HALOZYME THERAPEUTICS INC
Form 424B5
February 09, 2012
Table of Contents

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-179444

This preliminary prospectus supplement relates to an effective registration statement under the Securities Act of 1933, but is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Preliminary Prospectus Supplement dated February 9, 2012

PROSPECTUS SUPPLEMENT

(To Prospectus dated February 9, 2012)

6,800,000 Shares

Common Stock

This is an offering of 6,800,000 shares of the common stock of Halozyme Therapeutics, Inc.

Our common stock is listed on The NASDAQ Global Market under the symbol HALO. The last reported sale price of our common stock on The NASDAQ Global Market on February 8, 2012 was $11.28 per share.

Investing in our common stock involves significant risks. See Risk Factors beginning on page S-12 of this prospectus supplement and each of the Risk Factors on page 6 of the accompanying prospectus.

	Per Share	Total
Price to the public	$	$
Underwriting discounts and commissions	$	$
Proceeds to Halozyme Therapeutics, Inc. (before expenses)	$	$

We have granted Barclays Capital a 30-day option to purchase up to an additional 1,020,000 shares of common stock on the same terms and conditions set forth above.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus supplement or the prospectus to which it relates. Any representation to the contrary is a criminal offense.

Barclays Capital expects to deliver the shares on or about February , 2012.

Barclays Capital

Prospectus Supplement dated February , 2012

Table of Contents

TABLE OF CONTENTS

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement or the accompanying prospectus. You must not rely on any unauthorized information or representations. This prospectus supplement and the accompanying prospectus are an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of their respective dates.

Table of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of the offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated February 9, 2012, including the documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement. You should read this prospectus supplement and the accompanying prospectus, including the information incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, along with the information contained in any free writing prospectus that we have authorized for use in connection with this offering. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information in this prospectus supplement. We have not authorized anyone to provide you with different or additional information. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the respective dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

Table of Contents

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus, and may not contain all of the information that is important to you. This prospectus supplement and the accompanying prospectus include information about the offering as well as information regarding our business. You should read this prospectus supplement and the accompanying prospectus, including the information incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety. If you invest in our common stock, you are assuming a high degree of risk. See Risk Factors beginning on page S-12.

Our Business

Overview

Halozyme Therapeutics, Inc. is 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.

The company s research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, recombinant human PH20 enzyme, or rHuPH20, temporarily degrades hyaluronan, a matrix component in the skin, and facilitates the dispersion of drugs and fluids through the skin into circulation. rHuPH20 is the underlying drug delivery technology of *Hylenex*® recombinant (hyaluronidase human injection) for small molecules and fluids, and Enhanze Technology for the delivery of proprietary small and large molecules. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit.

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; and (iv) supporting the development of partnered product candidates. 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 these partners biological therapeutic compounds. We also had another partnership with Baxter, under which Baxter had worldwide marketing rights for our marketed product, *Hylenex* recombinant (hyaluronidase human injection), or Hylenex Partnership. *Hylenex* recombinant is a recombinant formulation of hyaluronidase that has received the approval from the U.S. Food and Drug Administration, or FDA, 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. We and Baxter mutually agreed to terminate the Hylenex Partnership in January 2011. In December 2011, we reintroduced *Hylenex* recombinant to the market. Our rHuPH20 technology is also being used in ICSI Cumulase®, a third party s marketed product used for *in vitro* fertilization, or IVF. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant and active pharmaceutical ingredients, or API, to the third party that produces ICSI Cumulase, 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

Table of Contents

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 has approved the submitted data and has granted the reintroduction of *Hylenex* recombinant. 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 will fill and finish *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 $226.6 million as of September 30, 2011.

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 an automatic shelf registration statement on Form S-3 (Registration No. 333-179444) on file 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 shelf registration statements 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.

Table of Contents

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:

Table of Contents

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. Combining rHuPH20 with a rapid acting analog insulin, i.e., insulin lispro (Humalog®), or Lispro-PH20, insulin aspart (Novolog®), or Aspart-PH20, and insulin glulisine (Apidra®), or collectively PH20 Analog, facilitates 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, a combination of analog insulin with rHuPH20 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, that will investigate the various attributes of our insulin candidates, have been completed or 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 insulin aspart co-mixed with rHuPH20 versus aspart alone at the Scientific Sessions of the American Diabetes Association in San Diego, California. The results demonstrated that aspart mixed with rHuPH20 has pharmacokinetic and glucodynamic profiles that were more consistent over infusion set life as compared to analog alone, and the combination 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 the 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 consistent insulin exposure 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 PH20 insulin analog formulations in patients with type 1 and type 2 diabetes. Both trials met the primary endpoint of non-inferiority of 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 PH20 Analog arms. Compared to insulin analog alone, PH20 Analog use resulted in a greater than 50% increase in the proportion of patients able to consistently achieve AACE (American Association of Clinical Endocrinologists) guidelines for post-prandial glucose targets in both type 1 and type 2 patients. Across all of the treatment groups, there was no meaningful difference in hypoglycemia incidence or event rates. Hypoglycemia events were generally mild, and adverse

events with PH20 Analog formulations were similar to those observed during the insulin analog comparator phase. Results are from two Phase 2 ultrafast insulin treatment studies, one in type 1 diabetes patients and one in type 2 patients, that compared two ultrafast insulin analog products formulated with rHuPH20 (Lispro-PH20 or Aspart-PH20) to an active comparator, Humalog. More than 110 patients enrolled in each of the trials and received an insulin analog alone and one of the Analog-PH20 treatments for 12 weeks along with basal insulin glargine. The primary endpoint of each study was a comparison of glycemic control, the main measurement that diabetes patients 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. We currently expect to present the results of these studies at a major medical meeting in June 2012.

We view insulin pens and pumps 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 pen market. We believe that the pre-administration of rHuPH20 would 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. We would expect to have results from this study in 2012.

PEGPH20

We have developed 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 our FDA-approved rHuPH20 enzyme, now known as PEGPH20, which converts rHuPH20 from 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. 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 tumor, which may enhance the chemotherapy s treatment effect. Increased blood flow may also enhance radiotherapy treatment effect. Our scientists have also shown that disrupting the specialized environment around tumors will directly inhibit the growth. Because HA accumulates in about 25% of all solid tumors, 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, or IV, 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 Phase 1b portion, the patients will receive the standard of care, gemcitabine, with PEGPH20. The objective of the first phase is to identity a safe and well-tolerated dose that will be selected for the second phase. The Phase 2 portion of the trial will compare gemcitabine alone versus gemcitabine with PEGPH20. The second phase will be a randomized, double-blind, placebo-controlled study to assess safety, tolerability, and efficacy of chemotherapy either with or without PEGPH20.

Table of Contents

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 medical 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 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 as once the mildly acidic conditions of the HTI-501 administration have been neutralized by the body, the enzyme becomes inactive. We are harnessing 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. HTI-501 is thought to act 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 medical 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, 2012 to 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, lasted a few minutes and did not require treatment. Data from this study support commencement of the Phase 2 portion of the clinical trial.

Enhanze Technology

Enhanze Technology is a proprietary delivery platform using our first approved enzyme: recombinant human hyaluronidase, or rHuPH20. This enzyme temporarily degrades HA. 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, 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

Table of Contents

subcutaneously. This change in the route of delivery to subcutaneous from 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 the Roche Partnership, under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds. 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 an additional ten targets. As of December 31, 2011, Roche has elected two additional 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 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.

Compounds directed at three of the five Roche exclusive targets have previously commenced clinical trials. One compound formulated with rHuPH20 (subcutaneous MabThera®) is in Phase 3 clinical trial, one compound formulated with rHuPH20 (subcutaneous Herceptin®) has completed 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 for a fixed dose of subcutaneously delivered version of Roche s anticancer biologic, Herceptin (trastuzumab), in women with early HER2-positive breast cancer who received a new, investigational subcutaneous injection of Herceptin. In the study, the subcutaneous formulation showed comparable results to Herceptin given as an IV infusion. The subcutaneous administration takes around 5 minutes to administer whereas the IV formulation (the current standard) takes around 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 and plans to file a marketing application to regulatory authorities in the European Union in 2012.

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab). The study investigates pharmacokinetics, efficacy and safety of MabThera SC. IV

Table of Contents

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 that they expect 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.

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 Enhanze Technology partnership, or the Gammagard Partnership. Under the terms of this partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID, or HyQ. 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, or ViroPharma Partnership, 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]). In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibition and to the Hereditary Angioedema, along with three additional orphan indications. Under the terms of the ViroPharma Partnership, ViroPharma paid a nonrefundable upfront license fee of $9.0 million. In addition, 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, 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 rHuPH20 API if requested by ViroPharma. In addition, we are entitled to receive additional cash payments potentially totaling $44.0 million for a product for treatment of Hereditary Angioedema and $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 and revert to us.

Table of Contents

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, delibitating 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 inhibitor relative to subcutaneous Cinryze administered alone. This cutting edge technology 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, or Intrexon Partnership, 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). Under the terms of the Intrexon Partnership, Intrexon paid a nonrefundable upfront license fee of $9.0 million. In addition, 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, 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 rHuPH20 API if requested by Intrexon. In addition, we are entitled to receive additional cash payments potentially totaling $44.0 million for each product for use in the exclusive field and $10.0 million for each product for use in the non-exclusive field upon achievement of development and regulatory milestones. We are also entitled to receive escalating royalties on product sales and a cash payment of $10.0 million upon achievement of a specified sales volume of product sales by Intrexon. 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 and revert to us. Intrexon s chief executive officer and chairman of its board of directors is also a member of the Company s board of directors.

Hylenex recombinant

Hylenex recombinant is a recombinant formulation of hyaluronidase that has received the 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. Pending the successful completion of a series of regulatory and sales events, Baxter would have been obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter was responsible for development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the Hylenex Partnership. We supplied Baxter with API for *Hylenex* recombinant, and Baxter prepared, filled, finished and packaged *Hylenex* recombinant and held it for subsequent distribution.

In October 2009, Baxter commenced the commercial launch of *Hylenex* recombinant for use in pediatric rehydration at the 2009 American College of Emergency Physicians (ACEP) scientific assembly. In addition, under the Hylenex Partnership, Baxter had a worldwide, exclusive license to develop and

Table of Contents

commercialize product combinations of rHuPH20 with Baxter hydration fluids and generic small molecule drugs, with the exception of combinations with (i) bisphosphonates, (ii) cytostatic and cytotoxic chemotherapeutic agents and (iii) proprietary small molecule drugs, the rights to which had been retained by us.

In May 2010, *Hylenex* recombinant was voluntarily recalled 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 has approved the submitted data and has granted the reintroduction of *Hylenex* recombinant. 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 in June 2011, under which Baxter will fill and finish *Hylenex* recombinant for us. On July 18, 2011, we and Baxter entered into the 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.

Corporate Information

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 us can be found on our website at www.halozyme.com. The information on our website is not part of this prospectus supplement.

Unless the context indicates otherwise or we expressly state to the contrary, as used in this prospectus supplement and the accompanying prospectus, the terms the Company, Halozyme, Halozyme Therapeutics, we, us and our refer to Halozyme Therapeutics, Inc., a Delaware corporation, and our operating subsidiary, Halozyme, Inc.

Table of Contents

THE OFFERING

Common stock we are offering	6,800,000 shares
Common stock covered by the underwriter s option to purchase additional shares	1,020,000 shares
Common stock outstanding immediately following this offering (excluding any shares subject to the underwriter s option to purchase additional shares)	110,447,930 shares
Risk Factors	Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-12.
Use of Proceeds	We intend to use the net proceeds from this offering to build commercial inventory for anticipated product launches, fund research and development of proprietary programs, and for general corporate purposes. See Use of Proceeds on page S-27.
NASDAQ Global Market symbol	HALO

The number of shares of common stock to be outstanding immediately after this offering as shown above assumes that all of the shares offered hereby are sold and is based on 103,647,930 shares of common stock outstanding as of September 30, 2011. This number of shares does not include 1,020,000 shares subject to the underwriter s option to purchase additional shares and also excludes, as of September 30, 2011:

- 5,413,331 shares of common stock issuable upon the exercise of outstanding stock options, having a weighted average exercise price of $4.40 per share;
- 163,000 shares of common stock issuable upon settlement of restricted stock units; and
- an aggregate of up to 5,666,687 shares of common stock reserved for future issuance under our equity incentive plans.

Randal J. Kirk, who serves as one of our directors, has indicated an interest in purchasing through one or more of his affiliates up to $15,000,000 of common stock in this offering at the price to the public. However, because indications of interest are not binding agreements or commitments to purchase, Mr. Kirk may elect not to purchase any shares in this offering or the underwriter may elect not to sell any shares in this offering to Mr. Kirk.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business.

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 revenue from product sales, licensing fees and milestone payments 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 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 September 30, 2011, we have incurred aggregate net losses of approximately $226.6 million.

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.*

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 Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce bulk API. These manufacturers each produce API under current Good Manufacturing Practices, or cGMP, for clinical uses. In addition,

Table of Contents

Avid currently produces API for commercialized products. 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.

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.

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. In January 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership and we reacquired all rights to *Hylenex* recombinant. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant. The FDA has approved the submitted data and has granted the reintroduction of *Hylenex* recombinant. We reintroduced *Hylenex* recombinant to the market in December 2011.

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

The rHuPH20 enzyme 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

Table of Contents

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;
- 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.

Table of Contents

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 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 has approved the submitted data and has granted the reintroduction of *Hylenex* recombinant. 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

Table of Contents

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 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,

Table of Contents

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
- injunctions or the imposition of civil or criminal penalties.

For example, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the HYLENEX 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 has approved the submitted data and has granted the rein