HALOZYME THERAPEUTICS INC
Form 10-K
March 12, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2011

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: 001-32335

Halozyme Therapeutics, Inc.

(*Exact name of registrant as specified in its charter*)

Delaware	**88-0488686**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
11388 Sorrento Valley Road, San Diego, California	**92121**
(Address of principal executive offices)	*(Zip Code)*

(858) 794-8889

(Registrant s Telephone Number, Including Area Code)

Securities registered under Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 Par Value	The NASDAQ Stock Market, LLC

Securities registered under 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. x Yes ¨ No

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 was approximately $581.9 million based on the closing price on the NASDAQ Stock Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2012, there were 112,093,601 shares of the registrant s $0.001 par value common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the issuer s Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant s 2012 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Parts II and III of this Annual Report.

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PART I

Item 1. ***Business***

This Annual Report on Form 10-K contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as expects, anticipates, intends, plans, believes, seeks, estimates, thinks, may, could, will, we potential, likely, opportunity and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters such as the development or regulatory approval of new products, enhancements of existing products or technologies, third party performance under key collaboration agreements, revenue and expense levels and other statements regarding matters that are not historical are forward-looking statements.

Although forward-looking statements in this Annual Report reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include without limitation those discussed under the heading Risk Factors below, as well as those discussed elsewhere in this Annual Report. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report. Readers are urged to carefully review and consider the various disclosures made in this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

Overview

We are a biopharmaceutical company dedicated to developing and commercializing innovative products that advance patient care. Our research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique scientific expertise that allows us to pursue this target-rich environment for the development of future therapies.

Our research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, the recombinant human hyaluronidase or rHuPH20, temporarily degrades hyaluronan, or HA, a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit. Our Enhanze technology is the platform for the delivery of proprietary small and large molecules. We apply our research to develop products in partnership with other companies as well as for our own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing products and a limited number of product candidates; (iv) supporting the development of partnered product candidates; and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have multiple proprietary programs in various stages of research and development. In addition, we currently have collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, Baxter Healthcare Corporation, or Baxter, ViroPharma Incorporated, or ViroPharma, and Intrexon Corporation, or Intrexon, to apply Enhanze technology to the partners biological therapeutic compounds. We

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also had another partnership with Baxter, under which Baxter had worldwide marketing rights for our marketed product, *Hylenex* recombinant, or the Hylenex Partnership. We and Baxter mutually agreed to terminate the Hylenex Partnership in January 2011. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from our partnerships.

In February 2007, we and Baxter amended certain existing agreements relating to *Hylenex* recombinant and entered into the Hylenex Partnership for kits and formulations with rHuPH20. In October 2009, Baxter commenced the commercial launch of *Hylenex* recombinant. *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the *Hylenex* recombinant manufactured by Baxter was not in compliance with regulatory requirements. During the second quarter of 2011, we submitted the data that the U.S. Food and Drug Administration, or FDA, had requested to support the reintroduction of *Hylenex* recombinant. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant and we reintroduced *Hylenex* recombinant to the market in December 2011.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements. In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, under which Baxter fills and finishes *Hylenex* recombinant for us. On July 18, 2011, we and Baxter entered into an agreement setting forth certain rights, data and assets to be transferred by Baxter to us during a transition period, or the Transition Agreement. The termination of these agreements does not affect the other relationships between the parties, including the application of our Enhanze technology to Baxter s GAMMAGARD LIQUID

We and our partners have product candidates in the research, preclinical and clinical stages, but future revenues from the sales and/or royalties of these product candidates will depend on our partners abilities and ours to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we and our partners are able to obtain regulatory approvals for these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately $245.0 million as of December 31, 2011.

We reincorporated from the State of Nevada to the State of Delaware in November 2007. Our principal offices and research facilities are located at 11388 Sorrento Valley Road, San Diego, California 92121. Our telephone number is (858) 794-8889 and our e-mail address is info@halozyme.com. Additional information about the Company can be found on our website at www.halozyme.com, and in our periodic and current reports filed with the SEC. Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and online at www.sec.gov and our website at www.halozyme.com.

Technology

Our existing products and our products under development are based primarily on intellectual property covering the family of human enzymes known as hyaluronidases. Hyaluronidases are enzymes (proteins) that break down HA, which is a naturally occurring space-filling, gel-like substance that is a major component of both normal tissues throughout the body, such as skin and cartilage, and abnormal tissues such as tumors. Our primary technology, Enhanze technology, is a proprietary delivery platform using rHuPH20, a human recombinant version of hyaluronidase. rHuPH20 is a naturally occurring enzyme that temporarily degrades HA, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. rHuPH20 is the active compound in our first commercially approved product, *Hylenex* recombinant. Our proprietary rHuPH20 technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones through the development of our own proprietary products. Through partnerships or other collaborations, the rHuPH20 technology may also be applied to existing and developmental products of biopharmaceutical companies that market drugs requiring or benefiting from injection via the subcutaneous route of administration.

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Strategy

We are dedicated to the development and commercialization of recombinant human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. By expanding upon our scientific expertise in the extracellular matrix, we hope to develop therapeutic and aesthetic drugs. Our lead enzyme, rHuPH20 hyaluronidase, facilitates the delivery of drugs and fluids through the extracellular matrix and into circulation. rHuPH20 is the underlying drug delivery technology of *Hylenex* recombinant for small molecules and fluids, and Enhanze technology for the delivery of proprietary small and large molecules. We continue to seek ways to combine rHuPH20 with previously approved drugs to develop new proprietary products, with potentially new patent protection.

We are also expanding our scientific work in the extracellular matrix by developing other enzymes and agents that target unique aspects of the extracellular matrix, giving rise to potential new molecular entities targeting indications in endocrinology, oncology and dermatology. For instance, we are developing a formulation of rHuPH20 and insulin for the treatment of diabetes mellitus. We are also developing a PEGylated version of the rHuPH20 enzyme, or PEGPH20, that lasts longer in the bloodstream, and may therefore better target solid tumors by clearing away the surrounding HA and reducing the interstitial fluid pressure within malignant tumors to allow better penetration by chemotherapeutic agents. In addition, we are developing an extracellular matrix-modifying enzyme that targets components of the skin and subcutaneous tissues that may have both therapeutic and aesthetic applications within dermatology. Key aspects of our corporate strategy include the following:

Develop our own proprietary products based on our PH20 enzyme;

Develop other new molecular entities or enzymes for the extracellular matrix;

Seek partnerships for our Enhanze technology drug delivery platform;

Support product development and commercialization under our Enhanze technology collaborations; and

Increase sales and continue to drive physician adoption of *Hylenex* recombinant in the United States.

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Product and Product Candidates

We have one marketed product and multiple product candidates targeting several indications in various stages of development. The following table summarizes our proprietary product and product candidates as well as our partnered product candidates:

Ultrafast Insulin Program

Our lead proprietary program focuses on the formulation of rHuPH20 with prandial (mealtime) insulins for the treatment of diabetes mellitus. Diabetes mellitus is an increasingly prevalent, costly condition associated with substantial morbidity and mortality. Attaining and maintaining normal blood sugar levels to minimize the long-term clinical risks is a key treatment goal for diabetic patients. We have combined rHuPH20 with a rapid acting analog insulin, e.g., insulin lispro (Humalog®), or Lispro-PH20, insulin aspart (Novolog®), or Aspart-PH20, and

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insulin glulisine (Apidra®), or each such combination, Analog-PH20, to accelerate their action. These Analog-PH20 combinations facilitate faster insulin dispersion in, and absorption from, the subcutaneous space into the vascular compartment, leading to faster insulin response. By making mealtime insulin onset faster, i.e., providing earlier insulin to the blood and thus earlier glucose lowering activity, Analog-PH20 may yield a better profile of insulin effect, more like that found in healthy, non-diabetic people.

The primary goal of our ultrafast insulin program is to develop a best-in-class insulin product, with demonstrated clinical benefits for type 1 and 2 diabetes mellitus patients, in comparison to the current standard of care analog products. With a more rapidly absorbed, faster acting insulin product, we seek to demonstrate one or more significant improvements relative to existing treatment, such as improved glycemic control, less hypoglycemia, and less weight gain. A number of Phase 1 and Phase 2 clinical pharmacology trials and registration trial-enabling treatment studies in connection with our ultrafast insulin program investigating the various attributes of our insulin candidates, have been completed, are ongoing or planned. The status of some of these trials is summarized below:

In June 2011, we reported results from the first stage of an insulin pump study comparing Aspart-PH20 versus aspart alone at the Scientific Sessions of the American Diabetes Association in San Diego, California. The results demonstrated that Aspart-PH20 has pharmacokinetic and glucodynamic profiles that were accelerated and showed more consistent absorption and action rates over infusion set life as compared to analog alone, and the Aspart-PH20 also provided a reduction of post-meal glycemic excursions relative to aspart alone.

In October 2011, we announced positive results from the second stage of an insulin pump study in patients with type 1 diabetes at the Diabetes Technology Meeting in San Francisco, California, which took place from October 27 to 29, 2011. This Phase 1b study was conducted as a randomized, double-blind, crossover design, to determine insulin pharmacokinetics, glucodynamics, safety and tolerability of rHuPH20 as a single injection prior to the start of three days of commercially available mealtime insulin aspart pump infusion therapy. The data demonstrated that pre-administration of rHuPH20 led to a consistent and faster insulin exposure profile over the infusion set life and superior glucose control following meals. Compared to insulin aspart alone, pre-administration with rHuPH20 reduced the variability in insulin exposure and action profiles observed with continuous insulin infusion and provided a consistent ultrafast profile over three days of use. In the test meal setting, the consistent ultrafast profile with pre-administration of rHuPH20 led to consistently reduced postprandial excursions. Insulin aspart infusion with and without rHuPH20 pretreatment was similarly well tolerated.

In October 2011, we announced the positive results from two Phase 2 clinical trials of our ultrafast Analog-PH20 injection formulations in patients with type 1 and type 2 diabetes. More than 110 patients enrolled in each of the trials and received an insulin analog alone or an Analog-PH20 treatment for 12 weeks along with basal insulin, followed by the opposite treatment for an additional 12 weeks in a 2-way double blind crossover design. The primary endpoint of each study was a comparison of glycemic control, the main measurement that people with diabetes use to assess treatment effectiveness, as assessed by the change in HbA1C from baseline. Data regarding post-prandial glucose levels, the proportion of patients that safely achieve HbA1C targets, rates of hypoglycemia, weight change and additional endpoints were collected as well. Both trials met the primary endpoint of non-inferiority for HbA1C, which reflects average blood sugar level over a prolonged period of time, compared to the insulin analog comparator, with superior reductions in post-prandial glucose excursions in the Analog-PH20 arms. Compared to insulin analog alone, Analog-PH20 use resulted in a greater than 50% increase in the proportion of both type 1 and type 2 patients able to consistently achieve AACE (American Association of Clinical Endocrinologists) post-prandial glucose targets at both one and two hours. In the study of patients with type 1 diabetes, overall hypoglycemia (defined either as blood glucose <70 mg/dL or <56 mg/dL) was modestly but statistically significantly reduced for both definitions of hypoglycemia compared to analog alone; in the study of patients with type 2 diabetes hypoglycemia rates were comparable between treatment groups. Hypoglycemia events were generally mild, and adverse events with Analog-PH20

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formulations were similar to those observed during the insulin analog comparator phase. We currently expect to present the detailed results of these studies at a major medical meeting in 2012.

We view Analog-PH20 for injection and pump therapy as distinct product opportunities that could be pursued separately. Based on the data we have seen thus far, we believe that a large biotech or pharmaceutical company with global access to the primary care markets would be best positioned to maximize the value of the injectable market, and therefore entering into a collaboration would be an attractive option for us to exploit this opportunity. We believe that the pre-administration of rHuPH20 could be the best product offering for the pump market. The next step will be for us to evaluate this opportunity using *Hylenex* recombinant in a clinical study (rHuPH20 is the underlying drug delivery technology in *Hylenex* recombinant). We expect to present results from this study at an appropriate scientific meeting in 2012.

PEGPH20

We are developing an investigational PEGylated form of rHuPH20, or PEGPH20, a new molecular entity as a candidate for the systemic treatment of tumors that accumulate HA. PEGylation refers to the attachment of polyethylene glycol to rHuPH20, now known as PEGPH20, which converts rHuPH20 from a transient and short-lived enzyme to a more stable entity in blood that can be used to treat systemic disease.

Certain cancers, including pancreatic, lung, breast, colon and prostate cancers, have been shown to accumulate high levels of HA. Aberrant accumulation of this component of the tumor s infrastructure supports a protective network that surrounds certain tumors. This pathologic accumulation of HA along with other matrix components creates a unique microenvironment for the growth of tumor cells compared to normal cells. We believe that depleting the HA component of the tumor architecture with PEGPH20 disrupts the tumor microenvironment and opens the previously constricted vessels to allow anti-cancer therapies to have greater access to the tumor, which may enhance the chemotherapy s treatment effect. Increased blood flow may also enhance radiotherapy treatment effect. We have generated data showing that disrupting the specialized environment around tumors will directly inhibit the growth. Because HA accumulates in about 25% of all solid tumors, we believe that PEGPH20 has the potential to help patients with many different kinds of cancer.

We are currently conducting a Phase 1 clinical trial with PEGPH20 in the treatment of solid tumors. This trial incorporates the use of oral dexamethasone as prophylactic treatment for all patients prior to receiving intravenous administration of PEGPH20 and subsequent post-dose oral dexamethasone. We are also conducting a Phase 2 clinical trial, with a Phase 1b run-in period, for patients with metastatic pancreatic cancer. In the on-going Phase 1b portion, the patients will receive PEGPH20 in combination with gemcitabine. The objective of the phase 1b is to identity the recommended phase 2 dose of PEGPH20 in combination with gemcitabine. The phase 2 will be a randomized, double-blind, placebo-controlled study to assess safety, tolerability, and efficacy of PEGPH20 in combination with gemcitabine versus gemcitabine alone.

HTI-501

HTI-501, a recombinant human proteinase known as cathepsin L, is a lysosomal proteinase that acts by degrading collagen and is our first conditionally-active biologic. Collagen is an abundant protein in the body, particularly in connective tissue, and is present in high amounts in the extracellular matrix in the form of collagen fibers. Collagens are a class of helical proteins that are assembled into macromolecular fibrils and fibers. The collagen fiber network provides a structural scaffolding framework in the extracellular matrix. In the skin, these collagen fibers connect the superficial epithelial tissues to the underlying connective tissues. Collagen abnormalities contribute to a number of conditions, including frozen shoulder, Dupuytren s contracture, Peyronie s disease and cellulite.

A conditionally active biologic is a molecule that is only active under certain physiological conditions. HTI-501 is active under mildly acidic conditions and inactive at the pH normally found in the tissue. The enzyme

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is combined with a low pH buffer and injected in its active state. The enzyme is only active locally and for a short period of time. Once the mildly acidic conditions of the HTI-501 administration have been neutralized by the body, the enzyme becomes inactive. We intend to harness this conditional activity to exert control over the duration and location of the enzyme s therapeutic activity, potentially improving the efficacy or safety of this product candidate for both medical and aesthetic conditions.

We are exploring HTI-501 as an approach to the treatment of edematous fibrosclerotic panniculopathy, also known as cellulite. The condition affects 80 to 90 percent of post-adolescent women and is prevalent in all races. The collagen fibers, or fibrous septa, anchor the epidermis against the swelling of subcutaneous fat, which creates the dimpled appearance associated with the condition. We believe that HTI-501 acts by releasing the tension in the collagenous fibrous septa and smooth the dimpled appearance of the skin. HTI-501 has the potential to be studied as a treatment for other conditions involving collagen, such as frozen shoulder, Dupuytren s contracture, Peyronie s disease, keloids and hypertrophic scarring.

In September 2011, we initiated a Phase 1/2 clinical trial of HTI-501 in women with moderate to severe cellulite. The Phase 1 dose escalation portion of the trial evaluates a single injection of different HTI-501 formulations into dimpled lesions of the skin followed by a Phase 2 portion of the trial where multiple lesions will be targeted with the optimal dose and formulation. Up to 48 and 76 subjects may be enrolled in the Phase 1 and Phase 2 portions of the trial, respectively. We presented interim results from the Phase 1 proof-of-concept and local tolerability study of HTI-501 at the 8th World Congress of the International Academy of Cosmetic Dermatology in Cancun, Mexico, which was held from January 31- February 3, 2012. In the ongoing Phase 1 portion of the clinical trial, no serious or severe adverse events have been reported and the injection has been well tolerated. The most common adverse event has been mild to moderate pain at the injection site that was generally bilateral (present at both investigational drug and buffer control injection sites), lasted a few minutes and did not require treatment. Data from this study support commencement of the future Phase 2 portion of the clinical trial.

Enhanze Technology

Enhanze technology is a proprietary delivery platform using rHuPH20. This enzyme temporarily degrades HA. We believe this temporary degradation creates an opportunistic window for the improved subcutaneous delivery of injectable biologics, such as monoclonal antibodies and other large therapeutic molecules, as well as small molecules and fluids. The HA reconstitutes its normal density within several days and, therefore, we anticipate that any effect of the rHuPH20 on the architecture of the subcutaneous space is temporary. By using our rHuPH20 enzyme, many therapeutics that could normally only be injected intravenously can now be administered subcutaneously. This change in the route of delivery to subcutaneous from intravenous, or IV, can often improve patient convenience, enhance pharmacokinetics, boost efficacy, extend the product lifecycle and reduce cost.

We currently have Enhanze technology partnerships with Roche, Baxter, ViroPharma and Intrexon. We are currently pursuing additional partnerships with biopharmaceutical companies that market drugs requiring or benefiting from injection via the subcutaneous route of administration.

Roche Partnership

In December 2006, we and Roche entered into an agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds, or the Roche Partnership. Roche initially had the exclusive right to apply rHuPH20 to only three pre-defined Roche biologic targets with the option to exclusively develop and commercialize rHuPH20 with ten additional targets. As of December 31, 2011, Roche has elected a total of five exclusive targets and retains the option to develop and commercialize rHuPH20 with three additional targets through the payment of annual license maintenance fees. Pending the successful completion of various clinical, regulatory and sales

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events, Roche will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership.

Clinical trials have commenced for compounds directed at three of the five Roche exclusive targets under the Roche Partnership. One compound formulated with rHuPH20 (subcutaneous Herceptin®) has completed a Phase 3 clinical trial, one compound formulated with rHuPH20 (subcutaneous MabThera®) is in a Phase 3 clinical trial and one compound formulated with rHuPH20 (subcutaneous Actemra®) has completed a Phase 1 clinical trial.

In October 2011, Roche announced positive top line results from the Phase 3 clinical trial in women with early HER2-positive breast cancer who received a fixed dose of a new subcutaneously delivered version of Roche s anticancer biologic, Herceptin (trastuzumab), or Herceptin SC. In the study, the subcutaneous formulation showed comparable results to Herceptin given as an IV infusion, or Herceptin IV. Herceptin SC takes about 5 minutes to administer whereas Herceptin IV takes about 30 minutes to infuse. Roche is also developing an auto-injector device that should further simplify the process and could enable patients to be dosed at home or in the doctor s office rather than at an infusion clinic or hospital. The ready to use formulation may also significantly reduce pharmacy time as no medicine preparation time is required. This Phase 3 clinical trial was an open-label trial involving 596 women with HER2-positive early breast cancer. The trial was designed to compare trastuzumab concentration in the blood (pharmacokinetics), efficacy (pathologic complete response) and safety of Herceptin SC to that of Herceptin IV. The trial met its co-primary endpoints that were trastuzumab concentration in the blood (serum concentrations) and efficacy. No new safety signals were observed and adverse events were overall consistent with Herceptin IV. Herceptin is approved to treat HER2-positive breast cancer and currently is given intravenously. Breast cancer is the most common cancer among women worldwide. Each year, more than 1.4 million new cases of breast cancer are diagnosed worldwide, and nearly 450,000 people will die of the disease annually. In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumor cells. This is known as HER2 positivity and affects approximately 15-20% of people with breast cancer. Roche recently announced that data from this trial will be presented at the European Breast Cancer Conference in Vienna, which will be held from March 21 to 24, 2012. In early March 2012, we announced that Roche has submitted a Line Extension Application to the European Medicines Agency for Herceptin SC.

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab) or MabThera SC. The study investigates pharmacokinetics, efficacy and safety of MabThera SC. IV administered MabThera is approved for the treatment of non-Hodgkin s lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), types of cancer that affects lymphocytes, or white blood cells. An estimated 66,000 new cases of NHL were diagnosed in the U.S. in 2009 with approximately 125,000 new cases reported worldwide. Roche has stated that they will present data from the program in 2012 and plans to file a marketing application to regulatory authorities in the European Union in 2012.

In 2009, Roche completed a Phase 1 clinical trial for a subcutaneous formulation of Actemra. This trial investigated the safety and pharmacokinetics of subcutaneous Actemra in patients with rheumatoid arthritis. The results from this Phase 1 trial suggest that further exploration may be warranted. Actemra administered intravenously is approved for the treatment of rheumatoid arthritis. Roche is separately developing a subcutaneous form of Actemra that does not use rHuPH20 and is being investigated for weekly or biweekly administration.

Additional information about the Phase 3 subcutaneous Herceptin and Phase 3 subcutaneous MabThera clinical trials can be found at www.clinicaltrials.gov and www.roche-trials.com. Information available on these websites is not incorporated into this report.

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Baxter Gammagard Partnership

GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, we and Baxter entered into an agreement under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID, or HyQ, or the Gammagard Partnership. Pending the successful completion of various regulatory and sales milestones, Baxter will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter is responsible for all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we will be responsible for the supply of the rHuPH20 enzyme. We perform research and development activities at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Partnership. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard License. Baxter filed for regulatory approval of HyQ in the US in the second quarter of 2011. In September 2011, Baxter announced that it had submitted an application to the European Medicines Agency s Committee for Human Medicinal products seeking marketing approval for HyQ.

ViroPharma Partnership

Effective May 10, 2011, we and ViroPharma entered into a collaboration and license agreement under which ViroPharma obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of ViroPharma s commercialized product, Cinryze® (C1 esterase inhibitor [human]), or the ViroPharma Partnership. In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibitor and to the hereditary angioedema indication, along with three additional orphan indications. ViroPharma is solely responsible for the development, manufacturing, regulatory approval and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of bulk formulation of rHuPH20 (active pharmaceutical ingredients, or API), if requested by ViroPharma. We are also entitled to receive milestone payments and royalties on product sales by ViroPharma. ViroPharma may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to ViroPharma (in total or with respect to the terminated product, as applicable) will terminate.

In September 2011, ViroPharma announced that they had initiated an open-label, multiple-dose Phase 2 clinical trial designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20 in 12 subjects with hereditary angioedema. Hereditary angioedema is a rare, debilitating and potentially fatal genetic disease. On December 6, 2011, we and ViroPharma announced positive top line data from this Phase 2 study of subcutaneous delivery of Cinryze in combination with rHuPH20, which are informative for the trial design of the upcoming Phase 2 dose ranging combination study. The preliminary data suggest that rHuPH20 enhances the delivery and absorption of Cinryze and increases systemic exposure to C1 esterase inhibitor relative to subcutaneous Cinryze administered alone. We believe this product candidate could improve flexibility and convenience, and potentially allow prevention-minded patients living with hereditary angioedema to self administer every three or four days, just as they do today with the current IV formulation, but with a single subcutaneous injection.

Intrexon Partnership

Effective June 6, 2011, we and Intrexon entered into a collaboration and license agreement under which Intrexon obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of Intrexon s recombinant human alpha 1-antitrypsin (rHuA1AT), or the Intrexon Partnership. In addition, the license provides Intrexon with exclusivity for a defined indication, or Exclusive Field. Intrexon is solely responsible for the development, manufacturing, regulatory approval and marketing of any products resulting from this partnership. We are entitled to receive payments for research and

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development services and supply of rHuPH20 API if requested by Intrexon. We are also entitled to receive milestone payments and royalties on product sales. Intrexon may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to Intrexon (in total or with respect to the terminated product, as applicable) will terminate. Intrexon s chief executive officer and chairman of its board of directors is also a member of our board of directors.

For the years ended December 31, 2011, 2010 and 2009, 19%, 52% and 76% of total revenues, respectively, were from Roche and 42%, 42% and 20% of total revenues, respectively, were from Baxter. In addition, for the year ended December 31, 2011, 22% and 16% of total revenues were from Viropharma and Intrexon, respectively. For information regarding our revenues from external customers, please see Note 2, *Summary of Significant Accounting Policies Concentrations of Credit Risk, Sources of Supply and Significant Customers*, in our consolidated financial statements included elsewhere in this report.

Hylenex Recombinant

Hylenex recombinant is a formulation of rHuPH20 that has received FDA approval to facilitate subcutaneous fluid administration for achieving hydration; to increase the dispersion and absorption of other injected drugs; and in subcutaneous urography for improving resorption of radiopaque agents.

In February 2007, we and Baxter amended certain existing agreements relating to *Hylenex* recombinant and entered into the Hylenex Partnership for kits and formulations with rHuPH20. In October 2009, Baxter commenced the commercial launch of *Hylenex* recombinant. *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the *Hylenex* recombinant manufactured by Baxter was not in compliance with regulatory requirements. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant and we reintroduced *Hylenex* recombinant to the market in December 2011.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements. In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, under which Baxter fills and finishes *Hylenex* recombinant for us. On July 18, 2011, we and Baxter entered into a Transition Agreement setting forth certain rights, data and assets to be transferred by Baxter to us during a transition period. The termination of these agreements does not affect the other relationships between the parties, including the application of our Enhanze technology to Baxter s GAMMAGARD LIQUID.

Patents and Proprietary Rights

Patents and other proprietary rights are essential to our business. Our success will depend in part on our ability to obtain patent protection for our inventions, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. Our strategy is to actively pursue patent protection in the United States and certain foreign jurisdictions for technology that we believe to be proprietary to us and that offers us a potential competitive advantage. Our patent portfolio includes thirteen issued patents, including one granted European patent, and a number of pending patent applications. We are the exclusive licensee of the University of Connecticut under a patent covering the DNA sequence that encodes human hyaluronidase. This patent expires in 2015. We have a patent issued by the U.S. Patent and Trademark Office pertaining to recombinant human hyaluronidase which expires in 2027. A European patent, EP1603541, claiming rHuPH20 was granted to us on November 11, 2009 with claims to the human PH20 glycoprotein, PEGylated variants, a method of producing the glycoprotein produced by recombinant methods, and pharmaceutical compositions with other agents, including antibodies, insulins, cytokines, a chemotherapeutic agent and additional therapeutic classes. A third party opposed this patent in the European Patent Office in 2010, but withdrew the opposition in March 2012. We are currently attempting to resolve the opposition with the European Patent Office, and although we expect to obtain

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European patent protection that would be no less broad than claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429), there can be no assurance that we will be able to do so. In addition, we have under prosecution throughout the world, multiple patent applications that relate to the recombinant human hyaluronidase and methods of using and manufacturing recombinant human hyaluronidase (expiration of which applications can only be definitely determined upon maturation to our issued patents). We believe our patent filings represent a barrier to entry for potential competitors looking to utilize these hyaluronidases.

In addition to patents, we rely on unpatented trade secrets, proprietary know-how and continuing technological innovation. We seek protection of these trade secrets, proprietary know-how and innovation, in part, through confidentiality and proprietary information agreements. Our policy is to require our employees, directors, consultants, advisors, partners, outside scientific collaborators and sponsored researchers, other advisors and other individuals and entities to execute confidentiality agreements upon the start of employment, consulting or other contractual relationships with us. These agreements provide that all confidential information developed or made known to the individual or entity during the course of the relationship is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees and some other parties, the agreements provide that all inventions conceived by the individual will be our exclusive property. Despite the use of these agreements and our efforts to protect our intellectual property, there will always be a risk of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

We also file trademark applications to protect the names of our products and product candidates. These applications may not mature to registration and may be challenged by third parties. We are pursuing trademark protection in a number of different countries around the world. There can be no assurances that registered or unregistered trademarks or trade names of our company will not infringe on third parties rights or will be acceptable to regulatory agencies.

Research and Development Activities

Our research and development expenses consist primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, clinical trials, facility costs and amortization and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our various product candidates.

Since our inception in 1998 through December 31, 2011, we have incurred research and development expenses of $259.1 million. From January 1, 2009 through December 31, 2011, approximately 30% and 16% of our research and development expenses were associated with the development of our ultrafast insulin and PEGPH20 product candidates, respectively. Due to the uncertainty in obtaining the FDA and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

Manufacturing

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce supplies of bulk rHuPH20 API. These manufacturers each produce API under current Good Manufacturing Practices, or cGMP, for clinical uses. In addition, Avid currently produces API for *Hylenex* recombinant. Avid and Cook will also provide support for the chemistry, manufacturing and controls sections for FDA and other regulatory filings. We rely on their ability to successfully manufacture these batches according to product specifications, though Cook has limited experience

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manufacturing our API. In addition, as a result of our contractual obligations to Roche, we have been required to significantly scale up our commercial API production at Cook during the last two years. The ability of Cook to obtain status as a cGMP-approved manufacturing facility and the ability of both manufacturers to (i) retain their status as cGMP-approved manufacturing facilities; (ii) to successfully scale up our API production; or (iii) manufacture the API required by our proprietary and partnered products and product candidates is essential to our corporate strategy.

In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, a cGMP-approved manufacturing facility. Under the terms of the manufacturing agreement with Baxter, Baxter provides the final fill and finish steps in the production process of *Hylenex* recombinant. The initial term of the agreement with Baxter extends until December 2012 and is renewable for one additional year upon mutual agreement. In June 2011, we entered into a services agreement with another third party manufacturer for the technology transfer and fill and finish of *Hylenex* recombinant in order to increase capacity and allow more favorable pricing.

Sales, Marketing and Distribution

HYLENEX Recombinant

We reintroduced *Hylenex* recombinant to the market in December 2011 after resolution of the voluntary recall and the return by Baxter of marketing rights to us. Upon its return to the market, we intend to take advantage of the initial marketing inroads achieved by Baxter. We are continuing to assess our commercial and strategic options for the product to address additional uses.

We sell *Hylenex* recombinant in the United States to wholesale distributors, who in turn sell to hospitals, ambulatory surgery centers and other end-users. Decisions made by the customers of the wholesale distributors regarding the levels of inventory they hold, and thus the amount of Hylenex they purchase, may affect the level of product sales in any particular period.

We have engaged Integrated Commercial Solutions, or ICS, a division of AmerisourceBergen Specialty Group, a subsidiary of AmerisourceBergen, to act as our exclusive distributor for commercial shipment and distribution of *Hylenex* recombinant to our customers in the United States. In addition to distribution services, ICS provides us with other key services related to logistics, warehousing, returns and inventory management, contract administration and chargeback processing and accounts receivable management. In addition, we utilize third parties to perform various other services for us relating to regulatory monitoring, including call center management, adverse event reporting, safety database management and other product maintenance services.

Competition

HYLENEX Recombinant

Other manufacturers have FDA-approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc., with an ovine (ram) hyaluronidase, Vitrase®. In addition, some commercial pharmacies compound hyaluronidase preparations for institutions and physicians even though compounded preparations are not FDA-approved products.

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Government Regulations

The FDA and comparable regulatory agencies in foreign countries regulate extensively the manufacture and sale of the pharmaceutical products that we have developed or currently are developing. The FDA has established guidelines and safety standards that are applicable to the laboratory and preclinical evaluation and clinical investigation of therapeutic products and stringent regulations that govern the manufacture and sale of these products. The process of obtaining regulatory approval for a new therapeutic product usually requires a significant amount of time and substantial resources. The steps typically required before a product can be produced and marketed for human use include:

- animal pharmacology studies to obtain preliminary information on the safety and efficacy of a drug; or
- laboratory and preclinical evaluation *in vitro* and *in vivo* including extensive toxicology studies.

The results of these laboratory and preclinical studies may be submitted to the FDA as part of an investigational new drug, or IND, application. The sponsor of an IND application may commence human testing of the compound 30 days after submission of the IND, unless notified to the contrary by the FDA.

The clinical testing program for a new drug typically involves three phases:

- Phase 1 investigations are generally conducted in healthy subjects (in certain instances, Phase 1 studies that determine the maximum tolerated dose and initial safety of the product candidate are performed in patients with the disease);
- Phase 2 studies are conducted in limited numbers of subjects with the disease or condition to be treated and are aimed at determining the most effective dose and schedule of administration, evaluating both safety and whether the product demonstrates therapeutic effectiveness against the disease; and
- Phase 3 studies involve large, well-controlled investigations in diseased subjects and are aimed at verifying the safety and effectiveness of the drug.

Data from all clinical studies, as well as all laboratory and preclinical studies and evidence of product quality, are typically submitted to the FDA in a new drug application, or NDA. The results of the preclinical and clinical testing of a biologic product candidate are submitted to the FDA in the form of a biologic license application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA or NDA, the FDA may grant marketing approval, request additional information, or deny the application. Although the FDA s requirements for clinical trials are well established and we believe that we have planned and conducted our clinical trials in accordance with the FDA s applicable regulations and guidelines, these requirements, including requirements relating to testing the safety of drug candidates, may be subject to change as a result of recent announcements regarding safety problems with approved drugs. Additionally, we could be required to conduct additional trials beyond what we had planned due to the FDA s safety and/or efficacy concerns or due to differing interpretations of the meaning of our clinical data. (See Part I, Item 1A, Risk Factors.)

The FDA s Center for Drug Evaluation and Research must approve an NDA and the FDA s Center for Biologics Evaluation and Research must approve a BLA for a drug before it may be marketed in the United States. If we begin to market our proposed products for commercial sale in the U.S., any manufacturing operations that may be established in or outside the United States will also be subject to rigorous regulation, including compliance with cGMP. We also may be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substance Control Act, the Export Control Act and other present and future laws of general application. In addition, the handling, care and use of laboratory animals are subject to the Guidelines for the Humane Use and Care of Laboratory Animals published by the National Institutes of Health.

Regulatory obligations continue post-approval, and include the reporting of adverse events when a drug is utilized in the broader patient population. Promotion and marketing of drugs is also strictly regulated, with

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penalties imposed for violations of FDA regulations, the Lanham Act and other federal and state laws, including the federal anti-kickback statute.

We currently intend to continue to seek, directly or through our partners, approval to market our products and product candidates in foreign countries, which may have regulatory processes that differ materially from those of the FDA. We anticipate that we will rely upon pharmaceutical or biotechnology companies to license our proposed products or independent consultants to seek approvals to market our proposed products in foreign countries. We cannot assure you that approvals to market any of our proposed products can be obtained in any country. Approval to market a product in any one foreign country does not necessarily indicate that approval can be obtained in other countries.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of drug products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency or reviewing courts in ways that may significantly affect our business and development of our product candidates and any products that we may commercialize. It is impossible to predict whether additional legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of any such changes may be.

Segment Information

We operate our business as one segment, which includes all activities related to the research, development and commercialization of human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and (ii) product sales of *Hylenex* recombinant. The chief operating decision-makers review the operating results on an aggregate basis and manage the operations as a single operating segment. We had no foreign based operations and no long-lived assets located in foreign countries for the years ended December 31, 2011, 2010 and 2009.

Executive Officers of the Registrant

Information concerning our executive officers, including their names, ages and certain biographical information can be found in Part III, Item 10. Directors, Executive Officers and Corporate Governance. This information is incorporated by reference into Part I of this report.

Employees

As of March 1, 2012, we had 135 full-time employees, including 95 engaged in research and clinical development activities. Included in our total headcount are 41 employees who hold Ph.D. or M.D. degrees. None of our employees are unionized and we believe our relationship with our employees is good.

Item 1A. ***Risk Factors***

Risks Related To Our Business

We have generated only minimal revenue from product sales to date; we have a history of net losses and negative cash flow, and we may never achieve or maintain profitability.

Relative to expenses incurred in our operations, we have generated only minimal revenues from product sales, licensing fees, milestone payments and research reimbursements to date and we may never generate sufficient revenues from future product sales, licensing fees and milestone payments to offset expenses. Even if we ultimately do achieve significant revenues from product sales, licensing fees, research reimbursements and/or milestone payments, we expect to incur significant operating losses over the next few years. We have never been profitable, and we may never become profitable. Through December 31, 2011, we have incurred aggregate net losses of approximately $245.0 million.

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If our proprietary and partnered product candidates do not receive and maintain regulatory approvals, or if approvals are not obtained in a timely manner, such failure or delay would substantially impair our ability to generate revenues.

Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States and the other countries in which we anticipate doing business have similar requirements. The process for obtaining FDA and other regulatory approvals is extensive, time-consuming and costly, and there is no guarantee that the FDA or other regulatory bodies will approve any applications that may be filed with respect to any of our proprietary or partnered product candidates, or that the timing of any such approval will be appropriate for the desired product launch schedule for a product candidate. We, and our partners, attempt to provide guidance as to the timing for the filing and acceptance of such regulatory approvals, but such filings and approvals may not occur on the originally anticipated timeline, or at all. Only one of our partnered product candidates is currently in the regulatory approval process and there are no proprietary product candidates currently in the regulatory approval process. We and our partners may not be successful in obtaining such approvals for any potential products in a timely manner, or at all. See *Our proprietary and partnered product candidates may not receive regulatory approvals for a variety of reasons, including unsuccessful clinical trials* for additional information relating the approval of product candidates.

Additionally, in order to continue to manufacture and market pharmaceutical products, we must maintain our regulatory approvals. If we or any of our partners are unsuccessful in maintaining our regulatory approvals, our ability to generate revenues would be adversely affected.

If our contract manufacturers are unable to manufacture significant amounts of the API used in our products and product candidates, our product development and commercialization efforts could be delayed or stopped and our collaborative partnerships could be damaged.

We have existing supply agreements with contract manufacturing organizations Avid and Cook to produce bulk API. These manufacturers each produce API under cGMP for clinical uses. In addition, Avid currently produces API for *Hylenex* recombinant. Avid and Cook will also provide support for the chemistry, manufacturing and controls sections for FDA and other regulatory filings. We rely on their ability to successfully manufacture these batches according to product specifications and Cook has relatively limited experience manufacturing our API. In addition, as a result of our contractual obligations to Roche, we have been required to significantly scale up our commercial API production at Cook during the last two years. If Cook is unable to obtain status as a cGMP-approved manufacturing facility, or if either Avid or Cook: (i) are unable to retain status as cGMP-approved manufacturing facilities; (ii) are unable to otherwise successfully scale up our API production; or (iii) fail to manufacture the API required by our proprietary and partnered products and product candidates for any other reason, our business will be adversely affected. We have not established, and may not be able to establish, favorable arrangements with additional API manufacturers and suppliers of the ingredients necessary to manufacture the API should the existing manufacturers and suppliers become unavailable or in the event that our existing manufacturers and suppliers are unable to adequately perform their responsibilities. We have attempted to mitigate the impact of supply interruption through the establishment of excess API inventory, but there can be no assurances that this safety stock will be maintained or that it will be sufficient to address any delays, interruptions or other problems experienced by Avid and/or Cook. Any delays, interruptions or other problems regarding the ability of Avid and/or Cook to supply API on a timely basis could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of proprietary or partnered product candidates; (ii) delay or prevent the effective commercialization of proprietary or partnered products and/or (iii) cause us to breach contractual obligations to deliver API to our partners. Such delays would likely damage our relationship with our partners under our key collaboration agreements and they would have a material adverse effect on our business and financial condition.

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If any party to a key collaboration agreement, including us, fails to perform material obligations under such agreement, or if a key collaboration agreement, or any other collaboration agreement, is terminated for any reason, our business could significantly suffer.

We have entered into multiple collaboration agreements under which we may receive significant future payments in the form of maintenance fees, milestone payments and royalties. In the event that a party fails to perform under a key collaboration agreement, or if a key collaboration agreement is terminated, the reduction in anticipated revenues could delay or suspend our product development activities for some of our product candidates, as well as our commercialization efforts for some or all of our products. In addition, the termination of a key collaboration agreement by one of our partners could materially impact our ability to enter into additional collaboration agreements with new partners on favorable terms, if at all. In certain circumstances, the termination of a key collaboration agreement would require us to revise our corporate strategy going forward and reevaluate the applications and value of our technology.

Most of our current proprietary and partnered products and product candidates rely on the rHuPH20 enzyme.

rHuPH20 is a key technological component of Enhanze technology, our ultrafast insulin program, our PEGPH20 program, *Hylenex* recombinant and other proprietary and partnered products and product candidates. An adverse development for rHuPH20 (e.g., an adverse regulatory determination relating to rHuPH20, we are unable to obtain sufficient quantities of rHuPH20, we are unable to obtain or maintain material proprietary rights to rHuPH20 or we discover negative characteristics of rHuPH20) would substantially impact multiple areas of our business, including current and potential partnerships, as well as proprietary programs.

Our proprietary and partnered product candidates may not receive regulatory approvals for a variety of reasons, including unsuccessful clinical trials.

Clinical testing of pharmaceutical products is a long, expensive and uncertain process and the failure or delay of a clinical trial can occur at any stage. Even if initial results of preclinical studies or clinical trial results are promising, we or our partners may obtain different results that fail to show the desired levels of safety and efficacy, or we may not, or our partners may not, obtain applicable regulatory approval for a variety of other reasons. Clinical trials for any of our proprietary or partnered product candidates could be unsuccessful, which would delay or prohibit regulatory approval and commercialization of the product candidates. In the United States and other jurisdictions, regulatory approval can be delayed, limited or not granted for many reasons, including, among others:

- clinical results may not meet prescribed endpoints for the studies or otherwise provide sufficient data to support the efficacy of our product candidates;
- clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates;
- regulatory review may not find a product candidate safe or effective enough to merit either continued testing or final approval;
- regulatory review may not find that the data from preclinical testing and clinical trials justifies approval, or they may require additional studies that would significantly delay or make continued pursuit of approval commercially unattractive;
- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;
- the cost of a clinical trial may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a trial;

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a regulatory agency may not approve our manufacturing processes or facilities, or the processes or facilities of our partners, our contract manufacturers or our raw material suppliers;

a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities, or the existing processes or facilities of our partners, our contract manufacturers or our raw material suppliers;

a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations or raise new issues or concerns late in the approval process; or

a product candidate may be approved only for indications that are narrow or under conditions that place the product at a competitive disadvantage, which may limit the sales and marketing activities for such product candidate or otherwise adversely impact the commercial potential of a product.

If a proprietary or partnered product candidate is not approved in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse impact on our business and we will become more dependent on the development of other proprietary or partnered product candidates and/or our ability to successfully acquire other products and technologies. There can be no assurances that any proprietary or partnered product candidate will receive regulatory approval in a timely manner, or at all.

We anticipate that certain proprietary and partnered products will be marketed, and perhaps manufactured, in foreign countries. The process of obtaining regulatory approvals in foreign countries is subject to delay and failure for the reasons set forth above, as well as for reasons that vary from jurisdiction to jurisdiction. The approval process varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory agencies may not provide approvals 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 foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

Our key partners are responsible for providing certain proprietary materials that are essential components of our partnered product candidates, and any failure to supply these materials could delay the development and commercialization efforts for these partnered product candidates and/or damage our collaborative partnerships.

Our partners are responsible for providing certain proprietary materials that are essential components of our partnered product candidates. For example, Roche is responsible for producing the Herceptin and MabThera required for its subcutaneous product candidates and Baxter is responsible for producing the GAMMAGARD LIQUID for its product candidate. If a partner, or any applicable third party service provider of a partner, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of either components of the partnered product candidate or the partnered product candidate itself, such difficulties could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of partnered product candidates; and/or (ii) delay or prevent the effective commercialization of partnered products. Such delays could have a material adverse effect on our business and financial condition. For example, Baxter received a Warning Letter from the FDA in January 2010 regarding Baxter s GAMMAGARD LIQUID manufacturing facility in Lessines, Belgium. The FDA indicated in March 2010 that the issues raised in the Warning Letter had been addressed by Baxter and we do not expect these issues to impact the development of the GAMMAGARD LIQUID product candidate.

If we have problems with third parties that either distribute API on our behalf or prepare, fill, finish and package our products and product candidates for distribution, our commercialization and development efforts for our products and product candidates could be delayed or stopped.

We rely on third parties to store and ship API on our behalf and to also prepare, fill, finish and package our products and product candidates prior to their distribution. If we are unable to locate third parties to perform

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these functions on terms that are acceptable to us, or if the third parties we identify fail to perform their obligations, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. For example, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the *Hylenex* recombinant manufactured by Baxter was not in compliance with the requirements of the underlying *Hylenex* recombinant agreements. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant and we reintroduced *Hylenex* recombinant to the market in December 2011. In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, under which Baxter will fill, finish and package *Hylenex* recombinant product for us. Under our commercial manufacturing and supply agreement with Baxter, Baxter has agreed to fill and finish *Hylenex* recombinant product for us for a limited period of time. The initial term of the commercial manufacturing and supply agreement with Baxter expires on December 31, 2012 and is renewable for one additional year upon mutual agreement. In June 2011, we entered into a services agreement with a third party manufacturer for the technology transfer and manufacture of *Hylenex* recombinant. While we expect to enter into a commercial manufacturing and supply agreement with a new manufacturer of *Hylenex* recombinant, if we are unable to find a suitable manufacturer of *Hylenex* recombinant prior to the expiration of the commercial manufacturing and supply agreement with Baxter or if a new manufacturer encounters difficulties in the manufacture, fill, finish or packaging of *Hylenex* recombinant, our business and financial condition could be adversely effected.

We may wish to raise additional capital in the next twelve months and there can be no assurance that we will be able to obtain such funds.

During the next twelve months, we may wish to raise additional capital to continue the development of our product candidates or for other current corporate purposes. Our current cash position and expected revenues during the next few years may not constitute the amount of capital necessary for us to continue the development of our proprietary product candidates and to fund general operations. In addition, if we engage in acquisitions of companies, products or technology in order to execute our business strategy, we may need to raise additional capital. We will need to raise additional capital in the future through one or more financing vehicles that may be available to us. Potential financing vehicles include: (i) the public or private issuance of securities; (ii) new collaborative agreements; and/or (iii) expansions or revisions to existing collaborative relationships.

Considering our stage of development, the nature of our capital structure and general market conditions, if we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If additional capital is not available on favorable terms when needed, we will be required to significantly reduce operating expenses through the restructuring of our operations. If we are successful in raising additional capital, a substantial number of additional shares may be issued and these shares will dilute the ownership interest of our current investors.

If we are unable to sufficiently develop our sales, marketing and distribution capabilities or enter into successful agreements with third parties to perform these functions, we will not be able to fully commercialize our products.

We may not be successful in marketing and promoting our existing product, *Hylenex* recombinant, product candidates or any other products we develop or acquire in the future. Our sales, marketing and distribution capabilities are very limited. In order to commercialize any products successfully, we must internally develop substantial sales, marketing and distribution capabilities or establish collaborations or other arrangements with third parties to perform these services. We do not have extensive experience in these areas, and we may not be able to establish adequate in-house sales, marketing and distribution capabilities or engage and effectively manage relationships with third parties to perform any or all of such services. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, whose

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efforts may not meet our expectations or be successful. These third parties would be largely responsible for the speed and scope of sales and marketing efforts, and may not dedicate the resources necessary to maximize product opportunities. Our ability to cause these third parties to increase the speed and scope of their efforts may also be limited. In addition, sales and marketing efforts could be negatively impacted by the delay or failure to obtain additional supportive clinical trial data for our products. In some cases, third party partners are responsible for conducting these additional clinical trials and our ability to increase the efforts and resources allocated to these trials may be limited. For example, in January 2011 we and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements.

If we or our partners fail to comply with regulatory requirements, regulatory agencies may take action against us or them, which could significantly harm our business.

Any approved products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We, and our partners, will be subject to ongoing regulatory requirements, including required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements. The cGMP regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of our products. We and our partners are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We or our partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

Regulatory requirements applicable to pharmaceutical products make the substitution of suppliers and manufacturers costly and time consuming. We have minimal internal manufacturing capabilities and are, and expect to be in the future, entirely dependent on contract manufacturers and suppliers for the manufacture of our products and for their active and other ingredients. The disqualification of these manufacturers and suppliers through their failure to comply with regulatory requirements could negatively impact our business because the delays and costs in obtaining and qualifying alternate suppliers (if such alternative suppliers are available, which we cannot assure) could delay clinical trials or otherwise inhibit our ability to bring approved products to market, which would have a material adverse effect on our business and financial condition.

Later discovery of previously unknown problems with our proprietary or partnered products, manufacturing processes or failure to comply with regulatory requirements, may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;

refusal to permit the import or export of our products;

refusal to approve pending applications or supplements to approved applications that we submit;

product seizure; or

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injunctions or the imposition of civil or criminal penalties.

If proprietary or partnered product candidates are approved by regulatory bodies such as the FDA but do not gain market acceptance, our business may suffer and we may not be able to fund future operations.

Assuming that our proprietary or partnered product candidates obtain the necessary regulatory approvals, a number of factors may affect the market acceptance of these existing product candidates or any other products which are developed or acquired in the future, including, among others:

the price of products relative to other therapies for the same or similar treatments;

the perception by patients, physicians and other members of the health care community of the effectiveness and safety of these products for their prescribed treatments;

our ability to fund our sales and marketing efforts and the ability and willingness of our partners to fund sales and marketing efforts;

the degree to which the use of these products is restricted by the approved product label;

the effectiveness of our sales and marketing efforts and the effectiveness of the sales and marketing efforts of our partners;

the introduction of generic competitors; and

the extent to which reimbursement for our products and related treatments will be available from third party payors.

If these products do not gain market acceptance, we may not be able to fund future operations, including the development or acquisition of new product candidates and/or our sales and marketing efforts for our approved products, which would cause our business to suffer.

In addition, our proprietary and partnered product candidates will be restricted to the labels approved by applicable regulatory bodies such as the FDA, and these restrictions may limit the marketing and promotion of the ultimate products. If the approved labels are restrictive, the sales and marketing efforts for these products may be negatively affected.

Developing and marketing pharmaceutical products for human use involves product liability risks, for which we currently have limited insurance coverage.

The testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product liability claims were to be made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could materially and adversely affect our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us. In addition, since many of our partnered product candidates include the pharmaceutical products of a third party, we run the risk that problems with the third party pharmaceutical product will give rise to liability claims against us.

Our inability to attract, hire and retain key management and scientific personnel could negatively affect our business.

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our relatively small staff size relative to the number of programs currently under development,

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we depend substantially on our ability to hire, train, motivate and retain high quality personnel, especially our scientists and management team. If we are unable to retain existing personnel or identify or hire additional personnel, we may not be able to research, develop, commercialize or market our products and product candidates as expected or on a timely basis and we may not be able to adequately support current and future alliances with strategic partners.

Furthermore, if we were to lose key management personnel, such as Gregory Frost, Ph.D., our President and Chief Executive Officer, we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained. For example, Dr. Frost has been with us from soon after our inception, and he possesses a substantial amount of knowledge about our development efforts. If we were to lose his services, we would experience delays in meeting our product development schedules. In 2008, we adopted a severance policy applicable to all employees and a change in control policy applicable to senior executives. We have not adopted any other policies or entered into any other agreements specifically designed to motivate officers or other employees to remain with us.

We do not have key man life insurance policies on the lives of any of our employees, including Dr. Frost.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our operations, including laboratories, offices and other research facilities, are located in a three building campus in San Diego, California. We depend on our facilities and on our partners, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, interruptions in the supply of natural resources, political and governmental changes, wildfires and other fires, floods, explosions, actions of animal rights activists, earthquakes and civil unrest could disrupt our operations or those of our partners, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs.

If we or our partners do not achieve projected development goals in the timeframes we publicly announce or otherwise expect, the commercialization of our products and the development of our product candidates may be delayed and, as a result, our stock price may decline.

We publicly articulate the estimated timing for the accomplishment of certain scientific, clinical, regulatory and other product development goals. The accomplishment of any goal is typically based on numerous assumptions and the achievement of a particular goal may be delayed for any number of reasons both within and outside of our control. If scientific, regulatory, strategic or other factors cause us to not meet a goal, regardless of whether that goal has been publicly articulated or not, the commercialization of our products and the development of our proprietary and partnered product candidates may be delayed. In addition, the consistent failure to meet publicly announced milestones may erode the credibility of our management team with respect to future milestone estimates.

Future acquisitions could disrupt our business and harm our financial condition.

In order to augment our product pipeline or otherwise strengthen our business, we may decide to acquire additional businesses, products and technologies. As we have limited experience in evaluating and completing acquisitions, our ability as an organization to make such acquisitions is unproven. Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following:

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we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

an acquisition may negatively impact our results of operations because it may require us to amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;

we may encounter difficulties in assimilating and integrating the business, products, technologies, personnel or operations of companies that we acquire;

certain acquisitions may impact our relationship with existing or potential partners who are competitive with the acquired business, products or technologies;

acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient value to justify acquisition costs;

an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;

acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and

key personnel of an acquired company may decide not to work for us.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results. We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market will not view such acquisitions positively.

Risks Related To Ownership of Our Common Stock

Our stock price is subject to significant volatility.

We participate in a highly dynamic industry which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low sales prices of our common stock during the twelve months ended December 31, 2011 were $9.82 and $5.54, respectively. We expect our stock price to continue to be subject to significant volatility and, in addition to the other risks and uncertainties described elsewhere in this annual report on Form 10-K and all other risks and uncertainties that are either not known to us at this time or which we deem to be immaterial, any of the following factors may lead to a significant drop in our stock price:

a dispute regarding our failure, or the failure of one of our third party partners, to comply with the terms of a collaboration agreement;

the termination, for any reason, of any of our collaboration agreements;

the sale of common stock by any significant stockholder, including, but not limited to, direct or indirect sales by members of management or our Board of Directors;

the resignation, or other departure, of members of management or our Board of Directors;

general negative conditions in the healthcare industry;

general negative conditions in the financial markets;

the failure, for any reason, to obtain regulatory approval for any of our proprietary or partnered product candidates;

the failure, for any reason, to secure or defend our intellectual property position;

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for those products that are waiting to be approved by the FDA, the failure of the FDA to approve such products in a timely manner consistent with the FDA s historical approval process;

the suspension of any clinical trial due to safety or patient tolerability issues;

the suspension of any clinical trial due to market and/or competitive conditions;

our failure, or the failure of our third party partners, to successfully commercialize products approved by applicable regulatory bodies such as the FDA;

our failure, or the failure of our third party partners, to generate product revenues anticipated by investors;

problems with an API contract manufacturer or a fill and finish manufacturer for any product or product candidate;

the sale of additional debt and/or equity securities by us;

our failure to obtain financing on acceptable terms; or

a restructuring of our operations.

Future sales of shares of our common stock may negatively affect our stock price.

We are currently a Well-Known Seasoned Issuer and may file automatic shelf registration statements at any time with the SEC. In addition, we currently have the ability to offer and sell additional equity, debt securities and warrants to purchase such securities, either individually or in units, under an effective automatic shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our shelf registration statements could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into our common stock.

Trading in our stock has historically been limited, so investors may not be able to sell as much stock as they want to at prevailing market prices.

Our stock has historically traded at a low daily trading volume. If low trading volume continues, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

Risks Related To Our Industry

Compliance with the extensive government regulations to which we are subject is expensive and time consuming and may result in the delay or cancellation of product sales, introductions or modifications.

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including ours, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, or DEA, and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storing, recordkeeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, we and our contract suppliers and manufacturers are subject to periodic inspection of our or their respective facilities, procedures and operations and/or the testing of products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we and our contract suppliers and manufacturers are in compliance with all applicable regulations. The FDA also conducts pre-approval and

post-approval reviews and plant inspections to determine whether our systems, or our contract suppliers and manufacturers processes, are in compliance with cGMP and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals including, but not limited to, standards and regulations for direct-to-consumer

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advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet.

We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping our products. Consequently, there is always a risk that the FDA or other applicable governmental authorities will not approve our products, or will take post-approval action limiting or revoking our ability to sell our products, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans or results of operations.

We may be required to initiate or defend against legal proceedings related to intellectual property rights, which may result in substantial expense, delay and/or cessation of the development and commercialization of our products.

We primarily rely on patents to protect our intellectual property rights. The strength of this protection, however, is uncertain. For example, it is not certain that:

- our patents and pending patent applications cover products and/or technology that we invented first;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate our technologies;
- any of our pending patent applications will result in issued patents; and
- any of our issued patents, or patent pending applications that result in issued patents, will be held valid and infringed in the event the patents are asserted against others.

We currently own or license several patents and also have pending patent applications applicable to rHuPH20 and other proprietary materials. There can be no assurance that our existing patents, or any patents issued to us as a result of our pending patent applications, will provide a basis for commercially viable products, will provide us with any competitive advantages, or will not face third party challenges or be the subject of further proceedings limiting their scope or enforceability. A European patent, EP1603541, claiming rHuPH20 was granted to us on November 11, 2009 with claims to the human PH20 glycoprotein, PEGylated variants, a method of producing the glycoprotein produced by recombinant methods, and pharmaceutical compositions with other agents, including antibodies, insulins, cytokines, a chemotherapeutic agent and additional therapeutic classes. A third party opposed this patent in the European Patent Office in 2010, but withdrew the opposition in March 2012. We are currently attempting to resolve the opposition with the European Patent Office, and although we expect to obtain European patent protection that would be no less broad than claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429), there can be no assurance that we will be able to do so. Any limitations in our patent portfolio could have a material adverse effect on our business and financial condition. In addition, if any of our pending patent applications do not result in issued patents, or result in issued patents with narrow or limited claims, this could result in us having no or limited protection against generic or biosimilar competition against our product candidates which would have a material adverse effect on our business and financial condition.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office, or other proceedings in other jurisdictions, to determine the priority, validity or enforceability of our patents. In addition, costly litigation could be necessary to protect our patent position.

We also rely on trademarks to protect the names of our products. These trademarks may not be acceptable to regulatory agencies. In addition, these trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect with confidentiality agreements with employees, consultants and others with whom we discuss our business. Disputes may arise

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concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and we might not be able to resolve these disputes in our favor.

In addition to protecting our own intellectual property rights, third parties may assert patent, trademark or copyright infringement or other intellectual property claims against us based on what they believe are their own intellectual property rights. If we become involved in any intellectual property litigation, we may be required to pay substantial damages, including but not limited to treble damages, for past infringement if it is ultimately determined that our products infringe a third party s intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management s attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights. If such a license is available at all, it may require us to pay substantial royalties or other fees.

Patent protection for protein-based therapeutic products and other biotechnology inventions is subject to a great deal of uncertainty, and if patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize products based on our discoveries.

Patent protection for protein-based therapeutic products is highly uncertain and involves complex legal and factual questions. In recent years, there have been significant changes in patent law, including the legal standards that govern the scope of protein and biotechnology patents. Standards for patentability of full-length and partial genes, and their corresponding proteins, are changing. Recent court decisions have made it more difficult to obtain patents, by making it more difficult to satisfy the requirement of non-obviousness, have decreased the availability of injunctions against infringers, and have increased the likelihood of challenging the validity of a patent through a declaratory judgment action. Taken together, these decisions could make it more difficult and costly for us to obtain, license and enforce our patents. In addition, the Leahy-Smith America Invents Act (HR 1249) was signed into law in September 2011, which among other changes to the U.S. patent laws, changes patent priority from "first to invent" to "first to file," implements a post-grant opposition system for patents and provides for a prior user defense to infringement. These judicial and legislative changes have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

There also have been, and continue to be, policy discussions concerning the scope of patent protection awarded to biotechnology inventions. Social and political opposition to biotechnology patents may lead to narrower patent protection within the biotechnology industry. Social and political opposition to patents on genes and proteins may lead to narrower patent protection, or narrower claim interpretation, for genes, their corresponding proteins and inventions related to their use, formulation and manufacture. Patent protection relating to biotechnology products is also subject to a great deal of uncertainty outside the United States, and patent laws are evolving and undergoing revision in many countries. Changes in, or different interpretations of, patent laws worldwide may result in our inability to obtain or enforce patents, and may allow others to use our discoveries to develop and commercialize competitive products, which would impair our business.

If third party reimbursement and customer contracts are not available, our products may not be accepted in the market.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health insurers, managed care organizations and other healthcare providers.

Third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of new drug products to contain costs. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Third party payors may not establish adequate levels of reimbursement for

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the products that we commercialize, which could limit their market acceptance and result in a material adverse effect on our financial condition.

Customer contracts, such as with group purchasing organizations and hospital formularies, will often not offer contract or formulary status without either the lowest price or substantial proven clinical differentiation. If our products are compared to animal-derived hyaluronidases by these entities, it is possible that neither of these conditions will be met, which could limit market acceptance and result in a material adverse effect on our financial condition.

The rising cost of healthcare and related pharmaceutical product pricing has led to cost containment pressures that could cause us to sell our products at lower prices, resulting in less revenue to us.

Any of the proprietary or partnered products that have been, or in the future are, approved by the FDA may be purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations and managed care organizations. Such third party payors increasingly challenge pharmaceutical product pricing. The trend toward managed healthcare in the United States, the growth of such organizations, and various legislative proposals and enactments to reform healthcare and government insurance programs, including the Medicare Prescription Drug Modernization Act of 2003, could significantly influence the manner in which pharmaceutical products are prescribed and purchased, resulting in lower prices and/or a reduction in demand. Such cost containment measures and healthcare reforms could adversely affect our ability to sell our products.

In March 2010, the United States adopted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Healthcare Reform Act. This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, the Healthcare Reform Act imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs that we believe will impact our revenues from our products. In addition, as part of the Healthcare Reform Act s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program, we will also be required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries under this prescription drug program. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

Furthermore, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third party payors or other restrictions could negatively and materially impact our revenues and financial condition. We anticipate that we will encounter similar regulatory and legislative issues in most other countries outside the United States.

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We face intense competition and rapid technological change that could result in the development of products by others that are superior to our proprietary and partnered products under development.

Our proprietary and partnered products have numerous competitors in the United States and abroad including, among others, major pharmaceutical and specialized biotechnology firms, universities and other research institutions that have developed competing products. The competitors for *Hylenex* recombinant will include, but are not limited to ISTA Pharmaceuticals, Inc. For our Analog-PH20 product candidates, such competitors may include Biodel Inc., Eli Lily, Sanofi Aventis, Novo Nordisk Inc. and Mannkind Corporation. These competitors may develop technologies and products that are more effective, safer, or less costly than our current or future proprietary and partnered product candidates or that could render our technologies and product candidates obsolete or noncompetitive. Many of these competitors have substantially more resources and product development, manufacturing and marketing experience and capabilities than we do. In addition, many of our competitors have significantly greater experience than we do in undertaking preclinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Our administrative offices and research facilities are currently located in San Diego, California. We lease an aggregate of approximately 58,000 square feet of office and research space for a monthly rent expense of approximately $117,000, net of costs and property taxes associated with the operation and maintenance of the subleased facilities. We believe the current space is adequate for our immediate needs.

Item 3. ***Legal Proceedings***

From time to time, we may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of our business. Any of these claims could subject us to costly legal expenses and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management s opinion, individually or in the aggregate, would have a material adverse effect on our consolidated results of operations or financial position.

In May 2010, we delivered a notice of breach to Baxter due to Baxter s failure to provide *Hylenex* recombinant in accordance with the terms of the Hylenex Partnership. Baxter had contested the claims made in our initial notice of breach and asserted their own breach claims against us. Pursuant to the terms of the Transition Agreement, signed on July 18, 2011, Baxter s breach claims against us were discharged.

Item 4. ***Mine Safety Disclosures***

Not applicable.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***
Market Information

Our common stock is listed on the NASDAQ Global Market under the symbol HALO. The following table sets forth the high and low sales prices per share of our common stock during each quarter of the two most recent fiscal years:

	2011		2010	
	High	Low	High	Low
First Quarter	$ 8.00	$ 5.79	$ 8.67	$ 5.22
Second Quarter	$ 7.21	$ 5.97	$ 9.11	$ 6.08
Third Quarter	$ 7.36	$ 5.54	$ 8.10	$ 6.41
Fourth Quarter	$ 9.82	$ 5.60	$ 8.31	$ 6.68

On March 1, 2012, the closing sales price of our common stock on the NASDAQ Stock Market was $11.39 per share. As of March 1, 2012, we had approximately 3,500 stockholders of record.

We have never declared or paid any dividends on our common stock. We currently intend to retain available cash for funding operations; therefore, we do not expect to pay any dividends on our common stock in the foreseeable future. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contract restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2011:

Plan Category	Number of Shares to Be Issued upon Exercise of Outstanding Options and Restricted Stock Units (a)	Weighted-Average Exercise Price of Outstanding Options and Restricted Stock Units (b)	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Shares Reflected in Column (a)) (c)
Equity compensation plans approved by stockholders (1)	6,017,784	$ 5.68	4,882,017

(1) Represents stock options and restricted stock units under the 2011 Stock Plan, 2008 Stock Plan, 2008 Outside Directors Stock Plan, 2006 Stock Plan, 2005 Outside Directors Stock Plan, 2004 Stock Plan and the 2001 Stock Plan. Options under the 2001 Stock Plan were assumed by Halozyme as part of the March 2004 merger between DeliaTroph Pharmaceuticals, Inc., or DeliaTroph, and Global Yacht Services, Inc. The 2001 Stock Plan was approved by the shareholders of DeliaTroph prior to the merger and the former shareholders of DeliaTroph held approximately 90% of the voting stock of Halozyme immediately following the merger. The 2001 Stock Plan expired in January 2011.

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Stock Performance Graph and Cumulative Total Return

Notwithstanding any statement to the contrary in any of our previous or future filings with the SEC, the following information relating to the price performance of our common stock shall not be deemed to be filed with the SEC or to be soliciting material under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and it shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent we specifically incorporate it by reference into such filing.

The graph below compares Halozyme Therapeutics, Inc. s cumulative five-year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph tracks the performance of a $100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from December 31, 2006 to December 31, 2011. The historical stock price performance included in this graph is not necessarily indicative of future stock price performance.

	12/06	12/07	12/08	12/09	12/10	12/11
Halozyme Therapeutics, Inc.	$ 100.00	$ 88.32	$ 69.57	$ 72.92	$ 98.39	$ 118.14
NASDAQ Composite	$ 100.00	$ 108.51	$ 64.13	$ 92.63	$ 109.33	$ 108.42
NASDAQ Biotechnology	$ 100.00	$ 103.41	$ 96.62	$ 106.15	$ 122.34	$ 137.11

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Item 6. ***Selected Financial Data***

The selected consolidated financial data set forth below as of December 31, 2011 and 2010, and for the fiscal years ended December 31, 2011, 2010 and 2009, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated financial data set forth below as of December 31, 2009, 2008 and 2007, and for the fiscal years ended December 31, 2008 and 2007, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC, not included herein.

Summary Financial Information

	Year Ended December 31,				
Statement of Operations Data:	**2011 (a)**	**2010**	**2009**	**2008**	**2007**
	(in thousands, except for per share amounts)				
Total revenues	$ 56,086	$ 13,624	$ 13,671	$ 8,764	$ 3,800
Net loss	(19,770)	(53,242)	(58,361)	(48,654)	(23,896)
Net loss per share, basic and diluted	$ (0.19)	$ (0.56)	$ (0.67)	$ (0.61)	$ (0.32)
Shares used in computing net loss per share, basic and diluted	102,566	94,358	86,700	79,844	74,318

	As of December 31,				
Balance Sheet Data:	**2011**	**2010**	**2009**	**2008**	**2007**
			(in thousands)		
Cash and cash equivalents	$ 52,826	$ 83,256	$ 67,465	$ 63,716	$ 97,679
Working capital	46,686	74,155	60,045	59,794	92,313
Total assets	65,759	91,345	77,150	76,563	103,460
Deferred revenues	40,884	58,094	60,482	49,448	39,269
Total liabilities	54,858	70,994	70,246	61,183	45,692
Stockholders equity	10,900	20,351	6,903	15,380	57,768

(a) Revenues for the year ended December 31, 2011 included revenues from collaborative agreements totaling $18.0 million related to the upfront payments received from the ViroPharma and Intrexon Partnerships and $18.1 million related to recognition of unamortized deferred prepaid product-based payments and unamortized deferred upfront payment under the Hylenex Partnership with Baxter as a result of the Transition Agreement signed in July 2011. See Note 3, Collaborative Agreements, and Note 7, Deferred Revenue, in the Notes to Consolidated Financial Statements for detailed discussion.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operation***

In addition to historical information, the following discussion contains forward-looking statements that are subject to risks and uncertainties. Actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the Part I, Item 1A Risks Factors and elsewhere in this Annual Report.

Overview

We are a biopharmaceutical company dedicated to developing and commercializing innovative products that advance patient care. Our research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique scientific expertise that allows us to pursue this target-rich environment for the development of future therapies.

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Our research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, the recombinant human hyaluronidase, or rHuPH20, temporarily degrades hyaluronan, or HA, a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit. Our Enhanze technology is the platform for the delivery of proprietary small and large molecules. We apply our research to develop products in partnership with other companies as well as for our own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing products and a limited number of product candidates; (iv) supporting the development of partnered product candidates; and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have multiple proprietary programs in various stages of research and development. In addition, we currently have collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, Baxter Healthcare Corporation, or Baxter, ViroPharma Incorporated, or ViroPharma, and Intrexon Corporation, or Intrexon, to apply Enhanze technology to the partners biological therapeutic compounds. We also had another partnership with Baxter, under which Baxter had worldwide marketing rights for our marketed product, *Hylenex* recombinant, or the Hylenex Partnership. We and Baxter mutually agreed to terminate the Hylenex Partnership in January 2011. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from our partnerships.

We and our partners have product candidates in the research, preclinical and clinical stages, but future revenues from the sales and/or royalties of these product candidates will depend on our partners abilities and ours to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we and our partners are able to obtain regulatory approvals for these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately $245.0 million as of December 31, 2011.

We are currently a Well-Known Seasoned Issuer and may file automatic shelf registration statements at any time with the SEC. In February 2011, we filed an automatic shelf registration statement on Form S-3 (Registration No. 333-179444) with the SEC, which allows us, from time to time, to offer and sell equity, debt securities and warrants to purchase any of such securities, either individually or in units. On February 15, 2012, we sold approximately 7.8 million shares of our common stock at a public offering price of $10.61 per share, generating approximately $81.8 million in proceeds after deducting the underwriting discounts and commissions but before any deductions for expenses. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

Revenues

We generate revenues from product sales and collaborative agreements. Revenue from product sales depends on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our products and product candidates. Payments received under collaborative agreements may include nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for the manufacture of bulk formulation of rHuPH20 (active pharmaceutical ingredient, or API) for the partner and/or royalties, as applicable, on sales of products resulting from collaborative agreements. We analyze each element of our collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition. See *Critical Accounting Policies and Estimates Revenue Recognition Revenue Under Collaborative Agreements* below for our revenue recognition policies for payments received under collaborative agreements.

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Costs and Expenses

Cost of Sales. Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight costs, internal costs and manufacturing overhead associated with the production of our products. Cost of sales also consists of the write-down of excess, dated and obsolete inventories.

Research and Development. Our research and development expenses include salaries and benefits, research-related manufacturing services, clinical trials, contract research services, supplies and materials, facilities and other overhead costs and other outside expenses. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our various product candidates.

Since our inception in 1998 through December 31, 2011, we have incurred research and development expenses of $259.1 million. From January 1, 2009 through December 31, 2011, approximately 30% and 16% of our research and development expenses were associated with the development of our Analog-PH20 and PEGPH20 product candidates, respectively. Research and development expenses incurred for the years ended December 31, 2011, 2010 and 2009 were as follows (in thousands):

	Year Ended December 31,		
	2011	**2010**	**2009**
Programs			
Product Candidates:			
Analog-PH20	$ 16,616	$ 15,355	$ 18,363
PEGPH20	8,399	7,179	11,112
HTI-501	3,918	4,959	3,356
Hylenex recombinant	4,125	1,436	957
Enhanze partnerships	7,464	8,568	5,509
rHuPH20 platform(1)	14,100	8,634	11,572
Other	2,941	5,643	5,745
Total research and development expenses	$ 57,563	$ 51,774	$ 56,614

(1) Includes research, development and manufacturing expenses related to our proprietary recombinant human PH20 enzyme, rHuPH20. These expenses were not designated to a specific program at the time the expenses were incurred.

Due to the uncertainty in obtaining the U.S Food and Drug Administration, or FDA, and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

Clinical development timelines, likelihood of success and total costs vary widely. We anticipate that we will make ongoing determinations as to which research and development projects to pursue and how much funding to direct to each project on an ongoing basis in response to existing resource levels, the scientific and clinical progress of each product candidate, and other market and regulatory developments. We plan on focusing our resources on those proprietary and partnered product candidates that represent the most valuable economic and strategic opportunities.

Product candidate completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn,

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have a material adverse effect on our results of operations. We cannot be certain when, or if, our product candidates will receive regulatory approval or whether any net cash inflow from our other product candidates, or development projects, will commence.

Selling, General and Administrative, or SG&A. Through the second quarter of 2011, our selling expenses, which include sales and marketing costs, primarily consisted of compensation, consulting fees, costs of market research studies related to our product and product candidates. In the third and fourth quarters of 2011, we expanded our commercial infrastructure, including hiring of sales and marketing management and sales representatives. In addition, we began incurring costs related to advertising, marketing and logistics services for *Hylenex* recombinant in connection with the reintroduction of *Hylenex* recombinant in December 2011.

Our general and administrative expenses consist primarily of compensation and other expenses related to our corporate operations and administrative employees, accounting and legal fees, other professional services expenses, as well as other expenses associated with operating as a publicly traded company.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial position and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We generate revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, license fees, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and/or royalties on sales of products resulting from collaborative arrangements.

We recognize revenue in accordance with the authoritative guidance on revenue recognition. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

Product Sales

Hylenex recombinant was approved for marketing by the FDA in December 2005. From 2005 through January 7, 2011, Baxter had the worldwide market rights for *Hylenex* recombinant under the terms of the Hylenex Partnership. Baxter commercially launched *Hylenex* recombinant in October 2009. However, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the product manufactured by Baxter was not in compliance with the requirements of the underlying partnership. Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant to the market. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant.

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In December 2011, we reintroduced *Hylenex* recombinant to the market, shipped initial stocking orders to its wholesaler customers and began promoting *Hylenex* recombinant through our sales force. We sell *Hylenex* recombinant in the United States to wholesale pharmaceutical distributors, who in-turn sell the product to hospitals and other end-user customers. The wholesale distributors take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales; however, we do allow the wholesale distributors to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to and ending twelve months following product expiration. Given our limited experience history of selling *Hylenex* recombinant and the lengthy return period, we currently cannot reliably estimate expected returns and chargebacks of *Hylenex* recombinant at the time of product received by the wholesale distributors. Therefore, we do not recognize revenue upon delivery of *Hylenex* recombinant to the wholesale distributor until the point at which we can reliably estimate expected product returns and chargebacks from the wholesale distributors. Shipments of *Hylenex* recombinant are recorded as deferred revenue until evidence exists to confirm that pull-through sales to the hospitals or other end-user customers have occurred. We recognize revenue when the product is sold through from the distributors to the distributors customers. In addition, the costs of manufacturing *Hylenex* recombinant associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized. We estimate sell-through revenue and certain gross to net sales adjustments based on analysis of third-party information including information obtained from certain distributors with respect to their inventory levels and sell-through to the distributors customers. At the time the Company can reliably estimate product returns and chargebacks from the wholesalers, we will record a one-time increase in net product sales revenue related to the recognition of product sales revenue previously deferred.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesaler customers, hospitals and the levels of inventory within the distribution channels that may result in future discounts taken. We must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make adjustment to these allowances in the future, which could have an effect on product sales revenue in the period of adjustment. Our product sales allowances include:

Distribution Fees. The distribution fees, based on contractually determined rates, arise from contractual agreements we have with certain wholesale distributors for distribution services they provide with respect to *Hylenex* recombinant. At the time the sale is made to the respective wholesale distributors, we record an allowance for distribution fees by reducing our accounts receivable and deferred revenue associated with such product sales.

Prompt Payment Discounts. We offer cash discounts to certain wholesale distributors as an incentive to meet certain payment terms. At the time the sale is made to the respective wholesale distributors, we record an allowance for distribution fees by reducing our accounts receivable and deferred revenue associated with such product sales.

Chargebacks. We provide discounts to certain hospitals. These hospitals purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the hospitals paid for the product. Given our lack of historical sales data, we recognize chargebacks in the same period the related product sales revenue is recognized and reduce our accounts receivable accordingly.

Product Returns. The product return reserve is based on management s best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The product returns reserve is recorded as a reduction of product sales revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.

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Prior to the termination of the Hylenex Partnership with Baxter in January 2011, we supplied Baxter with API for *Hylenex* recombinant at our fully burdened cost plus a margin. Baxter filled and finished *Hylenex* recombinant and held it for subsequent distribution, at which time we ensured it met product specifications and released it as available for sale. Because of our continued involvement in the development and production process of *Hylenex* recombinant, the earnings process was not considered to be complete. Accordingly, we deferred the revenue and related product costs on the API for *Hylenex* recombinant until the product was filled, finished, packaged and released. Baxter could only return the API for *Hylenex* recombinant to us if it did not conform to the specified criteria set forth in the Hylenex Partnership or upon termination of such agreement. In addition, we received product-based payments upon the sale of *Hylenex* recombinant by Baxter, in accordance with the terms of the Hylenex Partnership. Product-based revenues were recognized as we earned such revenues based on Baxter s shipments of *Hylenex* recombinant to its distributors when such amounts could be reasonably estimated.

Revenues under Collaborative Agreements

We entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of our proprietary rHuPH20 enzyme in the development and commercialization of the partners biologic compounds. The collaborative agreements contain multiple elements including nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the partner and/or royalties on sales of products resulting from collaborative agreements. We analyze each element of the collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of fair value of the undelivered items and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, we recognize revenue on nonrefundable upfront payments and license fees from these collaborative agreements over the period of significant involvement under the related agreements.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under our collaborative agreements include (i) the license to rHuPH20 technology, (ii) at the collaborator s request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator s request, supply of rHuPH20 API which is reimbursed at our cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not

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exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of rHuPH20 API, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the partner is fixed or determinable and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The terms of our collaborative agreements provide for milestone payments upon achievement of certain development and regulatory events and/or specified sales volumes of commercialized products by the collaborator. Prior to our adoption of the milestone method of revenue recognition, or the Milestone Method, we recognized milestone payments upon the achievement of specified milestones if: (1) the milestone was substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees were nonrefundable and (3) our performance obligations after the milestone achievement would continue to be funded by our collaborator at a level comparable to the level before the milestone achievement.

Effective January 1, 2011, we adopted on a prospective basis the Milestone Method. Under the Milestone Method, we recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone,

2. The consideration relates solely to past performance, and

3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the vendor s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the vendor.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of rHuPH20 API is recognized when the API has met all specifications required for the collaborator acceptance and title and risk of loss have transferred to the collaborator. We do not directly control when any collaborator will request research and development services or supply of rHuPH20 API; therefore, we cannot predict when we will recognize revenues in connection with research and development services and supply of rHuPH20 API. Royalties to be received based on sales of licensed products by our collaborators incorporating rHuPH20 will be recognized as earned.

The collaborative agreements typically provide the partners the right to terminate such agreement in whole or on a product-by-product or target-by-target basis at any time upon 90 days prior written notice to us. There are

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no performance, cancellation, termination or refund provisions in any of our collaborative agreements that contain material financial consequences to us.

Roche Partnership

In December 2006, we and Roche entered into an agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds, or the Roche Partnership. Under the terms of the Roche Partnership, Roche paid $20.0 million as an initial upfront license fee for the application of rHuPH20 to three pre-defined Roche biologic targets. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), revenues from the upfront payment, exclusive designation fees and annual license maintenance fees were deferred and are being recognized over the term of the Roche Partnership. As of December 31, 2011, we have received $33 million from Roche, including the $20 million upfront license fee payment and $13 million in clinical development milestone payments. If Roche successfully develops all of the three pre-defined targets and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $98 million, including up to $5 million for the achievement of clinical development milestones, up to $12 million for the achievement of regulatory milestones and up to $81 million for the achievement of sales-based milestones. We will earn the next milestone payment of $4 million when Roche submits a biologic license application of one of the three pre-defined targets. Under the terms of the Roche Partnership, Roche will also pay us royalties on product sales for these first three targets. For each of the additional targets, Roche may pay us further upfront and milestone payments of up to $47.0 million per target, as well as royalties on product sales, for each of the additional targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets.

Through December 31, 2011, Roche has paid an aggregate of $20.0 million in connection with its election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets. In 2010, Roche paid the annual license maintenance fees on only three of the remaining eight target slots. In 2011, Roche did not pay the annual exclusivity maintenance fee for any of the remaining additional target slots. As a result, Roche currently retains the option to develop and commercialize rHuPH20 with only three additional targets under the Roche partnership agreement, provided that it continues to pay annual maintenance fees to us.

We have determined that the clinical and regulatory milestones are substantive; therefore, we expect to recognize such clinical and regulatory milestone payments as revenue upon achievement. In addition, we have determined that the sales-based milestone payments are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, we will recognize such sales-based milestone payments as revenue upon achievement of the milestone. For the year ended December 31, 2011, we recognized $5.0 million as revenue under collaborative agreements in accordance with the Milestone Method related to the achievement of certain clinical milestones pursuant to the terms of the Roche Partnership. We recognized zero and $7.0 million for the years ended December 31, 2010 and 2009, respectively, as revenue under collaborative agreements upon achievement of certain clinical milestones pursuant to the terms of the Roche Partnership.

In early March 2012, we announced that Roche has submitted a Line Extension Application to the European Medicines Agency for Herceptin® formulated with rHuPH20 (subcutaneous Herceptin). Upon achievement of this milestone, we are entitled to receive a milestone payment of $4.0 million in the first half of 2012.

Gammagard Partnership

In September 2007, we entered into an agreement with Baxter, under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, with a current Baxter product, GAMMAGARD LIQUID, or the Gammagard Partnership. Under the terms of the Gammagard Partnership, Baxter paid us a nonrefundable upfront payment of $10.0 million. Due to our continuing

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involvement obligation (for example, support activities associated with rHuPH20 enzyme), the $10.0 million upfront payment was deferred and is being recognized over the term of the Gammagard Partnership. As of December 31, 2011, we have received $13 million under the Gammagard Partnership, including the $10 million upfront license fee payment and $3 million in regulatory milestone payment. If Baxter successfully receives marketing approval for the licensed product candidate and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $34 million for the achievement of sales-based milestones. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard Partnership is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we are responsible for the supply of the rHuPH20 enzyme. We perform research and development activities at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Partnership. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard Partnership.

We have determined that the regulatory milestones are substantive; therefore, we expect to recognize such regulatory milestone payments as revenue upon achievement. In addition, we have determined that sales-based milestone payments are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, will be recognized as revenue upon achievement of the milestone. For the year ended December 31, 2011, the Company recognized $3.0 million as revenue under collaborative agreements in accordance with the Milestone Method related to the achievement of regulatory milestones pursuant to the terms of the Gammagard Partnership. There were no milestone payments recognized as revenue under the terms of the Gammagard Partnership for the years ended December 31, 2010 and 2009.

ViroPharma and Intrexon Partnerships

Effective May 10, 2011, we and ViroPharma entered into a collaboration and agreement, under which ViroPharma obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of ViroPharma s commercialized product, Cinryze® (C1 esterase inhibitor [human]), or the ViroPharma Partnership. In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibitor and to the hereditary angioedema indication, along with three additional orphan indications. As of December 31, 2011, we have received $12 million from ViroPharma, including the $9 million nonrefundable upfront license fee payment and $3 million in clinical development milestone payment. If ViroPharma successfully develops the licensed product candidate, we could receive additional milestone payments of up to $41 million for the achievement of development and regulatory milestones. In addition, so long as the agreement is in effect, we are entitled to receive an annual exclusivity fee of $1.0 million commencing on May 10, 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. ViroPharma is solely responsible for the development, manufacturing and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by ViroPharma. In addition, we are entitled to receive additional cash payments potentially totaling $10.0 million for each product for treatment of each of the three additional orphan indications upon achievement of development and regulatory milestones. We are also entitled to receive royalties on product sales by ViroPharma. ViroPharma may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to ViroPharma (in total or with respect to the terminated product, as applicable) will terminate.

Effective June 6, 2011, we and Intrexon entered into a collaboration and agreement, under which Intrexon obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of Intrexon s recombinant human alpha 1-antitrypsin (rHuA1AT), or the Intrexon Partnership. In addition, the license provides Intrexon with exclusivity for a defined indication (Exclusive Field). As of December 31, 2011, we have received $9 million in nonrefundable upfront license fee payment from Intrexon. If Intrexon successfully develops the licensed product candidate and achieves the pre-agreed sales target, we could receive additional milestone payments of up to $54 million, including $44 million for the

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achievement of development and regulatory milestones and $10 million for the achievement of a sales-based milestone. In addition, so long as the agreement is in effect, we are entitled to receive an annual exclusivity fee of $1.0 million commencing on June 6, 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. Intrexon is solely responsible for the development, manufacturing and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by Intrexon. In addition, we are entitled to receive additional cash payments potentially totaling $10.0 million for each product for use outside the Exclusive Field upon achievement of development and regulatory milestones. We are also entitled to receive royalties on product sales at a royalty rate which increases with net sales of product. Intrexon may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to Intrexon (in total or with respect to the terminated product, as applicable) will terminate. Intrexon s chief executive officer and chairman of its board of directors is also a member of the Company s board of directors.

We identified the deliverables at the inception of the ViroPharma and Intrexon Partnerships which are the license, research and development services and API supply. We have determined that the license, research and development services and API supply individually represent separate units of accounting, because each deliverable has standalone value. The estimated selling prices for these units of accounting was determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotech industry and entity-specific factors such as the terms of our previous collaborative agreements, our pricing practices and pricing objectives and the nature of the research and development services to be performed for the partners. The arrangement consideration was allocated to the deliverables based on the relative selling price method. Based on the results of our analysis, we determined that the upfront payment was earned upon the granting of the worldwide exclusive right to our technology to the collaborator in both the ViroPharma Partnership and Intrexon Partnership. However, the amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the license was only to the extent of cash received. As a result, we recognized the $9.0 million upfront license fee received under the ViroPharma Partnership and $9.0 million upfront license fee received under the Intrexon Partnership as revenues under collaborative agreements upon the receipt of such upfront license fees for the year ended December 31, 2011.

We will recognize the exclusivity fees as revenue under collaborative agreements when they are earned. We will recognize reimbursements for research and development services as revenue under collaborative agreements as the related services are delivered. We will recognize payments from sales of API as revenue under collaborative agreements when such API has met all required specifications by the partners and the related title and risk of loss and damages have passed to the partners. We cannot predict the timing of delivery of research and development services and API as they are at the partners requests.

We are eligible to receive additional cash payments upon the achievement by the partners of specified development, regulatory and sales-based milestones. We have determined that each of the development and regulatory milestones is substantive; therefore, we expect to recognize such development and regulatory milestone payments as revenue under collaborative agreements upon achievement in accordance with the Milestone Method. In addition, we have determined that the sales-based milestone payment is similar to a royalty payment and is not considered milestone payment under the Milestone Method of revenue recognition; therefore, we will recognize the sales-based milestone payment as revenue upon achievement of the milestone because we have no future performance obligations associated with the milestone. For the year ended December 31, 2011, we recognized the $3.0 million payment from ViroPharma as revenue under collaborative agreements in accordance with the Milestone Method related to the achievement of a regulatory milestone pursuant to the terms of the ViroPharma Partnership.

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Hylenex Partnership

Under the terms of the Hylenex Partnership, Baxter paid us a nonrefundable upfront payment of $10.0 million in 2007. Due to our continuing involvement obligations (for example, support activities associated with rHuPh20 enzyme), the $10.0 million upfront payment was deferred and was being recognized over the term of the Hylenex Partnership.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements. The termination of these agreements does not affect the other relationships between the parties, including the application of our Enhanze technology to Baxter s GAMMAGARD LIQUID. On July 18, 2011, we and Baxter entered into an agreement, or the Transition Agreement, setting forth certain rights, data and assets to be transferred by Baxter to us during a transition period. Effective July 18, 2011, we had no future performance obligations to Baxter in connection with the Hylenex Partnership. Therefore, we recognized the unamortized deferred revenue of approximately $9.3 million relating to the prepaid product-based payments and the unamortized deferred revenue of approximately $7.8 million relating to deferred upfront payment from the Hylenex Partnership as revenues under collaborative agreements for the year ended December 31, 2011.

As a result of the termination of the Hylenex Partnership, at December 31, 2010 we had recharacterized deferred revenue of approximately $991,000 as a reserve for product returns for *Hylenex* recombinant API previously delivered to Baxter that could be returned, or Delivered Products. Pursuant to the terms of the Transition Agreement, Baxter no longer had the right to return the Delivered Products. Accordingly, we recharacterized the reserve for product returns for the Delivered Products of approximately $991,000 to current deferred revenue and recognized such deferred revenue as product sales revenue for the year ended December 31, 2011.

Share-Based Payments

We use the fair value method to account for share-based payments in accordance with the authoritative guidance for share-based compensation. The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model, or Black-Scholes model, that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on the historical volatility of our common stock. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience.

If factors change and we employ different assumptions for determination of fair value in future periods, the share-based compensation expense that we record may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our consolidated financial statements. Alternatively, values may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our consolidated financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with authoritative guidance on stock compensation using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

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The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP. There are also areas in which our management s judgment in selecting any available alternative would not produce a materially different result. Please see our audited consolidated financial statements and notes thereto included in Part II, Item 8 of this report, which contain accounting policies and other disclosures required by U.S. GAAP.

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, clinical trials, research-related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed or such time that the Company does not expect the goods to be delivered or services to be rendered.

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by regulatory bodies such as the FDA or when other significant risk factors are abated. Management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain and has expensed these amounts for accounting purposes.

Payments in connection with our clinical trials are often made under contracts with multiple contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time-and-material basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones. Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and clinical trial progress. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trials contracts, we are unable to quantify an estimate of the reasonably likely effect of any such changes on our consolidated results of operations or financial position. Historically, we have had no material changes in our clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

Inventories, Net

Inventories, net are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by the Company s contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

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Raw materials inventories consist of raw materials used in the manufacture of the Company s bulk drug material for *Hylenex* recombinant product. Work-in-process inventories consist of in-process *Hylenex* recombinant. Finished goods inventories consist of finished *Hylenex* recombinant product.

As a result of the termination of the Hylenex Partnership in January 2011, we recorded a reserve for inventory obsolescence of approximately $166,000 and $875,000 for *Hylenex* recombinant API for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011 and 2010, the reserve for inventory obsolescence was approximately zero and $875,000, respectively.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be realized. For products that have been approved by the FDA, inventories used in clinical trials are expensed at the time the inventories are packaged for the clinical trial. Prior to receiving approval from the FDA or comparable regulatory agencies in foreign countries, costs related to purchases of the API and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized into inventories.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP. There are also areas in which our management s judgment in selecting any available alternative would not produce a materially different result. Please see our audited consolidated financial statements and notes thereto included in Part II, Item 8 of this report, which contain accounting policies and other disclosures required by U.S. GAAP.

Results of Operations

Comparison of Years Ended December 31, 2011 and 2010

Product Sales, Net Product sales, net were $1.8 million for the year ended December 31, 2011 compared to $896,000 for the year ended December 31, 2010. Product sales for 2011 included the recognition of approximately $991,000 of deferred revenue related to API for *Hylenex* recombinant previously delivered to Baxter, because the earnings process related to these product sales was completed in 2011. Excluding the recognition of the $991,000 of deferred revenue, our product sales, net in 2011 would have been $845,000. Based on our reintroduction of *Hylenex* recombinant in December 2011, we expect product sales to increase in the future.

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Revenues Under Collaborative Agreements Revenues under collaborative agreements for the years ended December 31, 2011 and 2010 were as follows (in thousands):

	Years Ended December 31,		Increase (Decrease)	
	2011	2010	Amount	Percent
Upfront payments and amortization of deferred upfront, license fees and product-based payments:				
Baxter	$ 17,622	$ 1,024	$ 16,598	1621%
ViroPharma	9,000		9,000	N/A
Intrexon	9,000		9,000	N/A
Roche	1,969	1,985	(16)	(1%)
Other	71		71	N/A
	37,662	3,009	34,653	1152%
Milestone payments:				
Roche	5,000		5,000	N/A
Baxter	3,000		3,000	N/A
ViroPharma	3,000		3,000	N/A
	11,000		11,000	N/A
Reimbursements for research and development services:				
Baxter	1,681	4,245	(2,564)	(60%)
Roche	3,416	5,165	(1,749)	(34%)
ViroPharma	432		432	N/A
Others	59	310	(251)	(81%)
	5,588	9,720	(4,132)	(43%)
Total revenues under collaborative agreements	$ 54,250	$ 12,729	$ 41,521	326%

Pursuant to the terms of the Transition Agreement between us and Baxter, signed on July 18, 2011, we have no future performance obligations to Baxter in connection with the Hylenex Partnership. Accordingly, we recognized approximately $9.3 million related to the deferred prepaid product-based payments and approximately $7.8 million related to the deferred upfront payment under the Hylenex Partnership for the year ended December 31, 2011. For the year ended December 31, 2011, we received a total of $18.0 million in license fees under the partnerships with ViroPharma and Intrexon. The Company also received $11.0 million in milestone payments from the partners upon achievement of certain clinical and regulatory milestones. The decrease in reimbursements for research and development services was due to the decrease in services requested by the partners. Research and development services rendered by us on behalf of our partners are at the request of the partners; therefore, the amount of future revenues related to reimbursable research and development services is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to fluctuate in future periods based on our partners abilities to meet various clinical and regulatory milestones set forth in such agreements and our abilities to obtain new collaborative agreements.

Cost of Product Sales Cost of product sales were $258,000 for the year ended December 31, 2011 compared to $985,000 for the year ended December 31, 2010. The decrease of $727,000, or 74%, was primarily due to a reserve for inventory obsolescence of $875,000 for *Hylenex* recombinant API in 2010 in connection with the termination of the Hylenex Partnership in January 2011. Based on the reintroduction of *Hylenex* recombinant in December 2011, we expect cost of product sales to increase in future periods.

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Research and Development Research and development expenses were $57.6 million for the year ended December 31, 2011 compared to $51.8 million for the year ended December 31, 2010. The increase of $5.8 million, or 11%, was primarily due to a $4.7 million increase in manufacturing activities and a $6.8 million increase in clinical trial activities mainly supporting our ultrafast insulin and PEGPH20 programs. These increases were partially offset by a $4.2 million decrease in compensation costs mainly due to the reduction in force in October 2010. We expect research and development costs to increase slightly in future periods as we continue with our clinical trial programs and continue to develop and manufacture our product candidates.

Selling, General and Administrative SG&A expenses were $18.1 million for the year ended December 31, 2011 compared to $15.1 million for the year ended December 31, 2010. The increase of $3.0 million, or 20%, was primarily due to increases of $893,000 in marketing expenses, $704,000 in market research activities and $515,000 in professional fees. In connection with the reintroduction of *Hylenex* recombinant in December 2011, we expect SG&A expenses to increase in future periods as we plan to increase sales and marketing activities.

Share-Based Compensation Total compensation cost for our share-based payments was $5.6 million for the year ended December 31, 2011 compared to $4.9 million for the year ended December 31, 2010. Research and development expenses included share-based compensation of approximately $2.8 million and $2.5 million in 2011 and 2010, respectively. SG&A expenses included share-based compensation of approximately $2.8 million and $2.3 million in 2011 and 2010, respectively. As of December 31, 2011, $9.6 million of total unrecognized compensation costs related to non-vested share-based awards is expected to be recognized over a weighted average period of 2.8 years.

Other Income, net Other income, net for the year ended December 31, 2010 consisted of one-time grants of approximately $978,000 received in 2010 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, or QTDP. Other income, net also included interest income of $64,000 for the year ended December 31, 2011 compared to $49,000 for the year ended December 31, 2010. The increase in interest income was primarily due to higher average cash and cash equivalent balances and higher interest rates in 2011 as compared to the same period in 2010.

Net Loss Net loss for the year ended December 31, 2011 was $19.8 million, or $0.19 per common share, compared to $53.2 million, or $0.56 per common share for the year ended December 31, 2010. The decrease in net loss was primarily due to an increase in revenues under collaborative agreements resulting from $18.0 million in upfront license fees we received from the ViroPharma and Intrexon Partnerships and $11.0 million in milestone payments from Roche, Baxter and ViroPharma which were earned in 2011. The increase was also due to the recognition of deferred upfront license fees, deferred product-based payments and deferred product sales in connection with the termination of the Hylenex Partnership totaling $18.1 million in 2011. The decrease in net loss was offset in part by an increase in operating expenses and a decrease in other income in 2011 as compared to the same period in 2010.

Comparison of Years Ended December 31, 2010 and 2009

Product Sales Product sales were $896,000 for the year ended December 31, 2010 compared to $971,000 for the year ended December 31, 2009. The decrease of $75,000, or 8%, was primarily due to the decreases in sales of Cumulase and *Hylenex* recombinant.

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Revenues Under Collaborative Agreements Revenues under collaborative agreements for the years ended December 31, 2010 and 2009 were as follows:

	Year Ended December 31,		Increase (Decrease)	
	2010	2009	Amount	Percent
Upfront payments and amortization of deferred upfront, license fees and product-based payments:				
Baxter	$ 1,024	$ 1,193	$ (169)	(14%)
Roche	1,985	1,945	40	2%
	3,009	3,138	(129)	(4%)
Milestone payments:				
Roche		7,000	(7,000)	N/A
		7,000	(7,000)	N/A
Reimbursements for research and development services:				
Baxter	4,244	1,140	3,104	272%
Roche	5,165	1,422	3,743	263%
Others	310		310	N/A
	9,719	2,562	7,157	279%
Total revenues under collaborative agreements	$ 12,728	$ 12,700	$ 28	0%

Cost of Product Sales Cost of product sales were $985,000 for the year ended December 31, 2010 compared to $312,000 for the year ended December 31, 2009. The increase was primarily due to a reserve for inventory obsolescence of $875,000 for *Hylenex* recombinant API in 2010 in connection with the termination of the Hylenex Partnership in January 2011. The increase was offset in part by the decrease in the cost of product sales due to a decrease *Hylenex* recombinant API sales in 2010.

Research and Development Research and development expenses were $51.8 million for the year ended December 31, 2010 compared to $56.6 million for the year ended December 31, 2009. The decrease of $4.8 million, or 8%, was primarily due to a $3.4 million decrease in activities supporting our PEGPH20 program mainly manufacturing for clinical trial material and a $2.7 million decrease in activities supporting the ultrafast insulin program mainly due to the completion of several clinical trials in early 2010. The decrease was partially offset by a $1.2 million increase in activities supporting the HTI-501 program. In connection with the reduction in the workforce in October 2010, we incurred a one-time charge for separation costs in the fourth quarter of 2010 which was mostly offset by reduced compensation expenses during that quarter.

Selling, General and Administrative SG&A expenses were $15.1 million for the year ended December 31, 2010 compared to $15.2 million for the year ended December 31, 2009.

Share-Based Compensation Total compensation cost for our share-based payments was $4.9 million for the year ended December 31, 2010 compared to $4.5 million for the year ended December 31, 2009. Research and development expenses included share-based compensation of approximately $2.5 million and $2.4 million in 2010 and 2009, respectively. SG&A expenses included share-based compensation of approximately $2.3 million and $2.1 million in 2010 and 2009, respectively. As of December 31, 2010, $6.8 million of total unrecognized compensation costs related to non-vested stock options and restricted stock awards is expected to be recognized over a weighted average period of 2.5 years.

Other Income, net Other income consisted of one-time grants of approximately $978,000 received in 2010 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, or QTDP. Other income, net also included interest income of $49,000 for the year ended

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December 31, 2010 compared to $101,000 for the year ended December 31, 2009. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2010 as compared to the same period in 2009.

Net Loss Net loss for the year ended December 31, 2010 was $53.2 million, or $0.56 per common share, compared to $58.4 million, or $0.67 per common share for the year ended December 31, 2009. The decrease in net loss was primarily due to a decrease in operating expenses and receipt of QTDP grants in 2010.

Liquidity and Capital Resources

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2011, we had cash and cash equivalents of approximately $52.8 million. On February 15, 2012, we sold approximately 7.8 million shares of our common stock at a public offering price of $10.61 per share, generating approximately $81.8 million in proceeds after deducting the underwriting discounts and commissions but before any deductions for expenses. We will continue to have significant cash requirements to support product development activities. The amount and timing of cash requirements will depend on the success of our clinical development programs, regulatory and market acceptance, and the resources we devote to research and other commercialization activities.

We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months. Currently, we anticipate total net cash burn of approximately $50.0 to $55.0 million for the year ending December 31, 2012, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones under our existing collaborative agreements. We do not expect our revenues to be sufficient to fund operations for several years. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing collaborations and cash that we may raise through future transactions. We may finance future cash needs through any one of the following financing vehicles: (i) the public offering of securities; (ii) new collaborative agreements; (iii) expansions or revisions to existing collaborative relationships; (iv) private financings; and/or (v) other equity or debt financings.

We are currently a Well-Known Seasoned Issuer and may file automatic shelf registration statements at any time with the SEC. In February 2011, we filed an automatic shelf registration statement on Form S-3 (Registration No. 333-179444) with the SEC, which allows us, from time to time, to offer and sell equity, debt securities and warrants to purchase any of such securities, either individually or in units. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

Our existing cash and cash equivalents may not be adequate to fund our operations until we become cash flow positive, if ever. We cannot be certain that additional financing will be available when needed or, if available, financing will be obtained on favorable terms. If we are unable to raise sufficient funds, we may need to delay, scale back or eliminate some or all of our research and development programs, delay the launch of our product candidates, if approved, and/or restructure our operations. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders could result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations, the issuance of warrants that may ultimately dilute existing stockholders when exercised and covenants that may restrict our ability to operate our business.

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Cash Flows

Operating Activities

Net cash used in operations was $34.4 million during the year ended December 31, 2011 compared to $45.4 million of net cash used in operations during the year ended December 31, 2010. This change was primarily due to the decrease in net loss of $33.5 million adjusted for non-cash items including stock-based compensation and depreciation and amortization in addition to changes in working capital. The decrease in net loss after adjustments for non-cash items was mainly due to the receipts of $18.0 million in upfront license fees from the ViroPharma and Intrexon Partnerships and milestone payments totaling $11.0 million received under the collaborative partnership; offset in part by an increase in R&D and SG&A expenses.

Net cash used in operations was $45.4 million during the year ended December 31, 2010 compared to $40.1 million of net cash used in operations during the year ended December 31, 2009. This change was primarily due to a reduction in partnerships payments of approximately $13.5 million and an increase of approximately $3.2 million cash payments for prepaid expenses and other assets in 2010; partially offset by a decrease in operating expenses of approximately $4.2 million and a decrease of approximately $5.4 million in cash payments for accounts payable and accrued expenses. In addition, we received $978,000 in QTDP grants offsetting cash used in operating activities for the year ended December 31, 2010.

Investing Activities

Net cash used in investing activities was $829,000 during the year ended December 31, 2011 compared to $647,000 during the year ended December 31, 2010. This was primarily due to an increase in purchases of property and equipment during 2011.

Net cash used in investing activities was $647,000 during the year ended December 31, 2010 compared to $1.5 million during the year ended December 31, 2009. This was primarily due to a decrease in purchases of property and equipment during 2010.

Financing Activities

Net cash provided by financing activities was $4.7 million during the year ended December 31, 2011 compared to $61.8 million during the year ended December 31, 2010. Net cash provided by financing activities during 2011 consisted of proceeds from stock option exercises.

Net cash provided by financing activities was $61.8 million during the year ended December 31, 2010 compared to $45.4 million during the year ended December 31, 2009. Net cash provided by financing activities during 2010 primarily consisted of net proceeds of $60.0 million from the sale of our common stock in September 2010 and $1.8 million from stock option exercises. Net cash provided by financing activities during 2009 primarily consisted of net proceeds of $38.2 million from the sale of our common stock in June 2009 and $7.2 million from warrant and stock option exercises.

Off-Balance Sheet Arrangements

As of December 31, 2011, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we did not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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Contractual Obligations

As of December 31, 2011, future minimum payments due under our contractual obligations are as follows (in thousands):

		Payments Due by Period			
Contractual Obligations(1)	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**More than 5 Years**
Operating leases(2)	$ 10,144	$ 1,470	$ 3,331	$ 3,473	$ 1,870
License payments	1,200	300	600	300	
Purchase obligations(3):					
Research and development activities, excluding manufacturing activities	5,485	5,485			
Manufacturing activities	10,214	10,214			
Selling, general and administrative activities	1,822	1,822			
Total purchase obligations	17,521	17,521			
Total	$ 28,865	$ 19,291	$ 3,931	$ 3,773	$ 1,870

(1) Does not include milestone or contractual payment obligations if the amount and timing of such obligations are unknown or uncertain.

(2) Includes operating expenses of lease offices and research facilities.

(3) Includes non-cancelable and cancelable contracts made in the normal course of our business.

As of December 31, 2011, we had no long-term debt or capital lease obligations.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors may include, but are not limited to, the following:

- the rate of progress and cost of research and development activities;
- the number and scope of our research activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our ability to establish and maintain product discovery and development collaborations, including scale-up manufacturing costs for our partners product candidates;
- the amount of product sales for *Hylenex* recombinant;

the costs of obtaining and validating additional manufacturers of Hylenex recombinant;

the effect of competing technological and market developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

the extent to which we acquire or in-license new products, technologies or businesses.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies Adoption of Recent Accounting Pronouncements* and *Pending Adoption of Recent Accounting Pronouncements*, in the Notes to Consolidated Financial Statements for a discussion of recent accounting pronouncements and their effect, if any, on the Company.

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Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize this risk, we typically invest all, or substantially all, of our cash in money market funds that invest primarily in government securities. Our investment policy also permits investments in a variety of securities including commercial paper and government and non-government debt securities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of December 31, 2011 and 2010, we did not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions, and all of our cash and cash equivalents were in money market mutual funds and other investments that we believe to be highly liquid. If a 10% change in interest rates were to have occurred on December 31, 2011 and 2010, this change would not have had a material effect on the fair value of our investment portfolio as of that date nor our net loss for the years then ended. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

Item 8. ***Financial Statements and Supplementary Data***

Our financial statements are annexed to this report beginning on page F-1.

Item 9. ***Changes In and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decision regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

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Changes in Internal Control Over Financial Reporting

In connection with the reintroduction of *Hylenex* recombinant to the market in December 2011, we have developed additional internal controls over our processes for recognition of product sales revenue and cost of product sales and inventory related to *Hylenex* recombinant. Except for the additional internal controls related to *Hylenex* recombinant activities, there have been no significant changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our 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 our assets;

- 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 are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our 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 December 31, 2011. 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 December 31, 2011, our internal control over financial reporting is effective based on those criteria.

The independent registered public accounting firm that audited the consolidated financial statements that are included in this Annual Report on Form 10-K has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2011. The report appears below.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Halozyme Therapeutics, Inc.

We have audited Halozyme Therapeutics, Inc. s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Halozyme Therapeutics, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, Halozyme Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Halozyme Therapeutics, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, cash flows and stockholders equity for each of the three years in the period ended December 31, 2011 of Halozyme Therapeutics, Inc. and our report dated March 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 9, 2012

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Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item regarding directors is incorporated by reference to our Definitive Proxy Statement (the Proxy Statement) to be filed with the Securities and Exchange Commission in connection with our 2011 Annual Meeting of Stockholders under the heading Election of Directors. The information required by this item regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated by reference to the information under the caption Compliance with Section 16(a) of the Exchange Act to be contained in the Proxy Statement. The information required by this item regarding our code of ethics is incorporated by reference to the information under the caption Code of Conduct and Ethics to be contained in our Proxy Statement. The information required by this item regarding our audit committee is incorporated by reference to the information under the caption Board Meetings and Committees Audit Committee to be contained in our Proxy Statement. The information required by this item regarding material changes, if any, to the process by which stockholders may recommend nominees to our board of directors is incorporated by reference to the information under the caption Board Meetings and Committees Nominating and Governance Committee to be contained in our Proxy Statement.

Executive Officers

Gregory I. Frost, Ph.D. (40), President, Chief Executive Officer and Director. Dr. Frost was named Halozyme s President and Chief Executive Officer in December 2010. Dr. Frost was Vice President and Chief Scientific Officer from 1999 through December 2010. He brought the founding enzyme technologies to Halozyme in 1999 and has spent more than fifteen years conducting research on the extracellular matrix. Over his eleven years at Halozyme, Dr. Frost has led the R&D efforts from discovery through FDA approval for a number of biotechnology products. Prior to Halozyme, he was a Scientist at the Sidney Kimmel Cancer Center. In the Department of Pathology at the University of California, San Francisco, his work led directly to the purification, cloning, and characterization of the human hyaluronidase gene family, and the discovery of several metabolic disorders. He has authored multiple scientific peer-reviewed and invited articles in the hyaluronidase field and is an inventor on several key patents. Dr. Frost is a member of the American Association for Cancer Research and the American Society of Clinical Oncology and he is registered to practice before the U.S. Patent and Trademark Office. Dr. Frost earned his B.A. in biochemistry and molecular biology from the University of California, Santa Cruz, and his Ph.D. in the Department of Pathology at the University of California, San Francisco.

Kurt A. Gustafson (44), Vice President, Chief Financial Officer. Mr. Gustafson joined Halozyme in 2009 with extensive operational and managerial experience in financial planning and analysis, accounting, treasury and international responsibility gained during his 18 years with Amgen Inc. In his most recent position, as Vice President, Manufacturing Finance, Mr. Gustafson had financial responsibility for each of Amgen s worldwide manufacturing sites and the Cost Accounting Group. He was responsible for the financial planning, cost accounting, capital planning and procurement activities at each of these sites from 2006 to 2009. From 2004 to 2006, Mr. Gustafson was Vice President, Finance and CFO of Amgen International, responsible for financial planning and accounting for Ex-US operations. Stationed in Switzerland, Mr. Gustafson was responsible for Amgen s International Operations, which spanned Europe, the Middle East, Eastern Europe, North Africa and Australia. From 2000 to 2004, Mr. Gustafson headed up Corporate Financial Planning and Analysis, most recently as Vice President, Corporate Financial Planning & Analysis. In this role, he was responsible for worldwide consolidation of the company s forecasts. He also led the Corporate Business Analysis group, which provided financial and decision support to the Product Strategy Teams. From 1991 to 2000, Mr. Gustafson held multiple positions in Amgen s Treasury group with increasing levels of responsibility, most recently serving as

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Treasurer, where he oversaw the tax department and the customer finance group. Prior to joining Amgen, Mr. Gustafson worked in public accounting as Staff Auditor at Laventhol & Horwath in Chicago. He earned a B.A. in accounting from North Park University in Chicago and an M.B.A from University of California, Los Angeles.

James P. Shaffer (45), Vice President, Chief Commercial Officer. Mr. James Shaffer joined Halozyme in 2011 with over 23 years of Commercial Operations experience. From 2007 to 2011, he was at Clinical Data, Inc. where he was responsible for Marketing, Sales, Business Development and Manufacturing with his most recent position as Executive Vice President and Chief Commercial Officer. Prior to Clinical Data, he worked at New River Pharmaceuticals, Prestwick Pharmaceuticals, InterMune and GSK. He has experience in both large and small pharmaceutical companies in the areas of Neurology, Psychiatry, Oncology, GI and Pulmonary Care with specialized experience in developing and marketing genetic tests in Oncology and Cardiology. Mr. Shaffer received his M.B.A. in Marketing and B.S. in Economics from Ohio State University.

H. Michael Shepard, Ph.D. (62), Vice President, Chief Scientific Officer. Dr. Shepard joined Halozyme in 2009 as Vice President, Discovery Research with extensive experience in the biotechnology industry. He was promoted to Chief Scientific Officer in December 2010. Dr. Shepard has been a founder or co-founder of several biotechnology companies and his work has included protein therapeutics (Receptor BioLogix, Inc., 2003-2008), small molecules (NewBiotics, Inc., 1997-2002), gene therapy (Canji, Inc./Schering-Plough Corporation, 1992-1997), and monoclonal antibody therapeutics (Genentech, Inc. 1980-1992). While at Genentech, Dr. Shepard participated in many of the early programs that transformed Genentech into a commercial success. Among his most important accomplishments was the description of a key mechanism by which tumor cells can escape the host immune system. This work led to the discovery of the breast cancer drug Herceptin® (trastuzumab). In 2007, Dr. Shepard shared the Warren Alpert Prize from Harvard Medical School in recognition of this achievement. Dr. Shepard received his bachelor s degree in Zoology from the University of California, Davis and his Ph.D. in Molecular, Cellular and Developmental Biology from Indiana University. Dr. Shepard was also a postdoctoral fellow at Indiana University, supported by the Damon Runyon Cancer Research Foundation.

Jean I. Liu (43), Vice President, General Counsel and Secretary. Ms. Liu joined Halozyme in 2011. Prior to Halozyme, she served as the Chief Legal Officer and Secretary of Durect Corporation (Durect) from 1998 to 2011. She has 20 years of professional experience advising pharmaceutical and biotechnology companies. Ms. Liu s early career included work at Pillsbury, Madison & Sutro (now Pillsbury Winthrop) and the Venture Law Group where she focused on broad areas of legal advisory for early stage companies, including technology transfer, licensing, patents, and copyright and trademark litigation. During her tenure at Durect, she held a number of titled roles as the senior most legal officer where her experience expanded to include securities and regulatory law, M & A and financing, corporate governance and board matters. Ms. Liu obtained her B.S. in Biology with highest distinction from the University of Michigan at Ann Arbor, her M.S.in Biology from Stanford University, and her J.D. from Columbia University where she was a Harlan Fiske Scholar.

William J. Fallon (55), Vice President, Manufacturing & Operations. Mr. Fallon joined Halozyme in 2006 as Vice President, Manufacturing & Operations. His responsibilities include oversight of all aspects of internal and external manufacturing and facilities operations, as well as bioprocess development. Prior to Halozyme, he served as President and Chief Executive Officer of Cytovance Biologics, a contract manufacturing organization that provides manufacturing and development services to the biotechnology industry. From 2001 to 2003, he was Vice President of Technical Operations at Genzyme Corporation, having held the same position at Novazyme Pharmaceuticals, Inc. prior to its acquisition by Genzyme in 2001. Mr. Fallon joined Novazyme from Transkaryotic Therapies, where he was Vice President of Manufacturing from 1998 to 2001. From 1993 to 1998, he was employed in several management positions for the Ares-Serono Group, including Vice President, U.S. Manufacturing Operations. In this role, he served as general manager, overseeing the production and distribution of all of Serono s approved biotechnology products in the United States. From 1990 to 1992, he was Director of Manufacturing for Centocor, Inc. His prior experience also includes various management and operational roles at Invitron Corporation and Travenol-Genentech Diagnostics. Mr. Fallon earned a B.S. in marine science and a B.A. in biology from Long Island University, and an M.S. in biology from Northeastern University.

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Item 11. ***Executive Compensation***

The information required by this item is incorporated by reference to the information under the caption Executive Compensation to be contained in the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Information relating to securities authorized for issuance under our equity compensation plans is set forth in Part II, Item 5, Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities above in this Annual Report. The other information required by this item is incorporated by reference to the information under the caption Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters to be contained in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item is incorporated by reference to the information under the caption Certain Relationships and Related Transactions to be contained in the Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference to the information under the caption Principal Accounting Fees and Services contained in the Proxy Statement.

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PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) Documents filed as part of this report.

1. Financial Statements:

2. List of all Financial Statement schedules.

All other schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits:

2.1	Agreement and Plan of Merger, dated November 14, 2007, by and between the Registrant and the Registrant s predecessor Nevada corporation(1)
3.1	Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on October 7, 2007(2)
3.2	Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock(1)
3.3	Bylaws, as amended(2)
4.1	Amended Rights Agreement between Corporate Stock Transfer, as rights agent, and Registrant, dated November 12, 2007(18)
10.1	License Agreement between University of Connecticut and Registrant, dated November 15, 2002(3)
10.2	First Amendment to the License Agreement between University of Connecticut and Registrant, dated January 9, 2006(8)
10.3*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (6)
10.4*	First Amendment to the Commercial Supply Agreement between Avid Bioservices, Inc. and Registrant, dated December 15, 2006(13)
10.5*	Clinical Supply Agreement between Cook Pharmica, LLC and Registrant, dated August 15, 2008(22)
10.6#	DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder(5)
10.7#	2004 Stock Plan and Form of Option Agreement thereunder(4)

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10.8#	Halozyme Therapeutics, Inc. 2005 Outside Directors Stock Plan(7)
10.9#	Form of Stock Option Agreement (2005 Outside Directors Stock Plan)(11)
10.10#	Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan)(11)
10.11#	Halozyme Therapeutics, Inc. 2006 Stock Plan(10)
10.12#	Form of Stock Option Agreement (2006 Stock Plan)(11)
10.13#	Form of Restricted Stock Agreement (2006 Stock Plan)(11)
10.14#	Halozyme Therapeutics, Inc. 2008 Stock Plan(19)
10.15#	Form of Stock Option Agreement (2008 Stock Plan)(25)
10.16#	Form of Restricted Stock Agreement (2008 Stock Plan)(25)
10.17#	Halozyme Therapeutics, Inc. 2008 Outside Directors Stock Plan(19)
10.18#	Form of Restricted Stock Agreement (2008 Outside Directors Stock Plan)(25)
10.19#	Halozyme Therapeutics, Inc. 2011 Stock Plan(29)
10.20#	Form of Stock Option Agreement (2011 Stock Plan)(29)
10.21#	Form of Stock Option Agreement for Executive Officers (2011 Stock Plan)(29)
10.22#	Form of Restricted Stock Units Agreement (2011 Stock Plan)(29)
10.23#	Form of Restricted Stock Award Agreement (2011 Stock Plan)(29)
10.24#	Form of Indemnity Agreement for Directors and Executive Officers(17)
10.25#	Outside Director Compensation Plan(21)
10.26#	2008 Senior Executive Incentive Structure(20)
10.27#	2009 Senior Executive Incentive Plan(23)
10.28#	2010 Senior Executive Incentive Plan(26)
10.29#	Change in Control Policy(20)
10.30#	Severance Policy(21)
10.31*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.32*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.33*	License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.34	Termination Agreement between Halozyme Inc., Baxter Healthcare Corporation and Baxter Healthcare S.A, effective January 7, 2011(28)
10.35*	Enhanze Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(16)
10.36*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(12)
10.37	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(15)

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10.38	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(15)
10.39	Amended and Restated Lease (11388 Sorrento Valley Road), effective as of June 10, 2011(30)
10.40	Lease (11404 and 11408 Sorrento Valley Road), effective as of June 10, 2011(30)
10.41	Underwriting Agreement between Halozyme Therapeutics, Inc. and Jefferies & Company, Inc., dated June 23, 2009(27)
10.42	Underwriting Agreement between Halozyme Therapeutics, Inc. and Barclays Capital Inc., dated September 8, 2010(25)
10.43	Underwriting Agreement between Halozyme Therapeutics, Inc. and Barclays Capital Inc., dated February 10, 2012(31)
21.1	Subsidiaries of Registrant(9)
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Halozyme Therapeutics, Inc. Annual Report on Form 10-K for the year ended December 31, 2011 formatted in eXtensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows and (iv) related notes, tagged as block of text**.

(1) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed November 20, 2007 (File No. 001-32335).

(2) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed December 12, 2011 (File No. 001-32335).

(3) Incorporated by reference to the Registrant s Registration Statement on Form SB-2 filed with the Commission on April 23, 2004 (File No. 333-114776).

(4) Incorporated by reference to the Registrant s amendment number two to the Registration Statement on Form SB-2 filed with the Commission on July 23, 2004 (File No. 333-114776).

(5) Incorporated by reference to the Registrant s Registration Statement on Form S-8 filed with the Commission on October 26, 2004 (File No. 333-119969).

(6) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 22, 2005 (File No. 001-32335).

(7) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed July 6, 2005 (File No. 001-32335).

(8) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed January 12, 2006 (File No. 001-32335).

(9) Incorporated by reference to the Registrant s Annual Report on Form 10-KSB/A, filed March 29, 2005 (File No. 001-32335).

(10) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed March 24, 2006 (File No. 001-32335).

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(11) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q, filed August 8, 2006 (File No. 001-32335).

(12) Incorporated by reference to the Registrant s Current Report on Form 8-K/A, filed December 15, 2006 (File No. 001-32335).

(13) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed December 21, 2006 (File No. 001-32335).

(14) Incorporated by reference to the Registrant s Current Report on Form 8-K/A, filed February 20, 2007 (File No. 001-32335).

(15) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed July 31, 2007 (File No. 001-32335).

(16) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed September 12, 2007 (File No. 001-32335).

(17) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed December 20, 2007 (File No. 001-32335).

(18) Incorporated by reference to the Registrant s Annual Report on Form 10-K, filed March 14, 2008 (File No. 001-32335).

(19) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed March 19, 2008 (File No. 001-32335).

(20) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed April 21, 2008 (File No. 001-32335).

(21) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q, filed May 9, 2008 (File No. 001-32335).

(22) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q, filed November 7, 2008 (File No. 001-32335).

(23) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 9, 2009 (File No. 001-32335).

(24) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed June 23, 2009 (File No. 001-32335).

(25) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q, filed August 7, 2009 (File No. 001-32335).

(26) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 8, 2010 (File No. 001-32335).

(27) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed September 9, 2010 (File No. 001-32335).

(28) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed January 10, 2011 (File No. 001-32335).

(29) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed May 6, 2011 (File No. 001-32335).

(30) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed June 16, 2011 (File No. 001-32335).

(31) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 10, 2012 (File No. 001-32335).

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* Confidential treatment has been requested for certain portions of this exhibit. These portions have been omitted from this agreement and have been filed separately with the Securities and Exchange Commission.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

# Indicates management contract or compensatory plan or arrangement.

(c) Financial Statement Schedules. See Item 15(a) 2 above.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on March 9, 2012.

Halozyme Therapeutics, Inc.,

a Delaware corporation

Date: March 9, 2012

By: /s/ Gregory I. Frost, Ph.D.
Gregory I. Frost, Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Gregory I. Frost and Kurt A. Gustafson, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Annual Report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gregory I. Frost, Ph.D. Gregory I. Frost, Ph.D.	President and Chief Executive Officer (Principal Executive Officer), Director	March 9, 2012
/s/ Kurt A. Gustafson Kurt A. Gustafson	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2012
/s/ Kenneth J. Kelley Kenneth J. Kelley	Chairman of the Board of Directors	March 9, 2012
/s/ Robert L. Engler, M.D. Robert L. Engler, M.D.	Director	March 9, 2012
/s/ Kathryn E. Falberg Kathryn E. Falberg	Director	March 9, 2012
/s/ Randal J. Kirk Randal J. Kirk	Director	March 9, 2012

/s/ Connie L. Matsui Connie L. Matsui	Director	March 9, 2012
/s/ John S. Patton, Ph.D. John S. Patton, Ph.D.	Director	March 9, 2012

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Halozyme Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Halozyme Therapeutics, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, cash flows and stockholders equity for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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 consolidated financial position of Halozyme Therapeutics, Inc. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenue recognition as a result of the adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements*, effective January 1, 2011.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Halozyme Therapeutics, Inc. s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 9, 2012

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HALOZYME THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,825,527	$ 83,255,848
Accounts receivable, net	2,262,465	2,328,268
Inventories, net	567,263	193,422
Prepaid expenses and other assets	8,332,242	3,720,896
Total current assets	63,987,497	89,498,434
Property and equipment, net	1,771,048	1,846,899
Total Assets	$ 65,758,545	$ 91,345,333
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,556,859	$ 3,820,368
Accrued expenses	5,615,574	8,605,569
Deferred revenue, current portion	4,129,407	2,917,129
Total current liabilities	17,301,840	15,343,066
Deferred revenue, net of current portion	36,754,583	55,176,422
Deferred rent, net of current portion	802,006	474,389
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock $0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding		
Common stock $0.001 par value; 150,000,000 shares authorized; 103,989,272 and 100,580,849 shares issued and outstanding at December 31, 2011 and 2010, respectively	103,990	100,581
Additional paid-in capital	255,817,772	245,502,670
Accumulated deficit	(245,021,646)	(225,251,795)
Total stockholders equity	10,900,116	20,351,456
Total Liabilities and Stockholders Equity	$ 65,758,545	$ 91,345,333

See accompanying notes to consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2011	2010	2009
REVENUES:			
Product sales, net	$ 1,836,102	$ 895,518	$ 970,847
Revenues under collaborative agreements	54,250,334	12,728,597	12,700,458
Total revenues	56,086,436	13,624,115	13,671,305
OPERATING EXPENSES:			
Cost of product sales	257,834	985,283	311,891
Research and development	57,563,470	51,773,504	56,614,266
Selling, general and administrative	18,104,073	15,122,960	15,203,408
Total operating expenses	75,925,377	67,881,747	72,129,565
OPERATING LOSS	(19,838,941)	(54,257,632)	(58,458,260)
OTHER INCOME (EXPENSE):			
Interest income, net	63,530	49,015	100,747
Other income (expense)	5,560	966,967	(3,010)
Total other income, net	69,090	1,015,982	97,737
NET LOSS	$ (19,769,851)	$ (53,241,650)	$ (58,360,523)
Basic and diluted net loss per share	$ (0.19)	$ (0.56)	$ (0.67)
Shares used in computing basic and diluted net loss per share	102,566,089	94,357,695	86,700,094

See accompanying notes to consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2011	2010	2009
Operating activities:			
Net loss	$ (19,769,851)	$ (53,241,650)	$ (58,360,523)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	5,569,899	4,866,325	4,526,030
Depreciation and amortization	1,095,823	1,507,925	1,443,738
(Gain) loss on disposal of equipment	(1,566)	13,542	2,685
Changes in operating assets and liabilities:			
Accounts receivable	65,803	1,915,641	3,020,501
Inventory	(373,841)	966,129	(718,228)
Prepaid expenses and other assets	(4,611,346)	(2,147,119)	1,017,372
Accounts payable and accrued expenses	711,777	3,437,089	(2,000,233)
Deferred rent	172,438	(314,747)	(113,343)
Deferred revenue	(17,209,561)	(2,388,641)	11,033,736
Net cash used in operating activities	(34,350,425)	(45,385,506)	(40,148,265)
Investing activities:			
Purchases of property and equipment	(828,508)	(646,544)	(1,461,021)
Net cash used in investing activities	(828,508)	(646,544)	(1,461,021)
Financing activities:			
Proceeds from issuance of common stock, net		59,965,059	38,174,371
Proceeds from exercise of stock options, net	4,748,612	1,858,333	1,018,357
Proceeds from exercise of warrants, net			6,165,158
Net cash provided by financing activities	4,748,612	61,823,392	45,357,886
Net increase (decrease) in cash and cash equivalents	(30,430,321)	15,791,342	3,748,600
Cash and cash equivalents at beginning of period	83,255,848	67,464,506	63,715,906
Cash and cash equivalents at end of period	$ 52,825,527	$ 83,255,848	$ 67,464,506
Supplemental disclosure of non-cash investing and financing activities:			
Accounts payable for purchases of property and equipment	$ 189,898	$ 13,806	$ 143,493

See accompanying notes to consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

Year Ended December 31, 2011, 2010 and 2009

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount			
BALANCE AT JANUARY 1, 2009	81,553,654	$ 81,554	$ 128,948,064	$ (113,649,622)	$ 15,379,996
Share-based compensation expense			4,526,030		4,526,030
Issuance of common stock for cash, net	6,150,000	6,150	38,168,221		38,174,371
Issuance of common stock pursuant to exercise of warrants, net	3,140,780	3,141	6,162,017		6,165,158
Issuance of common stock pursuant to exercise of stock options	717,322	717	1,017,447		1,018,164
Issuance of restricted stock awards	120,000	120	73		193
Net loss				(58,360,523)	(58,360,523)
BALANCE AT DECEMBER 31, 2009	91,681,756	91,682	178,821,852	(172,010,145)	6,903,389
Share-based compensation expense			4,866,325		4,866,325
Issuance of common stock for cash, net	8,300,000	8,300	59,956,759		59,965,059
Issuance of common stock pursuant to exercise of stock options	479,093	479	1,857,734		1,858,213
Issuance of restricted stock awards	120,000	120			120
Net loss				(53,241,650)	(53,241,650)
BALANCE AT DECEMBER 31, 2010	100,580,849	100,581	245,502,670	(225,251,795)	20,351,456
Share-based compensation expense			5,569,899		5,569,899
Issuance of common stock pursuant to exercise of stock options	3,045,540	3,045	4,745,447		4,748,492
Issuance of restricted stock awards	347,883	349	(229)		120
Issuance of common stock pursuant to exercise of restricted stock units	15,000	15	(15)		
Net loss				(19,769,851)	(19,769,851)
BALANCE AT DECEMBER 31, 2011	103,989,272	$ 103,990	$ 255,817,772	$ (245,021,646)	$ 10,900,116

See accompanying notes to consolidated financial statements.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements

1. Organization and Business

Halozyme Therapeutics, Inc. (Halozyme or the Company) is a biopharmaceutical company dedicated to developing and commercializing innovative products that advance patient care. The Company s research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, the Company has developed unique scientific expertise that allows the Company to pursue this target-rich environment for the development of future therapies.

The Company s research focuses primarily on human enzymes that alter the extracellular matrix. The Company s lead enzyme, recombinant human hyaluronidase (rHuPH20), temporarily degrades hyaluronan, a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. The Company is also developing novel enzymes that may target other matrix structures for therapeutic benefit. The Company s Enhanze technology is the platform for the delivery of proprietary small and large molecules. The Company applies its research products in partnership with other companies as well as for its own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

The Company s operations to date have involved: (i) organizing and staffing its operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing its technology; (iii) undertaking product development for the Company s existing product and a limited number of product candidates; (iv) supporting the development of partnered product candidates and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). The Company continues to increase its focus on its proprietary product pipeline and has expanded investments in its proprietary product candidates. The Company currently has multiple proprietary programs in various stages of research and development. In addition, the Company currently has collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (Roche), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma), and Intrexon Corporation (Intrexon), to apply Enhanze technology to these partners biological therapeutic compounds. The Company also had another partnership with Baxter, under which Baxter had worldwide marketing rights for the Company s marketed product, *Hylenex* recombinant (Hylenex Partnership). The Company and Baxter mutually agreed to terminate the Hylenex Partnership in January 2011. In December 2011, the Company reintroduced *Hylenex* recombinant to the market. Currently, the Company has received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from its partnerships.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the amounts reported in the Company s consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management s estimates.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with original maturities of three months or less from the original purchase date.

Concentrations of Credit Risk, Sources of Supply and Significant Customers

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalent balances with one major commercial bank and a major investment firm. Deposits held with the bank and investment firm exceed the amount of insurance provided on such deposits.

The Company has collaborative partnerships with pharmaceutical companies under which the Company receives payments for license fees, milestone payments for specific achievements designated in the collaborative agreements and reimbursements of research and development services. In addition, the Company sells *Hylenex* recombinant in the United States to a limited number of established wholesale distributors in the pharmaceutical industry. Credit is extended based on an evaluation of the customer s financial condition, and collateral is not required. Management monitors the Company s exposure to accounts receivable by periodically evaluating the collectibility of the accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at December 31, 2011 and 2010. Approximately 82% of accounts receivable balance as of December 31, 2011 represents amounts due from Roche, Baxter and Viropharma. Approximately 100% of the accounts receivable balance as of December 31, 2010 represents amounts due from Roche and Baxter. For the years ended December 31, 2011, 2010 and 2009, 19%, 52% and 76% of total revenues were from Roche and 42%, 42% and 20% of total revenues were from Baxter, respectively. In addition, for the year ended December 31, 2011, 22% and 16% of total revenues were from Viropharma and Intrexon, respectively.

Worldwide revenues from external customers for the years ended December 31, 2011, 2010 and 2009 consisted of domestic revenues of approximately $44.9 million, $6.0 million and $2.8 million, respectively, and foreign revenues of approximately $11.2 million, $7.6 million and $10.8 million, respectively. Of the Company s total foreign revenues for the years ended December 31, 2011, 2010 and 2009, approximately $10.4 million, $7.2 million, $10.4 million, respectively, were attributable to Switzerland. The Company attributes revenues under collaborative agreement to the individual countries where the partner is headquartered. The Company attributes revenues from product sales to the individual countries to which the product is shipped. For the years ended December 31, 2011, 2010 and 2009, the Company had no foreign based operations and the Company did not have any long-lived assets located in foreign countries.

The Company relies on two third-party manufacturers for the supply of the bulk formulation of rHuPH20 which is the active pharmaceutical ingredient (API) in *Hylenex* recombinant and each of its partners product candidates. Payments due to these suppliers represent 59% and 32% of the accounts payable balance at December 31, 2011 and 2010, respectively. The Company also relies on a third-party manufacturer for the fill and finish of *Hylenex* recombinant product under a contract the Company entered into June 2011. Payments due to this supplier represent 3.7% of the accounts payable balance at December 31, 2011 and 2010, respectively.

Accounts Receivable

Accounts receivable is recorded at the invoiced amount and is non-interest bearing. Accounts receivable is recorded net of allowances for doubtful accounts, cash discounts for prompt payment and distribution fees.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Currently, the allowance for doubtful accounts is zero as the collectibility of accounts receivable is reasonably assured. Allowances for prompt payment discounts and distribution fees were approximately $15,000 as of December 31, 2011.

Inventories, Net

Inventories, net are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by the Company s contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

Raw materials inventories at December 31, 2011 and 2010 consists of raw materials used in the manufacture of the Company s bulk drug material for *Hylenex* recombinant product. Work-in-process inventories consist of in-process *Hylenex* recombinant. Finished goods inventories consist of finished *Hylenex* recombinant product.

As a result of the termination of the HYLENEX Partnership in January 2011, the Company recorded write-down for inventory obsolescence of approximately $166,000 and $875,000 for *Hylenex* recombinant API for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011 and 2010, the reserve for inventory obsolescence was approximately zero and $875,000, respectively.

The Company expenses costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as the Company believes future commercialization is probable and future economic benefit is expected to be realized. For products that have been approved by the FDA, inventories used in clinical trials are expensed at the time the inventories are packaged for the clinical trial. Prior to receiving approval from the FDA or comparable regulatory agencies in foreign countries, costs related to purchases of the API and the manufacturing of the product candidate is recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized into inventories.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Equipment is depreciated using the straight-line method over their estimated useful lives of three years and leasehold improvements are amortized using the straight-line method over the estimated useful life of the asset or the lease term, whichever is shorter.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. For the years ended December 31, 2011, 2010 and 2009, there has been no impairment of the value of such assets.

Fair Value of Financial Instruments

The Company follows the authoritative guidance for fair value measurements and disclosures, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The framework for measuring fair value provides a hierarchy that prioritizes the inputs to valuation techniques used in measuring fair value as follows:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities,

Level 2 Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, and

Level 3 Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The Company s financial instruments include cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses. The carrying amounts of financial instruments approximate their fair value due to their short maturities. Cash equivalents of approximately $51.8 million and $79.8 million at December 31, 2011 and 2010, respectively, are carried at fair value and are classified within Level 1 of the fair value hierarchy because they are valued based on quoted market prices for identical securities. The Company has no instruments that are classified within Level 2 and Level 3.

Deferred Rent

Rent expense is recorded on a straight-line basis over the initial term of any lease. The difference between rent expense accrued and amounts paid under any lease agreement is recorded as deferred rent in the accompanying consolidated balance sheets.

Comprehensive Income/Loss

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was the same as the Company s net loss for all periods presented.

Revenue Recognition

The Company generates revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, license fees, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and/or royalties on sales of products resulting from collaborative agreements.

The Company recognizes revenues in accordance with the authoritative guidance for revenue recognition. The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

Product Sales, Net *Hylenex* recombinant was approved for marketing by the U.S. Food and Drug Administration (FDA) in December 2005. From 2005 through January 7, 2011, the Company had a partnership with Baxter for the worldwide market rights for *Hylenex* recombinant. Baxter commercially launched *Hylenex*

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

recombinant in October 2009. However, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the product manufactured by Baxter was not in compliance with the requirements of the underlying partnership. Effective January 7, 2011, the Company and Baxter mutually agreed to terminate the partnership. During the second quarter of 2011, the Company submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant to the market. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant.

In December 2011, the Company reintroduced *Hylenex* recombinant to the market, shipped initial stocking orders to its wholesaler customers and began promoting *Hylenex* recombinant through its sales force. The Company sells *Hylenex* recombinant in the United States to wholesale pharmaceutical distributors, who in-turn sell the product to hospitals and other end-user customers. The wholesale distributors take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, the Company has no significant obligations for future performance to generate pull-through sales; however, it does allow the wholesale distributors to return product that is damaged or received in error. In addition, the Company allows for product to be returned beginning six months prior to and ending twelve months following product expiration. Given the Company s limited experience history of selling *Hylenex* recombinant and the lengthy return period, the Company currently cannot reliably estimate expected returns and chargebacks of *Hylenex* recombinant at the time of product receipt by the wholesale distributors. Therefore, the Company does not recognize revenue upon delivery of *Hylenex* recombinant to the wholesale distributor until the point at which the Company can reliably estimate expected product returns and chargebacks from the wholesale distributors. Shipments of *Hylenex* recombinant are recorded as deferred revenue until evidence exists to confirm that pull-through sales to the hospitals or other end-user customers have occurred. The Company recognizes revenue when the product is sold through from the distributors to the distributors customers. In addition, the costs of manufacturing *Hylenex* recombinant associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized. The Company estimates sell-through revenue and certain gross to net sales adjustments based on analyses of third-party information including information obtained from certain distributors with respect to their inventory levels and sell-through amounts to the distributors customers.

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with wholesaler customers, hospitals and the levels of inventory within the distribution channels that may result in future discounts taken. The Company must make significant judgments in determining these allowances. If actual results differ from the Company s estimates, the Company will be required to make adjustment to these allowances in the future, which could have an effect on product sales revenue in the period of adjustment. The Company s product sales allowances include:

Distribution Fees. The distribution fees, based on contractually determined rates, arise from contractual agreements the Company has with certain wholesale distributors for distribution services they provide with respect to *Hylenex* recombinant. At the time the sale is made to the respective wholesale distributors, the Company records an allowance for distribution fees by reducing its accounts receivable and deferred revenue associated with such product sales.

Prompt Payment Discounts. The Company offers cash discounts to certain wholesale distributors as an incentive to meet certain payment terms. At the time the sale is made to the respective wholesale distributors, the Company records an allowance for distribution fees by reducing its accounts receivable and deferred revenue associated with such product sales.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Chargebacks. The Company provides discounts to certain hospitals. These hospitals purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the hospitals paid for the product. Given the Company s lack of historical sales data, the Company recognizes chargebacks in the same period the related product sales revenue is recognized and reduces its accounts receivable accordingly.

Product Returns. The product return reserve is based on management s best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The product return reserve is recorded as a reduction of product sales revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.

For the year ended December 31, 2011, the Company recorded product sales revenue of approximately $35,000 related to *Hylenex* recombinant, net of estimated distribution fees, prompt payment discounts and product returns totaling approximately $8,000. The Company has a deferred revenue balance of approximately $167,000 at December 31, 2011 for *Hylenex* recombinant shipments, which is net of estimated distribution fees, prompt pay discounts and product returns. In addition, inventory at December 31, 2011 included a deferred cost of product sales of approximately $31,000 associated with *Hylenex* recombinant shipments to wholesalers. At the time the Company can reliably estimate product returns and chargebacks from the wholesalers, the Company will record a one-time increase in net product sales revenue related to the recognition of product sales revenue previously deferred.

Prior to the termination of the Hylenex Partnership with Baxter in January 2011, the Company supplied Baxter with API for *Hylenex* recombinant at its fully burdened cost plus a margin. Baxter filled and finished *Hylenex* recombinant and held it for subsequent distribution, at which time the Company ensured it met product specifications and released it as available for sale. Because of the Company s continued involvement in the development and production process of *Hylenex* recombinant, the earnings process was not considered to be complete. Accordingly, the Company deferred the revenue and related product costs on the API for *Hylenex* recombinant until the product was filled, finished, packaged and released. Baxter could only return the API for *Hylenex* recombinant to the Company if it did not conform to the specified criteria set forth in the Hylenex Partnership or upon termination of such agreement. In addition, the Company received product-based payments upon the sale of *Hylenex* recombinant by Baxter, in accordance with the terms of the Hylenex Partnership. Product-based revenues were recognized as the Company earned such revenues based on Baxter s shipments of *Hylenex* recombinant to its distributors when such amounts could be reasonably estimated. See Note 7, *Deferred Revenue*, for further discussion.

Revenues under Collaborative Agreements The Company entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of rHuPH20 in the development and commercialization of the collaborators biologic compounds. The collaborative agreements contain multiple elements including nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specific milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the collaborator and/or royalties on sales of products resulting from collaborative agreements. The Company analyzes each element of its collaborative agreements and considers a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13 on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

fair value of the undelivered items and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, the Company recognizes revenue on nonrefundable upfront payments and license fees from these collaborative agreements over the period of significant involvement under the related agreements.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, the Company follows the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under the Company s collaborative agreements include (i) the license to the Company s rHuPH20 technology, (ii) at the collaborator s request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator s request, supply of rHuPH20 API which is reimbursed at the Company s cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the collaborator and the availability of research expertise in this field in the general marketplace.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE), of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of rHuPH20 API, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the Company s price to the collaborator is fixed or determinable and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The terms of the Company s collaborative agreements provide for milestone payments upon achievement of certain development and regulatory events and/or specified sales volumes of commercialized products by the collaborator. Prior to the Company s adoption of the Milestone Method, the Company recognized milestone payments upon the achievement of specified milestones if: (1) the milestone was substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees were nonrefundable and (3) the Company s performance obligations after the milestone achievement would continue to be funded by the Company s collaborator at a level comparable to the level before the milestone achievement.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Effective January 1, 2011, the Company adopted on a prospective basis the Milestone Method. Under the Milestone Method, the Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone,

2. The consideration relates solely to past performance, and

3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of rHuPH20 API is recognized when the API has met all specifications required for the collaborator acceptance and title and risk of loss have transferred to the collaborator. The Company does not directly control when any collaborator will request research and development services or supply of rHuPH20 API; therefore, the Company cannot predict when it will recognize revenues in connection with research and development services and supply of rHuPH20 API. Royalties to be received based on sales of licensed products by the Company s collaborators incorporating the Company s rHuPH20 API will be recognized as earned.

The collaborative agreements typically provide the collaborators the right to terminate such agreement in whole or on a product-by-product or target-by-target basis at any time upon 90 days prior written notice to the Company. There are no performance, cancellation, termination or refund provisions in any of the Company s collaborative agreements that contain material financial consequences to the Company.

See Note 3, *Collaborative Agreements,* and Note 7, *Deferred Revenue,* for further discussion.

Cost of Product Sales

Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight costs, internal costs and manufacturing overhead associated with the production of *Hylenex* recombinant. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories. As a result of the termination of the Hylenex Partnership in January 2011, the Company recorded write-down of inventory obsolescence of $166,000 and $875,000 for *Hylenex* recombinant API for the years ended December 31, 2011 and 2010, respectively. There was no write-down of inventories for the year ended December 31, 2009.

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trials, research-related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as incurred when these expenditures relate to the Company s research and development efforts and have no alternative future uses.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed or such time when the Company does not expect the goods to be delivered or services to be performed.

Milestone payments that the Company makes in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. The Company considers the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the U.S. Food and Drug Administration or when other significant risk factors are abated. Management has viewed future economic benefits for all of the Company s licensed technology or product candidates to be uncertain and has expensed these amounts for accounting purposes.

Clinical Trial Expenses

Expenses related to clinical trials are accrued based on the Company s estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and clinical trials progress. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company modifies its accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Historically, the Company has had no material changes in its clinical trial expense accruals that would have had a material impact on its consolidated results of operations or financial position.

Restructuring Expense

In accordance with authoritative guidance for exit or disposal cost obligations, the Company records costs and liabilities associated with restructuring activities, mainly employee separation costs based on actual and estimates of fair value in the period the liabilities are incurred. In periods subsequent to initial measurement, liabilities are evaluated and adjusted as appropriate for changes in circumstances at least on a quarterly basis. See Note 13, *Restructuring Expense*, for further discussion.

Share-Based Payments

The Company records compensation expense associated with stock options and other share-based awards in accordance with the authoritative guidance for stock-based compensation. The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense on a straight-line basis, net of estimated forfeitures, over the requisite service period of the award. Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Share-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any recognized compensation expense is reversed. As share-based compensation expense recognized is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be approximately 10% for employees in the years ended December 31, 2011, 2010 and 2009 based on the Company s historical experience for the years ended December 31, 2011 and 2010 and those of its peer group for the year ended December 31, 2009.

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Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements (Continued)

Total share-based compensation expense related to share-based awards for the years ended December 31, 2011, 2010 and 2009 was comprised of the following:

	Year Ended December 31,		
	2011	2010	2009
Research and development	$ 2,815,362	$ 2,517,172	$ 2,441,907
Selling, general and administrative	2,754,537	2,349,153	2,084,123
Share-based compensation expense	$ 5,569,899	$ 4,866,325	$ 4,526,030