash	60	60	—	—
Subtotal	38,761	38,761	—	—
Liabilities:				
Common stock warrant liability	(996)	—	—	(996)
Subtotal	(996)	—	—	(996)
Total	$37,765	$ 38,761	$ —	$ (996)

The Company recognizes transfers into and out of the levels indicated above on the actual date of the event or change in circumstances that

(In thousands, except share and per share amounts)

caused the transfer of change. All changes within Level 3 can be found in the following Level 3 reconciliation table:

Balance at September 30, 2009	$ —
August 2010 warrant — initial fair value at the date of issuance	(2,915)
Increase in fair value	(1,254)
Balance at September 30, 2010	(4,169)
May 2011 warrant — initial fair value at the date of issuance	(9,438)
Exercise of warrants	29
Decrease in fair value	12,582
Balance at September 30, 2011	(996)

June 2012 warrant — initial fair value at the date of issuance	(4,832)
Increase in fair value	(1,510)
Balance at September 30, 2012	$(7,338)

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 30, 2011 and September 30, 2012:

Description	Quoted Prices in Active Markets for identical Assets and Liabilities (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2011	Quoted Prices in Active Markets for identical Assets and Liabilities (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of September 30, 2012
Derivative liabilities related to Warrants	$ —	$ —	$ 996	$ 996	$ —	$ —	$ 7,338	$ 7,338

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the twelve months ended September 30, 2012 and September 30, 2011:

Description	Balance at September 30, 2010	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of September 30, 2011	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of September 30, 2012
Derivative liabilities related to Warrants	$ 4,169	$ 9,438	$(12,611)	$ 996	$ 4,832	$1,510	$ 7,338

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.

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

(In thousands, except share and per share amounts)

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:

	Year Ended September 30,		
	2010	2011	2012
Common shares issuable upon conversion of Series A Preferred Stock	—	453,486	453,486
Common shares issuable upon conversion of Series B Preferred Stock	—	—	3,605,607
Common shares underlying warrants issued for common stock	629,254	2,875,647	5,006,398
Stock options	1,158,891	1,365,350	1,546,454
Restricted stock units	62,264	121,677	68,153

5. Property and Equipment

Property and equipment consists of the following:

	September 30,	
	2011	2012
Furniture and fixtures	$ 324	$ 324
Leasehold improvements	1,548	1,548
Construction-in-progress	38	0
Laboratory equipment	1,886	1,945
Manufacturing equipment	655	655
Facility equipment	65	65
Computer equipment and other	1,308	1,308
Sub-Total	5,824	5,845
Less: Accumulated depreciation and amortization	3,571	4,293
Total	$2,253	$1,552

Depreciation expense for the years ended September 30, 2010, 2011 and 2012 was $989, $935 and $722, respectively.

6. Related Party Transactions

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

Consulting and Clinical Research Services

Dr. Andreas Pfützner served as the Company's Chief Medical Officer in Europe until December 2008. During the fiscal year ended September 30, 2008, we paid Dr. Pfützner $386 in connection with his services in this capacity. Dr. Pfützner continues to perform consulting services for us from time to time, and during the fiscal years ended September 30, 2010, 2011 and 2012, we paid Dr. Pfützner $50, $11 and $0, respectively, in consulting fees. During the fiscal years ended September 30, 2010, 2011 and 2012, we paid approximately $867, $86 and $51, respectively, in

clinical related costs to the Institute for Clinical Research and Development in Mainz, Germany, where Dr. Pfützner serves as its managing director. Dr. Pfützner is majority

owner of the Institute together with his spouse. In July 2007, Steiner Ventures, LLC loaned Dr. Pfützner approximately $200. As of September 30, 2010, the remaining balance on the loan was approximately $89. Dr. Solomon Steiner, our former Chief Scientific Officer, was the sole managing member of Steiner Ventures, LLC at that time. Also at that time, Dr. Steiner and his spouse jointly owned 54% of Steiner Ventures, LLC, with the balance split equally among their four adult children, including Erik Steiner. Erik Steiner is our Vice President, Operations.

Issuance of Series A Convertible Preferred Stock

Between March and July 2005, the Company issued and sold an aggregate of 35,000 shares of its Series A convertible preferred stock (see Note 11) to two executive officers and one director.

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

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

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

Bridge Financing

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

In connection with the sales of units in the Bridge Financing, the Company paid MSI an aggregate commission of $70 and issued to MSI additional warrants to purchase 22,222 shares of Series B convertible preferred stock and a warrant to purchase 11,963 shares of common stock. The fair value of the warrants was $22 as computed using the Black-Scholes valuation model using the following assumptions: term of 3.5 years; volatility rate of 50%; risk free rate of 5.05% and a dividend yield of 0.0%.

Issuance of Series B Convertible Preferred Stock

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

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

7. Commitments

Chief Executive Officer Employment Agreement

On March 30, 2010, the Company announced the appointment of Errol B. De Souza, Ph.D., as the Company's President, Chief Executive Officer and a Director. In connection with his appointment, Dr. De Souza signed an employment agreement, dated March 26, 2010, setting forth the terms of his employment. The agreement provides for an initial term of employment for the period from March 29, 2010 to March 28, 2014 and it continues for successive one-year terms unless the agreement is terminated by either party on 120 days prior written notice in accordance with the terms of the agreement. The agreement provides for an annual salary of $450 and eligibility for a target bonus of 50% of the annual salary. In addition, Dr. De Souza was granted options to purchase 175,000 Shares of the Company's common stock pursuant to the Company's 2010 Plan. These options vest over a four-year period, with 25% vesting on the first anniversary of the grant date and the rest vesting in equal monthly amounts over the next three years.

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

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

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. The amount of compensation due as a result of this event is approximately $4,552, 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, 2012, no amounts have been accrued.

Former Chief Scientific Officer General Release

Effective December 14, 2010, Dr. Solomon Steiner, the Company's former Chief Scientific Officer, retired from all his management positions with the Company. On the same date, the Company and Dr. Steiner executed a general release agreement. Dr. Steiner is therefore entitled to receive the severance benefits set forth in his employment agreement with the Company that were conditioned upon his signing the release. We recorded a charge of $1,360 for salary, bonus and benefits continuation for twenty-four months and an option acceleration modification charge of $7 in the three

(In thousands, except share and per share amounts)

months ended December 31, 2010. As of September 30, 2012, the Company has paid $1,219 in salary, bonus and benefits continuation per the terms of the agreement and $141 has been classified as a short term obligation.

Leases

As of September 30, 2012, the Company leased three facilities in Danbury, Connecticut.

The Company renewed its lease for laboratory space in January 2010 for three years. The lease will expire in January 2013. This lease provides for annual basic lease payments of $65, plus operating expenses.

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

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

Lease expense for the years ended September 2010, 2011, and 2012 was $624, $633, and $636, respectively.

Minimum lease payments under these agreements as of September 30, 2012, as well as equipment leases subsequently entered into, are as follows:

Years Ending September 30,	
2013	$ 594
2014	463
2015	—
Total	$1,057

Purchase Commitments

The Company contracted with N.V. Organon, a global producer of RHI, to supply the Company with all of the RHI that the Company will need for testing and manufacturing of the Company's product candidates. In July 2011, the Company executed an amendment with N.V. Organon, which extends the term of the existing supply agreement to June 30, 2018 and releases the Company from any purchase commitments until the third

calendar quarter of 2014. These commitments commence in the third calendar quarter of 2014 and extend through the second calendar quarter of 2018 for a total purchase commitment of approximately 160 kilograms of RHI. Both parties have the right to terminate the agreement with six months notice, with the Company having the option to purchase significant additional quantities if the supplier terminates the agreement prior to June 30, 2018. As of September 30, 2012, the Company had purchase commitments of approximately $18,020 associated with the signing of the renewed contract with N.V. Organon.

Years Ending September 30,	
2013	$ —
2014	1,078
2015	4,367
2016	4,488
2017	4,577
2018	3,510
Total	$18,020

(In thousands, except share and per share amounts)

8. Income Taxes

The Company files its tax returns on a fiscal year basis. For the years ended September 30, 2010, 2011 and 2012, the Company paid only state taxes.

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

	Year Ended September 30,		
	2010	2011	2012
Current expense			
Federal	$ —	$—	$—
State	(104)	41	18
Actual tax provision (benefit)	$(104)	$41	$18

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

	Year Ended September 30,		
	2010	2011	2012
Federal statutory rate	34.00%	34.00%	34.00%
Federal taxes at statutory rate	$(13,054)	$(3,587)	$(7,028)
Tax expense on permanent differences (a)	2,296	(2,631)	1,137
Tax benefit on research and business credits	(425)	—	—
State taxes, net of federal tax effect	23	19	12
State benefit, net operating loss	(2,990)	(163)	(312)
Valuation allowance increase (b)	14,156	6,382	6,164
Connecticut research and development refund	(30)	—	—
Reserve for uncertain tax positions	4	—	—
Other	(84)	21	45
Actual tax provision (benefit)	$ (104)	$ 41	$ 18

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

(b) Net of the Section 382 Adjustment.

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

	Year Ended September 30,		
	2010	2011	2012
Balance, beginning of year	$ 188	$ 86	$75
Increase related to current year tax position	5	—	—
Increase related to prior year's tax position	—	—	—
Decrease related to prior year's tax position	(107)	(11)	—
Balance, at end of year	$ 86	$ 75	$75

(In thousands, except share and per share amounts)

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 2011 remain open due to net operating loss and are subject to examination by the appropriate governmental agencies in the United States and Connecticut carry-forwards.

As of September 30, 2012, the Company had net operating loss ("NOL") carry-forwards of approximately $53,994 (net of Section 382 limitation discussed below) for U.S. federal tax purposes and $110,182 for state tax purposes. These loss carry-forwards expire between 2024 and 2032. 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 the 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, 2011, 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 $55,890 and federal research and development credit carry-forwards by $1,815.

As of September 30, 2012, the Company has determined that ownership change, under Section 382, occurred as a result of the June 2012 financing and therefore, the ability to utilize its current NOLs is further limited.

The Company also has state research and development credit carry-forwards of approximately $477, which expire commencing in fiscal 2022.

The major components of deferred tax assets and valuation allowances and deferred tax liabilities at September 30, 2011 and 2012 are as follows:

	September 30,	
	2011	2012
Deferred Tax Assets		
Net operating losses	$ 23,699	$ 24,969
Capitalized expense	16,936	21,907
Research and development credits	477	477
Depreciation of fixed assets	303	51
Other	765	453
Total deferred tax asset	42,180	47,857
Valuation Allowance	(42,180)	(47,857)
Net Deferred Tax Assets	$ —	$ —

As the Company has not yet achieved profitable operation, management does not believe that it is more likely than not that the tax benefits as of September 30, 2012 will be realized and therefore has recorded a valuation allowance against its deferred tax assets.

9. Financings

June 2012 Private Placement

In June 2012, the Company completed a private placement (the "2012 Private Placement") of an aggregate of 4,250,020 shares of the Company's common stock, 3,605,607 shares of the Company's Series B preferred stock and warrants to purchase an aggregate of 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. The Company received net proceeds, after deducting placement agents' fees and other transaction expenses, of approximately $17,100 from the 2012 Private Placement.

(In thousands, except share and per share amounts)

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.

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.

At September 30, 2012, the fair value of the warrant liability utilizing the Black-Scholes valuation model was approximately $5,633.

During the year ended September 30, 2012, the Company recorded an adjustment to fair value of common stock warrant liability of $801, within Other (income) expense, to reflect a decrease in the valuation of the warrants from date of issuance to September 30, 2012.

The following summarizes the changes in value of the warrant liability from the date of issuance through September 30, 2012:

Balance at September 30, 2011	$ —
Initial fair value, at the date of issuance	4,832
Increase in fair value	801
Balance at September 30, 2012	$5,633

May 2011 Registered Direct Offering

In May 2011, the Company completed a registered direct offering of an aggregate of 3,018,736 shares of the Company's common stock, 453,486 shares of the Company's Series A preferred stock and warrants to purchase 2,256,929 shares of the Company's common stock. The shares and warrants were sold in units consisting of (i) one share of common stock and (ii) one warrant to purchase 0.1625 of a share of common stock, at an exercise price of $9.92 per share of the Company's common stock. However, one investor also purchased 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 $8.64 per unit. These units were not issued or certificated. The shares and warrants were immediately separated. The warrants will expire on May 17,

(In thousands, except share and per share amounts)

2016, five years from the issuance date of May 18, 2011. The Company received net

proceeds, after deducting placement agent fees and other offering expenses, of approximately $28.0 million from this financing.

Each share of Series A preferred stock is convertible into one quarter of a share of the Company's common stock at any time at the option of the holder, provided that the holder will 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 will 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 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 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 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.

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 Expense ("Adjustment 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. Because the warrants issued in the May 2011 financing do not contain a re-pricing provision, the Company is using the Black-Scholes valuation model to estimate the fair value of the warrants. Using this model, the Company recorded an initial warrant liability of $9,438 as of May 18, 2011 (the warrant issuance date). The significant assumptions of the model were warrants and common stock outstanding, remaining terms of the warrants, the per stock price of $2.06, a risk-free rate of 1.89% and expected volatility rate of 75%.

During the year ended September 30, 2012, the Company recorded an adjustment to fair value of common stock warrant liability of $709, within Other (income) expense, to reflect the increase in the valuation of the warrants from September 30, 2011 to September 30, 2012 due to the increase in the value of the Company's common stock price from September 30, 2011 to September 30, 2012. At September 30, 2012, the fair value of the warrant liability determined utilizing the Black-Scholes valuation model was approximately $1,705.

The following summarizes the changes in value of the warrant liability from the date of issuance through September 30, 2012:

Balance at September 30, 2010	$ —
Initial fair value, at the date of issuance	9,438
Decrease in fair value	(8,442)
Balance at September 30, 2011	996
Increase in fair value	709
Balance at September 30, 2012	$ 1,705

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

August 2010 Registered Direct Offering

In August 2010, the Company sold to two institutional investors an aggregate of 599,550 units, with each unit consisting of (i) one share of common stock and (ii) one warrant to purchase one share of common stock, for a purchase price of $15.72 per unit. These units were not issued or certificated. The shares and warrants were immediately separated and the Company issued 599,550 shares of its common stock and warrants to purchase an additional 599,550 shares of the Company's common stock. This financing resulted in net proceeds of $8,700.

In August 2011, one investor exercised 10,550 warrants, at $4.70 per share, and the Company received proceeds totaling approximately $50. Subsequently, on December 1, 2011 the remaining 589,000 warrants expired unexercised.

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, 2011 and 2012.

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, 2012
June 2012 Financing	
Stock price	$ 2.97
Exercise price	$ 2.66
Risk-free interest rate	0.62%
Expected remaining term	4.74 years
Expected volatility	98%
Dividend yield	0%
Warrants outstanding June 2012 registered direct	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, 2012 and 2011, respectively using the following assumptions:

	September 30, 2011	September 30, 2012
May 2011 Financing		
Stock price	$ 2.16	$ 2.97
Exercise price	$ 9.92	$ 9.92
Risk-free interest rate	0.96%	0.31%
Expected remaining term	4.63 years	3.63 years
Expected volatility	75%	82%
Dividend yield	0%	0%
Warrants outstanding May 2011 registered direct	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 period of time over which the warrant is expected to remain outstanding and is based on management's estimate, taking into consideration the remaining contractual life.

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. Extra weighting is attached to those companies most similar in terms of size and business activity. An increase in the expected volatility will increase the fair value and the associated derivative liability.

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

Participating Securities

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

As such, given that the warrant holders will participate fully on any dividends or dividend equivalents, the Company determined that the warrants are participating securities and therefore are subject to ASC 260-10-55 earnings per share. These securities were excluded for the years ended September 30, 2012, 2011 and 2010 earnings per share calculation since their inclusion would be anti-dilutive.

10. Stockholders' Equity

Common Stock

The Company's authorized common stock consists of 62,500,000 shares of a single class of common stock, having a par value of $0.01 per share. The holders of the common stock are entitled to one vote for each share and have no cumulative voting rights or preemptive rights.

On June 27, 2012 the Company completed a 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 2,256,929 shares of common stock at an exercise price of $2.66 per share. The Company received net proceeds, after deducting placement agent fees and other offering expenses of approximately $17,100 from this financing.

On May 12, 2011, the Company completed a registered direct offering of an aggregate of 3,018,736 shares of common stock, 1,813,944 shares of Series A preferred stock and warrants to purchase 2,256,929 shares of common stock at an exercise price of $9.92 per share. The Company received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $28,000 from this financing.

On August 24, 2010, the Company completed a registered direct offering of an aggregate of 599,550 shares of common stock and warrants to purchase an additional 599,550 shares of common stock at an exercise price of $18.864. The Company received net proceeds, after deducting placement agent fees and other offering expenses, of approximately $8,700 from this financing.

On February 12, 2008, the Company completed a follow-on public offering of 815,000 shares of its common stock at a price to the public of $62.00 per share. The Company received net proceeds from this offering, after deducting underwriting discounts and commissions and expenses, of $46,817. Certain of the Company's stockholders sold 137,500 shares in the offering. The Company did not receive any proceeds from the sale of shares from the selling stockholders.

On May 16, 2007, the Company completed an initial public offering of 1,437,500 shares of its common stock at a price to the public of $60.00 per share. The offering resulted in gross proceeds of $86,300. The Company received net proceeds from the offering of approximately $78,800 after deducting underwriting discounts and commissions and additional offering expenses. The completion of the initial public offering

resulted in the conversion of the Company's Series A and B convertible preferred stock. A total of 1,601,749 shares of common stock were issued upon the conversion of the preferred stock.

As of September 30, 2012, the Company had the following warrants outstanding:

(i) May 2011 financing —

(a) warrants to purchase 1,962,163 shares of the Company's common stock with an exercise price of $9.92 per share and

(b) Series A preferred stock — warrants to purchase 294,766 shares of the Company's common stock with an exercise price of $9.92 per share.

(ii) June 2012 financing —

(a) warrants to purchase 1,487,507 shares of the Company's common stock with an exercise price of $2.66 per share and

(b) Series B convertible preferred stock — warrants to purchase 1,261,922 shares of the Company's common stock with an exercise price of $2.66 per share.

Preferred Stock

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

Series A Preferred Stock May 2011 Financing

As part of the May 2011 registered direct offering, the Company issued 1,813,944 shares of the Company's Series A preferred stock to one investor. The investor purchased 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 at a price of $8.84 per unit.

Each share of Series A preferred stock is convertible into one share of the Company's common stock at any time at the option of the holder, provided that the holder will 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 will 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 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 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 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.

Series A Preferred Stock July 2005 Private Placement

In July 2005, the company authorized 1,050,000 shares of its Series A preferred stock and completed a private placement of 569,000 shares of these shares, of which 0 shares were issued and outstanding as of September 30, 2007. In addition, in connection with the July 2006 private placement, the Company issued warrants to purchase shares of the Company's series A preferred stock. All such warrants were expired as of September 30, 2012.

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

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

As part of the compensation agreement, the placement agent received 69,875 Series A warrants. Each warrant consists of the right to purchase one share of fully paid and non-assessable common stock for a period of seven years which expired on July 12, 2012.

Series B Preferred Stock June 2012 Private Placement

In June 2012, the Company completed a private placement of an aggregate of 4,250,020 shares of the Company's common stock, 3,605,607 shares of the Company's Series B Convertible Preferred Stock and warrants to purchase an aggregate of 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.

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.

Series B Preferred Stock July 2006 Private Placement

In July 2006, the Company authorized 6,500,000 shares of its Series B preferred stock and completed a private placement of 5,380,711 of these shares, of which 0 shares were issued and outstanding as of September 30, 2007. In addition, in connection with the July 2006 private placement the Company issued warrants to purchase shares of the Company's Series B preferred stock. All such warrants were expired as of September 30, 2012.

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

Shares Reserved for Future Issuance

As of September 30, 2012, the Company reserved shares of common stock for future issuance as follows:

(In thousands, except share and per share amounts)

2010 stock incentive plan	2,201,908
2005 employee stock purchase plan	450,000
Common shares issuable upon conversion of Series A Preferred Stock	453,486
Common shares issuable upon conversion of Series B Preferred Stock	3,605,607
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	11,717,399

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

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

2010 Stock Incentive Plan

In March 2010, the shareholders of the Company approved the 2010 Stock Incentive Plan (the "2010 Plan"). Up to 1,350,000 shares of the Company's common stock may be issued pursuant to awards granted under the 2010 Plan, plus 851,908 shares of common stock underlying already outstanding awards under the Company's prior plans. As of September 30, 2012, the Company had 1,546,454 shares of common stock subject to outstanding awards. The contractual life of options granted under the 2010 Plan may not exceed seven years. The 2010 Plan uses a "fungible share" concept under which any awards that are not a full-value award will be counted against the share limit as one (1) share for each share of common stock and any award that is a full-value award will be counted against the share limit as 1.6 shares for each one share of common stock. The Company has not made any new awards under any prior equity plans after March 2, 2010 — the effective date the 2010 Plan was approved by the Company's stockholders. The 2010 Plan replaces the 2004 Stock Incentive Plan and 2005 Non-Employee Directors Stock Option Plan.

2005 Employee Stock Purchase Plan

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

Under the Purchase Plan, eligible employees may contribute up to 15% of their eligible earnings for the period of that offering withheld for the purchase of common stock under the Purchase Plan. The employee's purchase price is equal to the lower of: 85% of the fair market value per share on the start date of the offering period in which the employee is enrolled or 85% of the fair market value per share on the semi-annual purchase date. The Purchase Plan imposes a limitation upon a participant's right to acquire common stock if immediately after the purchase, the employee would own 5% or more of the total combined voting power or value of the Company's common stock or of any of its affiliates not eligible to participate in the Purchase Plan. 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, 2010, 2011 and 2012 was $454, $53 and $16, respectively.

(In thousands, except share and per share amounts)

An aggregate of 450,000 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, 2011 and 2012, a total of 341,097 and 355,321 shares, respectively, were reserved and available for issuance under this plan. For the years ended September 30, 2010, 2011 and 2012, the Company issued a total of 66,852, 83,903 and 94,679 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 fair value per share is being recognized as compensation expense over the applicable vesting period. The fair value per share for awards granted as of December 31, 2008 through September 30, 2012 was calculated using the Black-Scholes valuation model.

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

The following table summarizes the stock option activity through September 30, 2012:

Options	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Balance, September 30, 2004	—	$ —		$ —
Granted	96,358	5.64		—
Outstanding balance, September 30, 2005	96,358	5.64		—
Granted	115,401	22.60		—
Forfeited, expired	15,054	13.60		—
Outstanding balance, September 30, 2006	196,705	12.92		—
Granted	238,961	55.84		—
Exercised	886	5.64		—
Forfeited, expired	13,283	22.60		—
Outstanding balance, September 30, 2007	421,497	27.20		—
Granted	431,849	67.52		—
Exercised	43,604	20.72		—
Forfeited, expired	25,892	44.16		—
Outstanding balance, September 30, 2008	783,850	55.68		—
Granted	152,875	10.76		—
Exercised	4,416	5.64		—
Forfeited, expired	80,398	55.52		—

(In thousands, except share and per share amounts)

Options	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Outstanding balance, September 30, 2009	851,911	47.24		—
Granted	328,530	16.37		—
Exercised	8,081	8.43		—
Forfeited, expired	13,469	52.16		—
Outstanding balance, September 30, 2010	1,158,891	38.72		—
Granted	290,834	6.36		—
Exercised	104	5.64		—
Forfeited, expired	84,271	38.48		—
Outstanding balance, September 30, 2011	1,365,350	32.68		—
Granted	215,877	2.54		—
Forfeited, expired	34,773	32.09		—
Outstanding balance September 30, 2012	1,546,454	$ 27.80	4	$ —
Exercisable shares, September 30, 2012	1,197,230	$ 33.39	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.

In addition, on March 8, 2012, the Company’s stockholders approved an amendment to the 2010 Plan to increase the number of shares of common stock authorized for issuance thereunder solely for the purpose of allowing the Company to issue an 191,719 restricted stock units to certain of the Company’s employees in place of an aggregate of $823 in discretionary cash bonuses in connection with the fiscal year ended September 30, 2011 (the “2011 Bonus RSUs”). The 2011 Bonus RSUs vested and were distributed on September 30, 2012. The Company had previously accrued and expensed the $823 in the fiscal year ended September 30, 2011. The 2011 Bonus RSUs vested in full and was distributed on September 30, 2012. Since the total fair value of the 2011 Bonus RSUs did not exceed the discretionary aggregate cash bonus value of $823, the Company did not record any additional stock-based compensation expense in the year ended September 30, 2012. The accrued bonus liability was settled in March 2012 and, accordingly, the liability, net of taxes, in the amount of $582 was reversed into additional paid-in-capital. Each RSU award that was granted in December 2010 to our executive officers and employees 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. For example, the December 2010 RSU awards vest over three years and are expensed 50% the first year and 25% the next two years; whereas, the December 2009 RSU awards are expensed ratably over the four year vesting period.

Based on historical experience of option cancellations, the Company has estimated an annualized forfeiture rate of 9% for employee RSUs. Forfeiture rates will be adjusted over the requisite service period when actual forfeitures differ, or are expected to differ, from the estimate. As of September 30, 2012, the executives, the board of directors and employees had 350,148 vested and distributed RSUs.

The stock-based compensation expense associated with the RSUs has been recorded in the statement of operations and in additional paid-in-

(In thousands, except share and per share amounts)

capital on the balance sheets is as follows:

	September 30,		
	2010	2011	2012
Stock compensation expense — RSUs	$205	$585	$1,202

At September 30, 2012, there was $418 of total unrecognized stock-based compensation expense related to RSU awards granted under the 2004 Stock Incentive Plan and the 2010 Plan. This expense is expected to be recognized over the remaining vesting periods up to four years.

The following table summarizes RSU activity from October 1, 2010 through September 30, 2012:

	Shares	Weighted Average Grant-Date Fair Value
Non-vested and outstanding balance at September 30, 2009	—	$ —
Shares granted	62,510	15.80
Shares forfeited or expired	246	15.80
Non-vested and outstanding balance at September 30, 2010	62,264	15.80
Changes during the period:		
Shares granted	90,639	7.56
Shares vested and issued	22,435	17.20
Shares forfeited or expired	8,791	9.40
Non-vested and outstanding balance at September 30, 2011	121,677	9.40
Changes during the period:		
Shares granted	274,189	2.36
Shares vested and issued	327,713	3.45
Non-vested and outstanding balance at September 30, 2012	68,153	$10.51

11. 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, 2010, 2011 and 2012, the Company had not elected to make any contributions to the plan.

12. Reverse Stock Splits

On June 11, 2012, the Company amended its certificate of incorporation in order to effect a one-for-four reverse split of its outstanding common stock and to fix on a post-split basis the number of authorized shares of its common stock at 25,000,000 (reduced from 100,000,000 authorized shares). As a result of the 2012 reverse stock split, each share of Company common stock outstanding at the effective time was automatically changed into one-quarter of a share of common stock. No fractional shares were issued in connection with the 2012 reverse stock split, and cash of $0.3 was paid in lieu of fractional shares. Also as a result of the 2012 reverse stock split, the number of shares of common stock subject to outstanding options, RSUs and warrants issued by the Company and the number of shares reserved for future issuance under the Company's stock plans have been reduced by a factor of four. There was no alteration to the par value of the common stock or any modification of the voting rights or other terms thereof. All references in these financial statements and accompanying notes to units of common stock or per share amounts are reflective of the 2012 reverse stock split for all periods reported.

On April 12, 2007, the Company completed a 0.7085 for one (0.7085:1) reverse stock split rounding all fractional shares down to the next full share. Stockholders received cash in lieu of fractional shares. After the 2007 reverse split, there were 2,000,957 shares of common stock outstanding. The 2007 reverse split did not reduce the number of authorized shares of common stock, alter the par value or modify the voting rights or other terms

thereof. As a result of the 2007 reverse split, the conversion prices and/or the numbers of shares issuable upon the exercise of any outstanding options and warrants to purchase common stock were proportionally adjusted pursuant to the respective anti-dilution terms of the 2004 Stock Incentive Plan and the respective warrant agreements. All references in these financial statements and accompanying notes to units of common stock or per share amounts are reflective of the 2007 reverse split for all periods reported.

13. Summary Selected Quarterly Financial Data (Unaudited)

The following table sets forth certain unaudited quarterly statement of operations data for the eight quarters ended September 30, 2012. This information is unaudited, but in the opinion of management, it has been prepared substantially on the same basis as the audited financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to state fairly the unaudited quarterly results of operations. The results of operations for any quarter are not necessarily indicative of the results of operations for any future period.

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

	December 31, 2011	March 31, 2012	June 30, 2012	September 30, 2012
Revenue	$ —	$ —	$ —	$ —
Net loss	$ (4,501)	$ (4,316)	$ (6,051)	$ (5,879)
Basic and diluted net loss per common share [1]	$ (0.47)	$ (0.45)	$ (0.60)	$ (0.42)
Weighted average common shares basic and diluted	9,673,529	9,688,384	10,152,194	13,982,826

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

	December 31, 2010	March 31, 2011	June 30, 2011	September 30, 2011
Revenue	$ —	$ —	$ —	$ —
Net (loss) income	$ (5,309)	$ (5,442)	$ (3,974)	$ 4,133
Basic net (loss) income per common share	$ (0.80)	$ (0.82)	$ (0.48)	$ 0.43
Diluted net (loss) income per common share [1]	$ (0.80)	$ (0.82)	$ (0.48)	$ 0.41
Weighted average common shares basic	6,604,726	6,617,422	8,254,413	9,657,795
Weighted average common shares diluted	6,604,726	6,617,422	8,254,413	10,111,336

(1) Basic earnings (loss) per share calculation for the third and fourth quarter include the weighted average effect of stock issuances; therefore, the sum of the quarterly earnings per share will not equal full-year earnings per share amounts which reflect the weighted average effect on an annual basis.

14. Subsequent Event

On December 20, 2012, the Company amended its certificate of incorporation in order to effect an increase in the number of shares of the Company's authorized common stock, par value $.01 per share, from 25,000,000 shares to 62,500,000 shares.

CERTIFICATE OF AMENDMENT OF
SECOND AMENDED AND RESTATED CERTIFICATE OF INCORPORATION,
AS AMENDED

OF

BIODEL INC.

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

Biodel Inc. (hereinafter called the "Corporation"), organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

By action of the Board of Directors of the Corporation at a meeting held on September 10, 2012, the Board of Directors duly adopted a resolution pursuant to Section 242 of the General Corporation Law of the State of Delaware setting forth an amendment to the Second Amended and Restated Certificate of Incorporation of the Corporation, as amended, (the "Restated Certificate of Incorporation") and declaring said amendment to be advisable and directing that it be submitted to and considered by the stockholders of the Corporation for approval. The stockholders of the Corporation duly approved said proposed amendment at a Special Meeting of Stockholders held on November 1, 2012, in accordance with Section 242 of the General Corporation Law of the State of Delaware. The resolution setting forth the amendment is as follows:

RESOLVED: That, subject to the approval of the stockholders of the Corporation, the second paragraph of Article FOURTH of the Restated Certificate of Incorporation (relating to the Corporation's authorized shares of capital stock) be and hereby is deleted in its entirety and the following second paragraph of Article FOURTH is inserted in lieu thereof:

"A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 112,500,000 shares, consisting of (i) 62,500,000 shares of Common Stock, $0.01 par value per share ("Common Stock"), and (ii) 50,000,000 shares of Preferred Stock, $0.01 par value per share ("Preferred Stock")."

Exhibit 3.5

IN WITNESS WHEREOF, the Corporation has caused its corporate seal to be affixed hereto and this Certificate of Amendment to be signed by its duly authorized officer this 19th day of December, 2012.

BIODEL INC.

By: /s/ Paul S. Bavier
Name: Paul S. Bavier
Title: Secretary

Exhibit 10.19

BASE SALARIES OF NAMED EXECUTIVE OFFICERS OF THE REGISTRANT

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

Name and Title	Base Salary(1)
Errol De Souza President and Chief Executive Officer	$477,405
Gerard J. Michel Chief Financial Officer, Vice President Corporate Development and Treasurer	$335,000
Alan Krasnser Chief Medical Officer	$331,000
Paul Bavier General Counsel and Secretary	$225,000
Erik Steiner Vice President, Operations	$215,500

(1) Base salaries effective October 1, 2012.

Exhibit 10.20

SUMMARY OF THE REGISTRANT'S NON-EMPLOYEE DIRECTOR COMPENSATION

The Company pays each of its non-employee directors $30,000 annually or $60,000 annually to its Chairman. In addition, non-employee directors receive the following committee-related fees annually: (1) $7,500 for participating on the Audit Committee or $15,000 for chairing the committee; (2) $5,000 for participating on the Compensation Committee or $15,000 for chairing the committee; and (3) $2,500 for participating on the Nominating and Governance Committee or $5,000 for chairing the committee.

Upon appointment, non-employee directors receive a one-time grant of an option to purchase 6,250 shares of common stock. These options vest pro rata over one year. Annually, non-employee directors receive an option to purchase 5,000 shares of common stock, which also vest pro rata over one year. The exercise price of these options is the fair market value on the date of grant. Each such option expires seven years after the date of grant under the Company's 2010 Stock Incentive Plan.

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

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Biodel UK Limited

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 (No. 333-153167) and (182877) and the Registration Statements on Form S-8 (No. 333-144407), (333-168903) and (180409) of Biodel Inc. of our report dated December 21, 2012, relating to the financial statements, which appears in this Form 10-K for the year ended September 30, 2012.

/s/ BDO USA, LLP
New York, New York
December 21, 2012

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/ E RROL D E S OUZA

Errol De Souza
President and Chief
Executive Officer
Date: December 21, 2012

Exhibit 31.02

CERTIFICATION

I, Gerard Michel, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ G ERARD M ICHEL

Gerard Michel
Chief Financial Officer, Vice President,
Corporate Development and Treasurer
Date: December 21, 2012

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, 2012 as filed with the Securities and Exchange Commission on the date hereof (the " Report "), the undersigned Errol De Souza, President and Chief Executive Officer of the Company and Gerard Michel, Chief Financial Officer, Vice President Corporate Development and Treasurer of the Company, each hereby certifies that: (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ E RROL D E S OUZA

Errol De Souza,
President and
Chief Executive Officer
Dated: December 21, 2012

/s/ G ERARD M ICHEL

Gerard Michel
Chief Financial Officer,
Vice President, Corporate
Development and Treasurer
Date: December 21, 2012