

HALOZYME THERAPEUTICS INC  
Form 10-K  
March 01, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K

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

For the fiscal year ended December 31, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32335

Halozyyme Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

11388 Sorrento Valley Road,  
San Diego, California

(Address of principal executive offices)  
(858) 794-8889

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class

Common Stock, \$0.001 Par Value

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.  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  No

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

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

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

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

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

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2012 was approximately \$784.5 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 February 25, 2013, there were 113,122,900 shares of the registrant's common stock issued, \$0.001 par value per share, and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2013 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part 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 “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “estimate,” “think,” “could,” “will,” “would,” “should,” “continue,” “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.

References to “Halozyme,” “the Company,” “we,” “us” and “our” refer to Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc. References to “Notes” refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

#### Overview

Halozyme is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding 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 technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

Our proprietary enzymes can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or to alter abnormal tissue structures for clinical benefit. We have chosen to exploit our technology and expertise in a balanced way to modulate both risk and spend by: (1) developing our own proprietary products in therapeutic areas with significant unmet medical needs, such as diabetes, oncology and dermatology, and (2) licensing our technology to biopharmaceutical companies to collaboratively develop products which combine our technology with the collaborators' proprietary compounds.

Our proprietary pipeline consists of multiple clinical stage products in diabetes, oncology and dermatology. We currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Pfizer Inc. (Pfizer), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma) and Intrexon Corporation (Intrexon), with three product candidates which have been submitted for regulatory approval in the U.S. and/or Europe as well as several others at various stages of development.

We were founded in 1998 and reincorporated from the State of Nevada to the State of Delaware in November 2007. Our operations to date have involved: (i) building infrastructure for and staffing our operations; (ii) acquiring, developing and securing proprietary protection for our technology; (iii) developing our proprietary product pipeline; (iv) entering into and supporting our

collaborations with other companies to advance licensed product candidates; and (v) selling our own approved commercial product, Hylenex<sup>®</sup> recombinant (hyaluronidase human injection). Currently, we have received only limited revenue from the sales of Hylenex recombinant, in addition to other revenues from our collaborations. Future revenues from the sales and/or royalties of our product candidates which have not been approved will depend on the ability of Halozyme and our collaborators to develop, manufacture, secure regulatory approvals and commercialize the product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$298.6 million as of December 31, 2012.

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](mailto:info@halozyme.com). Our website address is [www.halozyme.com](http://www.halozyme.com). Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. Our periodic and current reports that we filed with the SEC are available on our website at [www.halozyme.com](http://www.halozyme.com), free of charge, as soon as reasonably practicable after we have electronically filed such material with, or furnished them to, the SEC, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports. Further copies of these reports are located at the SEC's Public Reference Room at 100 F Street, N.W., Washington, D.C. 20549, and online at <http://www.sec.gov>.

#### Technology

##### rHuPH20

The majority of the product candidates in our current pipeline are based on rHuPH20, a patented human recombinant hyaluronidase enzyme. rHuPH20 temporarily breaks down hyaluronic acid (HA) - a naturally occurring substance that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. 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 rHuPH20 on the architecture of the subcutaneous space is temporary. rHuPH20 can thus be applied as a drug delivery platform to increase dispersion and absorption of other injected drugs and fluids that are injected under the skin or in the muscle thereby enhancing efficacy or convenience. For example, rHuPH20 can be used to convert drugs that must be delivered intravenously into subcutaneous injections or to reduce the number of subcutaneous injections needed for effective therapy. We refer to the application of rHuPH20 to facilitate the delivery of other drugs or fluids as Enhance<sup>™</sup> technology. rHuPH20 is also the active ingredient in our first commercially approved product, Hylenex recombinant.

##### Other Enzymes/Technologies

Additionally, we are expanding our scientific work to develop other enzymes and agents that target the extracellular matrix's unique aspects, giving rise to potentially new molecular entities that can be applicable to endocrinology, oncology and dermatology. For example, 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 (PEGPH20), that lasts for an extended period in the bloodstream, and may therefore better target solid tumors by degrading the surrounding HA and reducing the interstitial fluid pressure within malignant tumors to allow better penetration by chemotherapeutic agents. Also in development is HTI-501, which is an engineered drug formulation variant of cathepsin L (a lysosomal proteinase), that acts by degrading collagen. HTI-501 is a proprietary product candidate which is being developed for cellulite and other diseases/conditions involving collagen. HTI-501 is the first enzyme in the category of what we call conditionally-active biologic (CAB) - that is, biologics that are only active under certain physiologic conditions such as acidic conditions in the case of HTI-501. In theory, CABs should have the benefit of reducing side effects of therapeutic molecules through their selective action. We continue to conduct research aimed at further development of CABs.

### Strategy

Our business model is based both on developing our own proprietary products as well as entering into high value collaborations. This business model allows for growth in which revenue garnered from collaboration products buffers the spend on proprietary products, resulting in long term sustained growth with a quicker evolution to positive cash flow.

Key aspects of our corporate strategy include the following:

- Secure revenues from existing channels
- Grow existing and pursue new collaborations leveraging the clinical benefit of rHuPH20
- Advance proprietary programs
- Maintain fiscal discipline to manage business toward positive cash flow

#### 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 product candidates under development with our collaborators:

#### Proprietary Pipeline

##### Hylenex Recombinant (hyaluronidase human injection)

Hylenex recombinant is a formulation of rHuPH20 that has received the U.S. Food and Drug Administration (FDA) approval to facilitate subcutaneous fluid administration for achieving hydration, to increase the dispersion and absorption of other injected drugs and, in subcutaneous urography and to improve resorption of radiopaque agents. We reintroduced Hylenex recombinant to the market in December 2011 after resolution of a voluntary recall and the return by Baxter of marketing rights to us. Upon its return to the market, our focus was to take advantage of the initial markets previously developed by Baxter. We are continuing to assess our commercial and strategic options for the product to address additional uses such as in connection with insulin pumps as described further below under “More Physiologic (Ultrafast) Insulin Program.”

#### More Physiologic (Ultrafast) Insulin Program

Our lead proprietary program uses rHuPH20 with prandial (mealtime or rapid-acting) insulin 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 people living with diabetes.

The primary goal of our more physiologic 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 insulin 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 clinical trials investigating the various attributes of our insulin candidates have been completed.

We currently view two distinct opportunities to exploit the prandial insulin market. The first opportunity (what we refer to as the Multiple Daily Injection (MDI) market) is to combine rHuPH20 with a rapid acting analog insulin, e.g., insulin lispro (Humalog®) (Lispro-PH20), insulin aspart (Novolog®) (Aspart-PH20) and insulin glulisine (Apidra®), (each such combination, Analog-PH20), to accelerate their action. Based on the data we have seen thus far, we believe that a large biotechnology or pharmaceutical company with global access to the primary care markets would be best positioned to maximize the value of the MDI market, and therefore entering into a collaboration would be an attractive option for us to leverage this opportunity. The second opportunity (what we refer to as the Continuous Subcutaneous Insulin Injection (CSII) market) is to pre-administer Hylenex recombinant in analog insulin pump therapy at the time of infusion site change (once every 48-72 hours). We believe that the pre-administration of Hylenex recombinant could be the best product offering for the CSII market, and we currently intend to commercially exploit this opportunity ourselves.

We are currently conducting preparation activities to commercially launch Hylenex recombinant in the CSII market for pre-administration with analog insulin, including product manufacturing, delivery device development and supportive clinical studies. In each case, pairing rHuPH20 with prandial insulin 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, PH20 may yield a more physiologic insulin effect, similar to that found in healthy, non-diabetic people.

The following sets forth the current development status of our insulin programs with respect to the MDI and CSII markets:

#### MDI

With regard to MDI opportunity, we published data from two treatment studies - one in type 1 diabetes patients and one in type 2 diabetes patients. Copies of these publications can be found at <http://www.halozyme.com/Technology/Journals-Abstracts-And-Posters/default.aspx>. Both studies met their primary endpoints of A1C non-inferiority (A1C is a measure of average blood sugar over three months) and improved post-prandial glucose control compared to patients who were treated with analog insulin alone. Additionally, data from the type 1 diabetes treatment study indicated that Analog-PH20 formulations reduced hypoglycemia compared to analog insulin alone.

#### CSII

For the CSII market, we have published interim data from a study evaluating the use of Hylenex recombinant in analog insulin pump therapy that showed pre-administration of Hylenex recombinant provided a “faster-on faster-off” more physiologic profile than current rapid insulin analogs. Copies of these publications can be found at <http://www.halozyme.com/Technology/Journals-Abstracts-And-Posters/default.aspx>. Data from the double-blind cross-over study showed that pre-administration of Hylenex recombinant, at the time of infusion set change, not only accelerated the absorption and action of mealtime insulin, but also provided a more consistent insulin action profile over the three days of the infusion set life which resulted in improved post-prandial glucose control.



## PEGPH20

We are developing an investigational PEGylated form of rHuPH20 (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, thereby creating PEGPH20. One of the novel properties of PEGPH20 is that it lasts for an extended duration in the bloodstream and, therefore, can be used to maintain therapeutic effect to treat systemic disease.

Overall, approximately 25 percent of solid malignancies accumulate high levels of HA, including pancreatic, lung, breast, colon and prostate cancers, and therefore we believe that PEGPH20 has the potential to help patients in these types of cancer. Among solid tumors, pancreatic ductal adenocarcinoma is associated with the highest frequency of HA overexpression (approximately 87%). 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 with PEGPH20 alone may also directly inhibit the tumor growth.

We are currently conducting clinical trials with PEGPH20 in the treatment of solid tumors. In these trials, a dose of oral dexamethasone, a steroid, is administered to all patients prior to and subsequent to intravenous administration of PEGPH20 to minimize the side effect of PEGPH20. Our Phase 2 clinical trial, with a Phase 1b run-in period, for patients with metastatic pancreatic cancer is currently ongoing, and the enrollment of the run-in phase is complete. We have identified our intended Phase 2 dose of PEGPH20 in combination with gemcitabine, a chemotherapeutic drug. In a recent publication on a metastatic pancreatic adenocarcinoma Phase 3 study conducted by Celgene Corporation, it was reported that ABRAXANE™ plus gemcitabine demonstrated a 59% increase in one-year survival and doubling the survival rate at two years as compared to gemcitabine alone. Based on such reported data, we believe that the ABRAXANE plus gemcitabine regimen will become the standard treatment for metastatic pancreatic cancer. As a result, we have made the strategic decision to start a new randomized Phase 2 trial to assess the safety, tolerability and efficacy of PEGPH20 in combination with gemcitabine and ABRAXANE. We expect to initiate this trial in the first half of 2013.

## HTI-501

HTI-501, an engineered drug formulation variant of cathepsin L (a lysosomal proteinase), that acts by degrading collagen, 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 neutral pH normally found in the tissue. The enzyme is combined with a mildly acidic 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 the great majority of post-adolescent women and is prevalent in all races. We believe that the collagen fibers (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 deposited under the skin can release the tension in the collagenous fibrous septa and



thereby smoothing the dimpled appearance of the skin. HTI-501 may also be potentially utilized 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 evaluated 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 are 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. The interim results from the Phase 1 proof-of-concept and local tolerability study of HTI-501 were presented at the 8th World Congress of the International Academy of Cosmetic Dermatology in Cancun, Mexico, which was held from January 31 to February 3, 2012. In the Phase 1 portion of the clinical trial, no serious or severe adverse events were reported and the injection was well tolerated. The most common adverse event was 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. We expect to present data from the randomized Phase 2 study in the first half of 2013.

#### Collaborations

##### Roche Collaboration

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 (the Roche Collaboration). 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, 2012, 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. Refer to Note 3 for a further discussion of the material terms of the Roche Collaboration.

In March 2012 and December 2012, respectively, Roche submitted Line Extension Applications to the European Medicines Agency (EMA) for compounds, directed at two of the five Roche exclusive targets, formulated with rHuPH20 (subcutaneous Herceptin and subcutaneous MabThera). Additionally, Roche has completed a Phase 1 clinical trial for the exclusive target subcutaneous Actemra that is formulated with rHuPH20.

In March 2012, Roche announced positive 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) formulated with rHuPH20 (Herceptin SC). 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. The trial was designed to compare trastuzumab (active ingredient of Herceptin) 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 of showing that the subcutaneous formulation produced comparable results to the IV formulation including 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 SC is administered in about 5 minutes whereas Herceptin IV requires about 30-90 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. Herceptin SC is also a ready-to-use formulation, and thus may also significantly reduce pharmacy time as no medicine preparation time is required. This Phase 3 clinical trial was an open-label trial involving 595 women with HER2-positive early breast cancer.

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab) (MabThera SC). MabThera IV is approved for the treatment of non-Hodgkin's lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), types of cancer that affect lymphocytes (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. In December 2012, Roche presented positive data from the



first stage of this two-stage study at the annual meeting of the American Society of Hematology. The study investigates pharmacokinetics, efficacy and safety of MabThera SC. The primary endpoint in the first stage of the study was met, showing the MabThera SC injection resulted in non-inferior MabThera concentrations in the blood compared with IV-infused MabThera (MabThera IV).

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 Herceptin SC and Phase 3 MabThera SC clinical trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.roche-trials.com](http://www.roche-trials.com). Information available on these websites is not incorporated into this report.

#### Baxter Gammagard Collaboration

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 (HyQ), or the Gammagard Collaboration. Refer to Note 3 for a further discussion of the material terms of the Gammagard Collaboration.

Baxter filed a biologic license application (BLA) for HyQ in the U.S. in the second quarter of 2011. In September 2011, Baxter submitted an application to the EMA for HyQ. On August 1, 2012, we announced that the FDA had issued a complete response letter (CRL) for Baxter's HyQ BLA. The CRL requested additional preclinical data to support the BLA. The primary issues raised in the CRL focused on non-neutralizing antibodies generated against rHuPH20 and the possible effects of these antibodies on reproduction, development and fertility. Elevated anti-rHuPH20 antibody titers were detected in the registration trial, but have not been associated with any adverse events. Pending Baxter and us providing additional preclinical data sufficient to address the regulatory questions, the FDA has requested that patients should no longer be dosed with rHuPH20 in the Baxter HyQ program. We are working in collaboration with Baxter to conduct the required preclinical studies requested by the FDA. Baxter expects to meet with the FDA in Q2 2013 to discuss interim preclinical data as well as the proposed path forward.

#### Pfizer Collaboration

In December 2012, we and Pfizer entered into a collaboration and license agreement, under which Pfizer has the worldwide license to develop and commercialize products combining rHuPH20 enzyme with Pfizer proprietary biologics directed to up to six targets (the Pfizer Collaboration). Targets may be selected on an exclusive or non-exclusive basis. As of December 31, 2012, Pfizer has elected three exclusive therapeutic targets in primary care and specialty care indications. Refer to Note 3 for a further discussion of the material terms of the Pfizer Collaboration.

#### ViroPharma Collaboration

In May 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]) (the ViroPharma Collaboration). In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibitor and to the hereditary angioedema indication, along with three additional orphan indications. Refer to Note 3 for a further discussion of the material terms of the ViroPharma Collaboration.

In March 2012, ViroPharma reported positive data from ViroPharma's Phase 2 subcutaneous trial of Cinryze in combination with Enhance technology in patients with hereditary angioedema, a rare, debilitating and potentially fatal genetic disease. These data demonstrate that subcutaneous co-administration of Cinryze with rHuPH20 was easy to administer, well tolerated and resulted in sustained physiologically relevant C1 INH functional concentrations. This innovative combination administered subcutaneously



as a single injection will be further evaluated for the prevention of hereditary angioedema attacks. The results were presented in March 2012 at the annual meeting of the American Academy of Allergy Asthma & Immunology. The open-label, multiple-dose Phase 2 clinical trial was conducted in 12 subjects with hereditary angioedema. The study was designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. 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.

On August 1, 2012, ViroPharma announced that the FDA had requested that studies of the combination of Cinryze and rHuPH20 be placed on temporary clinical hold pending the FDA's evaluation of potential safety concerns with Halozyme's rHuPH20 enzyme raised by the presence of anti-rHuPH20 non-neutralizing antibodies that were detected in Baxter's HyQ program.

On September 21, 2012, ViroPharma and we announced that the FDA has provided guidance enabling ViroPharma to resume clinical studies of the subcutaneous administration of Cinryze in combination with rHuPH20. The FDA informed ViroPharma that based on their ongoing assessment, the FDA believes the potential safety signals regarding antibodies to rHuPH20 that were detected in Baxter's HyQ clinical development program are limited to that specific program. The FDA has advised ViroPharma to amend the study protocol, allowing for increased laboratory sampling to monitor anti-rHuPH20 antibody levels, and keep the FDA informed of elevated antibody levels, if any should occur, during the treatment phase of the study. On December 19, 2012, ViroPharma and Halozyme announced that ViroPharma initiated its Phase 2b double blind, multicenter, dose ranging study to evaluate the safety and efficacy of subcutaneous administration of Cinryze in combination with rHuPH20.

#### Intrexon Collaboration

In June 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) (the Intrexon Collaboration). In addition, the license provides Intrexon with exclusivity for a defined indication. Refer to Note 3 for a further discussion of the material terms of the Intrexon Collaboration.

#### Customers

For the years ended December 31, 2012, 2011 and 2010, 45%, 19% and 52% of total revenues, respectively, were from Roche and 17%, 42% and 42% of total revenues, respectively, were from Baxter. For the year ended December 31, 2012, 22% of total revenues were from Pfizer. In addition, for the year ended December 31, 2011, 22% of total revenues were from ViroPharma, and 16% of total revenues were from Intrexon. For information regarding our revenues from external customers, refer to Note 2, Summary of Significant Accounting Policies — Concentrations of Credit Risk, Sources of Supply and Significant Customers.

#### 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. In general, patents have a term of 20 years from the application filing date or earlier claimed priority date. Our issued patents will expire between 2022 and 2030. 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. The European Patent Office has announced that the opposition has been resolved.





in our favor and that European patent, EP1603541, has been maintained as amended (European Patent Bulletin 13/04) with claims that are no less broad than claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429). 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, collaborators, 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, 2012, we have incurred research and development expenses of \$329.1 million. From January 1, 2010 through December 31, 2012, approximately 21% and 16% of our research and development expenses were associated with the development of our more physiologic 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 do not have our own manufacturing facility for our product and product candidates, or their active pharmaceutical ingredient (API), or the capability to package our product. We have engaged third parties to manufacture bulk rHuPH20 API and our product Hylenex recombinant.

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc. (Avid), and Cook Pharmica LLC (Cook) to produce supplies of bulk rHuPH20 API. These manufacturers each produce API under current Good Manufacturing Practices (cGMP) for clinical uses. In addition, Avid currently produces API for Hylenex recombinant. In addition to supply obligations, 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 limited experience manufacturing our API. In addition, as a result of our contractual obligations to supply API to Roche for the product candidates they are developing including rHuPH20, we have been required to significantly scale up our



commercial API production at Cook during the last three years. It is essential for our business for Cook and Avid 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 collaboration products and product candidates.

We have a commercial manufacturing and supply agreement with Baxter, a cGMP-approved manufacturing facility, under which Baxter provides the final fill and finish steps in the production process of Hylenex recombinant for a limited period of time. The initial term of the agreement with Baxter expires on December 31, 2013; however, upon regulatory approval of a second filling line, the initial term will automatically be extended to December 31, 2015, subject to further extensions in accordance with the terms and conditions of the agreement. We also have 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

Our commercial activities currently focus on Hylenex recombinant. We have a team of sales specialists that provide hospital and surgery center customers with the information about Hylenex recombinant and information needed to obtain formulary approval for, and increase utilization of, Hylenex recombinant. Our commercial activities also include marketing and related services and commercial support services such as commercial operations, managed markets and commercial analytics. We also employ third-party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services to assist with our commercial activities. We sell Hylenex recombinant in the United States to wholesale distributors, who sell to hospitals, ambulatory surgery centers and other end-users. We have engaged Integrated Commercial Solutions (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

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our product or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us. We face competition not only in the commercialization of Hylenex recombinant, but also for the in-licensing or acquisition of additional product candidates, and the out-licensing of our Enhance technology. In addition, our collaborators face competition in the commercialization of the product candidates for which the collaborators seek marketing approval from the FDA or other regulatory authorities.

##### HYLENEX Recombinant

Hylenex recombinant is currently the only FDA-approved recombinant human hyaluronidase on the market. Bausch & Lomb Inc. is currently the only other manufacturer that has an FDA-approved product, Vitrase<sup>®</sup>, an ovine (ram) hyaluronidase. In addition, some commercial pharmacies compound hyaluronidase preparations for institutions and physicians even though compounded preparations are not FDA-approved products.

#### 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 introduced 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 (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 (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 (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 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 collaborators, 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 the delivery of injected drugs and fluids or to alter abnormal 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-maker reviews the operating results on an aggregate basis and manages 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, 2012, 2011 and 2010.

#### 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 February 25, 2013, we had 152 full-time employees. None of our employees are unionized and we believe our employee relations to be 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, bulk rHuPH20 supply 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, bulk rHuPH20 supply payments 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, 2012, we have incurred aggregate net losses of approximately \$298.6 million.

If our 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, risky 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 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 collaborators, 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 when we or our collaborators expect or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs. For example, we announced on August 1, 2012 that the FDA had issued a CRL for Baxter's HyQ BLA. The CRL requested additional preclinical data to support the BLA. The primary issues raised in the letter focused on non-neutralizing antibodies generated against rHuPH20 and the possible effects of these antibodies on reproduction, development and fertility. Elevated anti-rHuPH20 antibody titers were detected in the registration trial, but have not been associated with any adverse events. Pending Baxter and us providing additional preclinical data sufficient to address the regulatory questions, the FDA has requested that patients should no longer be dosed with rHuPH20 in the Baxter clinical studies. In view of the issues raised in the HyQ CRL, we had contacted the FDA regarding the impact on Hylenex recombinant. After reviewing the applicable data submitted by us, FDA had confirmed that there was no need for actions against Hylenex recombinant or clinical programs under the Hylenex recombinant IND application(s).

There can be no assurance that Baxter and we will be able to resolve the issues raised by the FDA in a timely manner which could result in a delay or failure to gain regulatory approval for the HyQ product candidate. Furthermore, although we do not believe at this time that the issues raised by the FDA with respect to the HyQ BLA will have a significant impact on our proprietary and other collaboration product candidates, there can be no assurance that these concerns will not also be raised by the FDA or other health authorities in the future.

Only three of our collaboration product candidates are currently in the regulatory approval process and there are no proprietary product candidates currently in the regulatory approval process. We and our collaborators may not be successful in obtaining such approvals for any potential products in a timely manner, or at all. Refer to the risk factor titled "Our proprietary and collaboration product candidates may not receive regulatory approvals for a variety of reasons, including unsuccessful clinical trials" for additional information relating to 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 collaborators are unsuccessful in maintaining our regulatory approvals, our ability to generate revenues would be adversely affected.

If our contract manufacturers are unable to manufacture and supply to us API in the quantity and quality required by us or our collaborators for use in our products and product candidates, our product development and commercialization efforts could be delayed or stopped and our collaborations 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 current cGMP for clinical uses. In addition, Avid currently produces API for Hylenex recombinant. In addition to supply obligations, 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 three years. If Cook is unable to obtain status as a cGMP-approved manufacturing facility, or if either Avid or Cook: (i) is unable to retain status as cGMP-approved manufacturing facilities; (ii) is unable to otherwise successfully scale up our API production; (iii) fails to manufacture and supply API in the quantity and quality required by us or our collaborators for use in our proprietary and collaboration products and product candidates for any other reason, or (iv) provides the necessary support for the chemistry, manufacturing and controls sections for FDA and other regulatory filings, our business will be adversely affected. In addition, a significant change in such parties' business or financial condition could adversely affect their abilities to fulfill their contractual obligations to us. In particular, due to announced adverse clinical results, Avid's parent, Peregrine Pharmaceuticals, Inc., has recently experienced a significant decline in its stock price, a lender has recently recalled a loan to the company, and the company is currently party to multiple securities

lawsuits. 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

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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 collaboration product candidates; (ii) delay or prevent the effective commercialization of proprietary or collaboration products; and/or (iii) cause us to breach contractual obligations to deliver API to our collaborators. Such delays would likely damage our relationship with our collaborators 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 milestone payments, target designation fees, maintenance fees and royalties. We are dependent on our collaborators to develop and commercialize product candidates subject to our collaborations in order for us to realize any financial benefits from these collaborations. Our collaborators may not devote the attention and resources to such efforts that we would to such efforts ourselves or simultaneously develop and commercialize products in competition to those products we have licensed to them. In addition, 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. Specifically, the termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators 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 collaboration products and product candidates rely on the rHuPH20 enzyme. rHuPH20 is a key technological component of Enhance technology and our most advanced proprietary and collaboration products and product candidates, including the product candidates under our Roche, Pfizer, Baxter, ViroPharma and Intrexon collaborations, our more physiologic insulin program, our PEGPH20 program and Hylenex recombinant. An adverse development for rHuPH20 (e.g., an adverse regulatory determination relating to rHuPH20, if we are unable to obtain sufficient quantities of rHuPH20, if we are unable to obtain or maintain material proprietary rights to rHuPH20 or if we discover negative characteristics of rHuPH20) would substantially impact multiple areas of our business, including current and potential collaborations, as well as proprietary programs. For example, we announced on August 1, 2012 that the FDA has issued a CRL for Baxter's HyQ BLA. The CRL requested additional preclinical data to support the BLA. The primary issues raised in the letter focused on non-neutralizing antibodies generated against rHuPH20 and the possible effects of these antibodies on reproduction, development and fertility. Elevated anti-rHuPH20 antibody titers were detected in the registration trial, but have not been associated with any adverse events. Pending Baxter and us providing additional preclinical data sufficient to address the regulatory questions, the FDA has requested that patients should no longer be dosed with rHuPH20 in the Baxter clinical studies. Although we do not believe at this time that the issues raised by the FDA with respect to the HyQ BLA will have a significant impact on our proprietary and other collaboration product candidates, there can be no assurance that these concerns will not also be raised by the FDA or other health authorities in the future. For example, due to the issues raised by the FDA in the Baxter CRL, ViroPharma's subcutaneous Cinryze program was put on temporary hold although the hold was subsequently lifted by FDA.



Our proprietary and collaboration 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 and nonclinical studies or clinical trial results are promising, we or our collaborators may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not, or our collaborators may not, obtain applicable regulatory approval for a variety of other reasons. Preclinical, nonclinical, and clinical trials for any of our proprietary or collaboration 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 clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product;
- a regulatory agency may not approve our manufacturing processes or facilities, or the processes or facilities of our collaborators, 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 collaborators, 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 collaboration 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 collaboration product candidates and/or our ability to successfully acquire other products and technologies. There can be no assurances that any proprietary or collaboration product candidate will receive regulatory approval in a timely manner, or at all.

We anticipate that certain proprietary and collaboration 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 third party collaborators are responsible for providing certain proprietary materials that are essential components of our collaboration product candidates, and any failure to supply these materials could delay the development and commercialization efforts for these collaboration product candidates and/or damage our collaborations.

Our development and commercialization collaborators are responsible for providing certain proprietary materials that are essential components of our collaboration 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 collaborator, or any applicable third party service provider of a collaborator, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of the collaboration product candidate or component of such product candidate, such difficulties could (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of collaboration product candidates; and/or (ii) delay or prevent the effective commercialization of collaboration 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.

We rely on third parties to prepare, fill, finish and package our products and product candidates, and if such third parties should fail to perform, 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 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, 2013. However, upon regulatory approval of a second filling line, the initial term will automatically be extended to December 31, 2015, subject to further extensions in accordance with the terms and conditions of the agreement. In June 2011, we entered into a services agreement with a third party manufacturer for the technology transfer and manufacture of Hylenex recombinant. If we are unable to receive regulatory approval for the third party manufacturer prior to the expiration of the commercial manufacturing and supply agreement with Baxter or if the new manufacturer encounters difficulties in the manufacture, fill, finish or packaging of Hylenex recombinant, our business and financial condition could be adversely effected.

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 approved product, Hylenex recombinant 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

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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 collaborators 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 Collaboration and the associated agreements.

If we or our collaborators fail to comply with regulatory requirements applicable to promotion, sale and manufacturing of approved products, 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, state and foreign regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We, our collaborators and our respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising, promotion and sales of drug products, required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies. We, our collaborators and our respective contractors, suppliers and vendors, may be slow to adapt or may not be able to adapt to these changes or new requirements.

In particular, 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. Likewise, if we, our collaborators and our respective contractors, suppliers and vendors involved in sales and promotion of our products do not comply with applicable laws and regulations, for example off-label or false or misleading promotion, this could materially harm our business and financial condition.

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

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 reserves and expected revenues during the next few years may not be

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sufficient for us to continue the development of our proprietary product candidates, to fund general operations and conduct our business. In addition, if we engage in acquisitions of companies, products or technologies in order to execute our business strategy, we may need to raise additional capital. We may raise additional capital in the future through one or more financing vehicles that may be available to us including (i) the public or private issuance of securities; (ii) new collaborative agreements; and/or (iii) expansions or revisions to existing collaborative relationships.

In view of our stage of development, business prospects, 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 raise capital on adverse terms or significantly reduce operating expenses through the restructuring of our operations. If we raise additional capital, a substantial number of additional shares may be issued, and these shares will dilute the ownership interest of our current investors.

We currently have significant debt and failure by us to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate

On December 28, 2012, we and our subsidiary, Halozyme, Inc., a California corporation, entered into a Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC, a Delaware limited liability company, and Silicon Valley Bank, a California corporation, providing for a \$30 million secured single-draw term loan facility with a maturity date of January 1, 2017. The term loan was fully drawn at close and the proceeds are to be used for working capital and general business requirements. The term loan facility is secured by substantially all of the assets of the Company and Halozyme, Inc., except that the collateral does not include any equity interests in Halozyme, Inc., any intellectual property (including all licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, as well as customary events of default and our indemnification obligations. One of the events of default is a material adverse change which is defined as a material adverse change in our business, operations or condition (financial or otherwise); a material impairment of the prospect of repayment of any portion of the loan; or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. If we are unable to fulfill our obligations to the lenders under the applicable loan agreements, this could create a material default such that our obligation to repay the loan is accelerated which could harm our financial condition.

If proprietary or collaboration product candidates are approved for marketing 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 collaboration product candidates obtain the necessary regulatory approvals for commercial sale, 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 relative to other therapies for the same or similar treatments;
- our ability to fund our sales and marketing efforts and the ability and willingness of our collaborators 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 collaborators;
- the introduction of generic competitors; and
- the extent to which reimbursement for our products and related treatments will be available from third party payors including government insurance programs (Medicare and Medicaid) and private insurers.

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 collaboration product candidates will be restricted to the labels approved by FDA and applicable regulatory bodies, 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 significant 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 the liabilities may exceed the limits of our insurance policy, or 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 higher insurance requirements could impose additional costs on us. In addition, since many of our collaboration 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 relevant experience. We depend substantially on our ability to hire, train, motivate and retain high quality personnel, especially our scientists and management team. Particularly in view of the small number of employees on our staff to cover our numerous programs and key functions, 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 collaborators. 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 and business. If we were to lose his services, we would experience delays in meeting our product development schedules. We currently have 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 three buildings in San Diego, California. We depend on our facilities and on our collaborators, 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 collaborators, 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 may 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 collaborators do not achieve projected development, clinical or regulatory 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, and we may face lawsuits relating to such declines.

From time to time, we or our collaborators may 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, our stock price may decline rapidly. For example, the announcement of the CRL received for HyQ caused a rapid decline in our stock price. Stock price declines may also trigger direct or derivative shareholder lawsuits. As with any litigation proceeding, the eventual outcome of any legal action is difficult to predict. If any such lawsuits occur, we will incur expenses in connection with the defense of these lawsuits, and we may have to pay substantial damages or settlement costs in connection with any resolution thereof. Although we have insurance coverage against which we may claim recovery against some of these expenses and costs, the amount of coverage may not be adequate to cover the full amount or certain expenses and costs may be outside the scope of the policies we maintain. In the event of an adverse outcome or outcomes, our business could be materially harmed from depletion of cash resources, negative impact on our reputation, or restrictions or changes to our governance or other processes that may result from any final disposition of the lawsuit. Moreover, responding to and defending pending litigation significantly diverts management's attention from our operations.

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:

- 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 collaborators 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;
- we may take on liabilities from the acquired company such as debt, legal liabilities or business risk which could be significant;
- 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. There is no assurance 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, 2012 were \$13.50 and \$3.86, 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:

- the presence of competitive products to those being developed by us;
- failure (actual or perceived) of our collaborators to devote attention or resources to the development or commercialization of product candidates licensed to such collaborator;
- a dispute regarding our failure, or the failure of one of our third party collaborators, 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 collaboration product candidates;
- the failure, for any reason, to secure or defend our intellectual property position;
- for those products that are not yet approved for commercial sale, the failure or delay of applicable regulatory bodies to approve such products;
- identification of safety or patient tolerability issues;
- failure of clinical trials to meet efficacy endpoints;
- suspensions or delays in the conduct of clinical trials or securing of regulatory approvals;
- our failure, or the failure of our third party collaborators, to successfully commercialize products approved by applicable regulatory bodies such as the FDA;
- our failure, or the failure of our third party collaborators, 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 transactions where we raise capital 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.

Our rights agreement and anti-takeover provisions in our charter documents and Delaware law may make an acquisition of us more difficult.

We are party to a Rights Agreement designed to deter abusive takeover tactics and to encourage prospective acquirors to negotiate with our board of directors rather than attempt to acquire us in a manner or on terms that our board deems unacceptable, which could delay or discourage takeover attempts that stockholders may consider favorable.

In addition, anti-takeover provisions in our charter documents and Delaware law may make an acquisition of us more difficult. First, our board of directors is classified into three classes of directors. Under Delaware law, directors of a corporation with a classified board may be removed only for cause unless the corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation, as amended, does not provide otherwise. In addition, our bylaws limit who may call special meetings of stockholders, permitting only stockholders holding at least 50% of our outstanding shares to call a special meeting of stockholders. Our amended and restated certificate of incorporation, as amended, does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Finally, our bylaws establish procedures, including advance notice procedures, with regard to the nomination of candidates for election as directors and stockholder proposals.

These provisions may discourage potential takeover attempts, discourage bids for our common stock at a premium over market price or adversely affect the market price of, and the voting and other rights of the holders of, our common stock. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors other than the candidates nominated by our board of directors.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of, us.

These provisions may deter an acquisition of us that might otherwise be attractive to stockholders.

#### Risks Related To Our Industry

Our products must receive regulatory approval before they can be sold, and compliance with the extensive government regulations 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 health regulatory agencies including the FDA (and with respect to controlled drug substances, the U.S. Drug Enforcement Administration (DEA)) and equivalent foreign regulatory agencies and state and local/regional 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. 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 may impose onerous, costly and time-consuming requirements such as additional clinical or animal testing. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators' development and commercialization activities due to safety concerns. In addition, even if our products are approved, regulatory agencies may also take post-approval action limiting or revoking our ability to sell our products. Any of these regulatory actions may adversely affect the economic benefit we may derive from our products and therefore harm our financial condition.

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

- we will be able to obtain patent protection for our products and technologies;
- the scope of any of our issued patents will be sufficient to provide commercially significant exclusivity for our products and technologies;
- others will not independently develop similar or alternative technologies or duplicate our technologies and obtain patent protection before we do; and
- any of our issued patents, or patent pending applications that result in issued patents, will be held valid, enforceable 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; however, the opposition has been resolved with claims maintained in amended form. Any weaknesses or 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 (e.g. Hylenex recombinant). We may not be able to obtain trademark protection for any proposed product names we select. In addition, product names for pharmaceutical products must be approved by health regulatory authorities such as the FDA in addition to meeting the legal standards required for trademark protection and product names we propose may not be timely approved by regulatory agencies which may delay product launch. In addition, our 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 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. If we become involved in any intellectual property litigation, we may be required to pay substantial damages, including but not limited to treble damages, attorneys' fees and costs, 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 changes, 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 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 collaboration 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 (the Healthcare Reform Act). This law substantially changes the way healthcare 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.

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 collaboration products under development.

Our proprietary and collaboration 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 include, but are not limited to Bausch & Lomb Inc. For our Analog-PH20 product candidates, such competitors may include Bidel Inc., Eli Lilly, 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 collaboration 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 76,000 square feet of office and research space for a monthly rent expense of approximately \$145,000, 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.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

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

## Market Information

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:

	2012		2011	
	High	Low	High	Low
First Quarter	\$13.50	\$9.00	\$8.00	\$5.79
Second Quarter	\$13.05	\$7.17	\$7.21	\$5.97
Third Quarter	\$9.92	\$3.86	\$7.36	\$5.54
Fourth Quarter	\$7.63	\$4.80	\$9.82	\$5.60

On February 25, 2013, the closing sales price of our common stock on the NASDAQ Stock Market was \$5.72 per share. As of February 25, 2013, we had approximately 8,000 stockholders of record.

## Dividends

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.

## 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, 2007 to December 31, 2012. The historical stock price performance included in this graph is not necessarily indicative of future stock price performance.

	12/2007	12/2008	12/2009	12/2010	12/2011	12/2012
Halozyme Therapeutics, Inc.	\$100.00	\$78.76	\$82.56	\$111.39	\$133.76	\$94.37
NASDAQ Composite	\$100.00	\$59.10	\$85.37	\$100.75	\$99.92	\$117.35
NASDAQ Biotechnology	\$100.00	\$93.44	\$102.65	\$118.31	\$132.60	\$175.41

## Item 6. Selected Financial Data

The selected consolidated financial data set forth below as of December 31, 2012 and 2011, and for the fiscal years ended December 31, 2012, 2011 and 2010, 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, 2010, 2009 and 2008, and for the fiscal years ended December 31, 2009 and 2008, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC, not included herein.

## Summary Financial Information

Statement of Comprehensive Loss Data:	Year Ended December 31,				
	2012 (a)	2011 (b)	2010	2009	2008
	(in thousands, except for per share amounts)				
Total revenues	\$42,325	\$56,086	\$13,624	\$13,671	\$8,764
Net loss	(53,552 )	(19,770 )	(53,242 )	(58,361 )	(48,654 )
Net loss per share, basic and diluted	\$(0.48 )	\$(0.19 )	\$(0.56 )	\$(0.67 )	\$(0.61 )
Shares used in computing net loss per share, basic and diluted	111,077	102,566	94,358	86,700	79,844
	As of December 31,				
Balance Sheet Data:	2012	2011	2010	2009	2008
	(in thousands)				
Cash and cash equivalents	\$99,901	\$52,826	\$83,256	\$67,465	\$63,716
Working capital	112,082	46,686	74,155	60,045	59,794
Total assets	134,728	65,759	91,345	77,150	76,563
Deferred revenue	43,846	40,884	58,094	60,482	49,448
Long-term debt, net	29,662	—	—	—	—
Total liabilities	85,875	54,858	70,994	70,246	61,183
Stockholders’ equity	48,854	10,900	20,351	6,903	15,380

(a) Revenues in 2012 included \$9.5 million in revenue under collaborative agreements from the Pfizer Collaboration.

Revenues in 2011 included revenue under collaborative agreements totaling \$18.0 million related to the upfront payments received from the ViroPharma and Intrexon Collaborations and \$18.1 million related to recognition of

(b) unamortized deferred prepaid product-based payments and unamortized deferred upfront payment in connection with the termination of the collaboration with Baxter for the marketing rights of Hylenex recombinant (the Hylenex Collaboration) in July 2011.

## 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. References to “Notes” are Notes included in our Notes to Consolidated Financial Statements.

## Overview

Halozyme is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding 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 technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

Our proprietary enzymes can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or can be used to alter abnormal tissue structures for clinical benefit. We have chosen to exploit our technology and expertise in a balanced way to modulate both risk and spend by: (1) developing our own proprietary products in therapeutic areas with significant unmet medical needs, such as diabetes, oncology and dermatology, and (2) licensing our technology to biopharmaceutical companies to collaboratively develop products which combine our technology with the collaborators' proprietary compounds.

The majority of the product candidates in our current pipeline are based on rHuPH20, a patented human recombinant hyaluronidase enzyme. rHuPH20 temporarily breaks down hyaluronic acid (HA) - a naturally occurring substance that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. 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 rHuPH20 on the architecture of the subcutaneous space is temporary. rHuPH20 can thus be applied as a drug delivery platform to increase dispersion and absorption of other injected drugs and fluids that are injected under the skin or in the muscle thereby enhancing efficacy or convenience. For example, rHuPH20 can be used to convert drugs that must be delivered intravenously into subcutaneous injections or reducing the number of subcutaneous injections needed for effective therapy. We refer to the application of rHuPH20 to facilitate the delivery of other drugs or fluids as Enhanze™ technology. rHuPH20 is also the active ingredient in our first commercially approved product, Hylenex recombinant. Additionally, we are expanding our scientific work in the extracellular matrix by developing other enzymes and agents that target its unique aspects, giving rise to potentially new molecular entities that can be indicated in endocrinology, oncology and dermatology.

Our proprietary pipeline consists of multiple clinical stage products in diabetes, oncology and dermatology. We currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Pfizer Inc. (Pfizer), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma) and Intrexon Corporation (Intrexon), with three product candidates which have been submitted for regulatory approval in the U.S. and/or Europe as well as several others at various stages of development.

Our operations to date have involved: (i) building infrastructure for and staffing our operations; (ii) acquiring, developing and securing proprietary protection for our technology; (iii) developing our proprietary product pipeline; (iv) entering into and supporting our collaborations with other companies to advance licensed product candidates; and (v) selling our own approved commercial product, Hylenex® recombinant (hyaluronidase human injection). Currently, we have received only limited revenue from the sales of Hylenex recombinant, in addition to other revenues from our collaborations.

Future revenues from the sales and/or royalties of our product candidates which have not been approved will depend on the ability of Halozyme and our collaborators to develop, manufacture, secure regulatory approvals and commercialize the product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$298.6 million as of December 31, 2012.

Highlights of our activities and events in 2012 are as follows:

In December 2012, we and Pfizer entered into a collaboration and license agreement, under which Pfizer has the worldwide license to develop and commercialize products combining rHuPH20 with Pfizer proprietary biologics directed to up to six targets (the Pfizer Collaboration). Targets may be selected on an exclusive or non-exclusive basis. We recognized \$9.5





million in revenue for the licenses of three specified exclusive therapeutic targets in primary care and specialty care indications and three additional targets which Pfizer has the right to elect upon payment of additional fees.

In December 2012, Roche filed the Line Extension Application of subcutaneous MabThera® (rituxumab with rHuPH20) (MabThera SC) to the European Medicines Agency (EMA) for the treatment of Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia and Follicular Lymphoma. In addition, Roche presented positive data from the first stage of a two-stage Phase 3 clinical trial for MabThera SC at the annual meeting of the American Society of Hematology.

In December 2012, we entered in a loan and security agreement for a \$30 million secured single-draw term loan facility and received net proceeds of \$29.7 million from the loan facility.

In August 2012, we announced that the U.S. Food and Drug Administration (FDA) had issued a complete response letter for Baxter's HyQ Biologics License Application (BLA) requesting additional preclinical data to support the application. Additionally, the Blood Products Division requested that patients no longer be dosed with rHuPH20 in the Baxter and ViroPharma subcutaneous plasma derivative programs, pending review of preclinical data. Based on the most recent data submitted to FDA's Drug Division (the group regulating the other investigational rHuPH20 programs, including insulin and PEGPH20), the division has confirmed that no action is required against Hylenex recombinant or ongoing clinical programs under the Hylenex IND. In September 2012, we and ViroPharma announced that the FDA provided guidance enabling ViroPharma to resume clinical studies of the subcutaneous administration of Cinryze® in combination with rHuPH20.

The European Patent Office has announced that a hearing scheduled in opposition of the European patent for our recombinant human hyaluronidase enzyme (rHuPH20) has been resolved in our favor and that European patent, EP1603541, has been maintained as amended (European Patent Bulletin 13/04) with claims that are no less broad than claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429).

In March 2012, Roche submitted a Line Extension Application for subcutaneous Herceptin® (trastuzumab) (Herceptin SC) with the EMA. In addition, Roche presented Phase 3 registration data from the HannaH trial at the Early Breast Cancer Conference in Vienna. The study met its co-primary endpoints of pharmacokinetics and efficacy. Herceptin SC, using rHuPH20, may provide greater convenience to patients versus the traditional IV method due to its less invasive administration route and quicker administration time (5 minutes versus 30 - 90 minutes).

#### Results of Operations

##### Comparison of Years Ended December 31, 2012, 2011 and 2010

Product Sales, Net — Product sales were \$2.9 million in 2012 compared to \$1.8 million in 2011 and \$896,000 in 2010. Product sales in 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 in 2011 would have been \$845,000. Product sales increased in 2012 compared to 2011 and 2010 primarily due to the increased product sales of Hylenex recombinant resulting from the reintroduction of Hylenex recombinant in December 2011. Based on our reintroduction of Hylenex recombinant in December 2011, we expect product sales to increase in the future.

Revenues Under Collaborative Agreements — Revenues under collaborative agreements for the years ended December 31, 2012, 2011 and 2010 were as follows (in thousands):

	2012	Change	2011	Change	2010
Upfront payments, license maintenance fees and amortization of deferred upfront, license fees and product-based payments:					
Pfizer	\$9,500	n/a	\$—	n/a	\$—
Roche	2,016	2	% 1,969	(1	%) 1,985
ViroPharma	1,000	(89	%) 9,000	n/a	—
Intrexon	1,000	(89	%) 9,000	n/a	—
Baxter	483	(97	%) 17,622	1621	% 1,024
Other	429	504	% 71	n/a	—
	14,428	(62	%) 37,662	1152	% 3,009
Milestone payments:					
Roche	8,000	60	% 5,000	n/a	—
Baxter	—	n/a	3,000	n/a	—
ViroPharma	—	n/a	3,000	n/a	—
	8,000	(27	%) 11,000	n/a	—
Reimbursements for research and development services and supply of bulk rHuPH20:					
Roche	8,897	160	% 3,416	(34	%) 5,165
Baxter	6,742	301	% 1,681	(60	%) 4,245
ViroPharma	1,270	194	% 432	n/a	—
Other	101	71	% 59	(81	%) 310
	17,010	204	% 5,588	(43	%) 9,720
Total revenues under collaborative agreements	\$39,438	(27	%) \$54,250	326	% \$12,729

In 2012, we recognized \$9.5 million of revenue in connection with the Pfizer Collaboration. In 2011, we recognized \$18 million of revenue in connection with the ViroPharma and Intrexon Collaborations. In addition, in 2011 we recognized revenue of 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 Baxter Hylenex Collaboration resulting from the termination of such collaboration in 2011.

Revenue from reimbursements for research and development services and supply of bulk rHuPH20 increased in 2012 compared to 2011 due to the increase in services requested by the collaborators, particularly manufacturing services. Revenue from reimbursements for research and development services decreased in 2011 compared to 2010 due to the decrease in services requested by the collaborators. Research and development services rendered by us on behalf of our collaborators are at the request of the collaborators; therefore, the amount of future revenues related to reimbursable research and development services and supply of bulk rHuPH20 is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to fluctuate in future periods based on our collaborators' 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 \$1.1 million in 2012 compared to \$258,000 in 2011 and \$985,000 in 2010. Cost of product sales increased in 2012 compared to 2011 primarily due to the increased product sales of Hylenex recombinant. Cost of product sales decreased in 2011 compared to 2010 primarily due to a reserve for inventory obsolescence of \$875,000 for Hylenex recombinant API in 2010 in connection with the termination of the Baxter Hylenex Collaboration in January 2011. Based

on the reintroduction of Hylenex recombinant in December 2011, we expect cost of product sales to continue to increase in future periods.

Research and Development — Research and development expenses incurred for the years ended December 31, 2012, 2011 and 2010 were as follows (in thousands):

	2012	2011	2010
Programs			
Product Candidates:			
PEGPH20	\$12,479	\$8,399	\$7,179
Hylenex recombinant	11,682	4,125	1,436
Analog-PH20	5,251	16,616	15,355
HTI-501	1,962	3,918	4,959
Enhance collaborations	26,152	7,464	8,568
rHuPH20 platform(1)	7,705	14,100	8,634
Other	4,813	2,941	5,643
Total research and development expenses	\$70,044	\$57,563	\$51,774

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

Research and development expenses increased in 2012 compared to 2011 primarily due to a \$11.8 million increase in manufacturing activities to support our collaborators' potential launches of the collaboration product candidates and to produce validation batches of Hylenex recombinant with the second fill/finish manufacturer and a \$5.3 million increase in research activities; offset in part by a \$5.2 million decrease in clinical trial activities primarily related to our more physiologic insulin program. Research and development expenses increased in 2011 compared to 2010 primarily due to a \$4.7 million increase in manufacturing activities and a \$6.8 million increase in clinical trial activities mainly supporting our more physiologic 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 in future periods as we continue with our clinical trial programs and continue to develop and manufacture our product candidates.

Selling, General and Administrative — Selling, general and administrative (SG&A) expenses were \$24.8 million in 2012 compared to \$18.1 million in 2011 and \$15.1 million in 2010. SG&A expenses were higher in 2012 compared to 2011 primarily due to a \$4.5 million increase in compensation costs, including \$1.4 million increase in stock-based compensation, mainly resulting from building the infrastructure of our commercial organization in connection with the reintroduction of Hylenex recombinant in December 2011. SG&A expenses were higher in 2011 compared to 2010 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.

Through the second quarter of 2011, our selling expenses, which include sales and marketing costs, primarily consisted of compensation, consulting fees and 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 the 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.

Other Income, net — Other income in 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.

### Liquidity and Capital Resources

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2012, we had cash and cash equivalents of approximately \$99.9 million. 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 \$45 to \$50 million for the year ending December 31, 2013, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones and royalties under our existing collaborative agreements. We do not expect our revenues to be sufficient to fund operations until 2014, at the earliest. 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 2012, 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 \$81.5 million in net proceeds. We may, in the future, offer and sell equity, debt securities and warrants to purchase any of such securities, either individually or in units 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.

### Cash Flows

#### Operating Activities

Net cash used in operations was \$64.3 million in 2012 compared to \$34.4 million of net cash used in operations in 2011. This change was primarily due to the increase in net loss of \$33.8 million adjusted for non-cash items including stock-based compensation and depreciation and amortization in addition to changes in working capital.

Net cash used in operations was \$34.4 million in 2011 compared to \$45.4 million of net cash used in 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 Collaborations and milestone payments totaling \$11.0 million received under the collaborative agreements; offset in part by an increase in research and development services and SG&A expenses.

#### Investing Activities

Net cash used in investing activities was \$1.4 million in 2012 compared to \$0.8 million in 2011. This was primarily due to an increase in purchases of property and equipment during 2012. Net cash used in investing activities was \$0.8 million in 2011 compared to \$0.6 million in 2010. This was primarily due to an increase in purchases of property and equipment during 2011.



### Financing Activities

Net cash provided by financing activities was \$112.8 million in 2012 compared to \$4.7 million in 2011. Net cash provided by financing activities in 2012 consisted of net proceeds of \$81.5 million from the sale of our common stock in February 2012, \$29.7 million from the long-term debt and \$2.0 million from option exercises. Net cash provided by financing activities during 2011 consisted of proceeds from stock option exercises.

Net cash provided by financing activities was \$4.7 million in 2011 compared to \$61.8 million in 2010. Net cash provided by financing activities during 2010 primarily consisted of net proceeds of \$60 million from the sale of our common stock in September 2010.

### Off-Balance Sheet Arrangements

As of December 31, 2012, 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.

### Contractual Obligations

As of December 31, 2012, future minimum payments due under our contractual obligations are as follows (in thousands):

Contractual Obligations(1,4)	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Long-term debt, including interest	\$38,435	\$2,076	\$32,875	\$3,484	\$—
Operating leases(2)	10,245	1,865	6,174	2,206	—
License payments	900	300	600	—	—
Third-party manufacturing obligations (3)	25,038	18,861	6,177	—	—
Total	\$74,618	\$23,102	\$45,826	\$5,690	\$—

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

(2) Includes minimum lease payments related to leases of our office and research facilities and certain autos under non-cancelable operating leases.

(3) We have contracted with third-party manufacturers for the supply of bulk rHuPH20 and fill/finish of Hylenex recombinant. Under these agreements, we are required to purchase certain quantities each year during the terms of the agreements. The amounts presented represent our estimates of the minimum required payments under these agreements.

(4) Excludes contractual obligations already recorded on our consolidated balance sheet as current liabilities.

Contractual obligations for purchases of goods or services include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. For obligations with cancellation provisions, the amounts included in the preceding table were limited to the non-cancelable portion of the agreement terms or the minimum cancellation fee.

For the restricted stock units granted, the number of shares issued on the date the restricted stock units vest is net of the minimum statutory withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. The obligation to pay the relevant taxing authority is not included in the preceding table, as the amount is contingent upon continued

employment. In addition, the amount of the obligation is unknown, as it is based in part on the market price of our common stock when the awards vest.

The expected timing of payments of the obligations above is estimated based on current information. Timing of payments and actual amounts paid may be different, depending on the time of receipt of goods or services, or changed to agreed-upon amounts for some 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 collaborators' 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.

#### Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition 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 supply of bulk rHuPH20, 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. Refer to Note 2 for a further discussion of our revenue recognition policies for product sales and revenues under our collaborative agreements and Note 3 for a further discussion of our collaborative agreements.



#### 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 (Black-Scholes model) that uses assumptions regarding a number of complex and subjective variables. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments. Refer to Note 2 for a further discussion of share-based payments.

#### Research and Development Expenses

Research and development expenses include salaries and benefits, research-related manufacturing services, clinical trial expenses, contract services, facilities and other overhead expenses and other outside expenses. Research and development expenses are charged to operations as they are incurred when these expenditures relate to our research and development efforts and have no alternative future uses. Refer to Note 2 for a further discussion of research and development expenses.

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. 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 collaboration 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, 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.

#### Inventories

Inventories are stated at lower of cost or market. Cost is determined on a first-in, first-out basis. Refer to Note 2 for a further discussion of our 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. Refer to Note 2 for a further discussion of our significant accounting policies and other disclosures required by U.S. GAAP.

#### Recent Accounting Pronouncements

Refer to Note 2, Summary of Significant Accounting Policies - Adoption of Recent Accounting Pronouncements, for a discussion of recent accounting pronouncements and their effect, if any, on us.

#### 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, 2012 and 2011, 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, 2012 and 2011, 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. Control 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.

**Changes in Internal Control Over Financial Reporting**

There have been no significant changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2012 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, 2012. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of December 31, 2012, 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, 2012. The report appears below.

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, 2012, 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, 2012, 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, 2012 and 2011, and the related consolidated statements of comprehensive loss, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2012 of Halozyme Therapeutics, Inc. and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP  
San Diego, California  
February 28, 2013

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 2013 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. (41), President, Chief Executive Officer and Director. Dr. Frost was named Halozyme’s President and Chief Executive Officer in 2010 and has served on the Board of Directors and in various operation roles over the past thirteen years at the Company, including Chief Scientific Officer since 2002. He brought the founding technologies to Halozyme in 1999 and has spent more than sixteen years conducting research on the extracellular matrix. Over the past decade, Dr. Frost has led the R&D efforts at Halozyme 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 research 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 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 (45), 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. 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. From 1991 to 2000, Mr. Gustafson held multiple positions in Amgen’s Treasury group with increasing levels of responsibility, most recently serving as 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 (46), 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. (63), 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 (44), 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.

#### 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.

## Equity Compensation Plan Information

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2012:

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) (2)	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)	7,062,013	\$6.59	2,730,059

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 (1) 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.

(2) This amount does not include restricted stock units as there is no exercise price for restricted stock units.

## 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.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets at December 31, 2012 and 2011	F-2
Consolidated Statements of Comprehensive Loss for Each of the Years Ended December 31, 2012, 2011 and 2010	F-3
Consolidated Statements of Cash Flows for Each of the Years Ended December 31, 2012, 2011 and 2010	F-4
Consolidated Statements of Stockholders' Equity for Each of the Years Ended December 31, 2012, 2011 and 2010	F-5
Notes to the Consolidated Financial Statements	F-6

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)



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- 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)
- 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(28)
- 10.20# Form of Stock Option Agreement (2011 Stock Plan)(28)
- 10.21# Form of Stock Option Agreement for Executive Officers (2011 Stock Plan)(28)
- 10.22# Form of Restricted Stock Units Agreement (2011 Stock Plan)(28)
- 10.23# Form of Restricted Stock Award Agreement (2011 Stock Plan)(28)
- 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 Change In Control Agreement with Gregory Frost, dated December 21, 2012
- 10.32# Form of Amended and Restated Change In Control Agreement with Officer
- 10.33# Form of Change In Control Agreement with Officer
- 10.34\* Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.35\* Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.36\* Enhance License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.37 Termination Agreement between Halozyme Inc., Baxter Healthcare Corporation and Baxter Healthcare S.A, effective January 7, 2011(27)
- 10.38\* Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(16)
- 10.39\* License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(12)
- 10.40 Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(15)
- 10.41 Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(15)
- 10.43 Amended and Restated Lease (11388 Sorrento Valley Road), effective as of June 10, 2011(29)
- 10.44 Lease (11404 and 11408 Sorrento Valley Road), effective as of June 10, 2011(29)
- 10.45 Lease (11436 Sorrento Valley Road), dated October 31, 2012
- 10.46 Loan and Security Agreement and Disbursement Letter, dated December 28, 2012
- 10.47 First Amendment to Loan and Security Agreement and Disbursement Letter, dated February 5, 2013
- 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.INS\*\* Instance Document
- 101.SCH\*\* Taxonomy Extension Schema Document
- 101.CAL\*\* Taxonomy Extension Calculation Linkbase Document
- 101.DEF\*\* Taxonomy Extension Definition Linkbase Document
- 101.LAB\*\* Taxonomy Extension Label Linkbase Document
- 101.PRE\*\* Taxonomy Extension Presentation Linkbase Document

- (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).
- (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 January 10, 2011 (File No. 001-32335).
- (28) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed May 6, 2011 (File No. 001-32335).
- (29) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed June 16, 2011 (File No. 001-32335).

\* 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 applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files 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 Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

# Indicates management contract or compensatory plan or arrangement.

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



## 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 February 28, 2013.

Halozyme Therapeutics, Inc.,  
a Delaware corporation

Date: February 28, 2013

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	February 28, 2013
/s/ Kurt A. Gustafson Kurt A. Gustafson	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2013
/s/ Kenneth J. Kelley Kenneth J. Kelley	Chairman of the Board of Directors	February 28, 2013
/s/ Robert L. Engler, M.D. Robert L. Engler, M.D.	Director	February 28, 2013
/s/ Kathryn E. Falberg Kathryn E. Falberg	Director	February 28, 2013
/s/ Randal J. Kirk Randal J. Kirk	Director	February 28, 2013
/s/ Connie L. Matsui Connie L. Matsui	Director	February 28, 2013
/s/ John S. Patton, Ph.D. John S. Patton, Ph.D.	Director	February 28, 2013

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, 2012 and 2011, and the related consolidated statements of comprehensive loss, cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

February 28, 2013

HALOZYME THERAPEUTICS, INC.  
CONSOLIDATED BALANCE SHEETS

	December 31, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$99,901,264	\$52,825,527
Accounts receivable, net	15,703,087	2,262,465
Inventories	2,670,696	567,263
Prepaid expenses and other assets	12,752,888	8,332,242
Total current assets	131,027,935	63,987,497
Property and equipment, net	3,700,462	1,771,048
Total Assets	\$134,728,397	\$65,758,545
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$2,271,689	\$7,556,859
Accrued expenses	7,783,447	5,615,574
Deferred revenue, current portion	8,891,017	4,129,407
Total current liabilities	18,946,153	17,301,840
Deferred revenue, net of current portion	34,954,966	36,754,583
Long-term debt, net	29,661,680	—
Lease financing obligation	1,450,000	—
Deferred rent, net of current portion	861,879	802,006
Commitments and contingencies (Note 9)		
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; 112,709,174 and 103,989,272 shares issued and outstanding at December 31, 2012 and 2011, respectively	112,709	103,990
Additional paid-in capital	347,314,658	255,817,772
Accumulated deficit	(298,573,648 )	(245,021,646 )
Total stockholders' equity	48,853,719	10,900,116
Total Liabilities and Stockholders' Equity	\$134,728,397	\$65,758,545
See accompanying notes to consolidated financial statements.		

HALOZYME THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2012	2011	2010
<b>REVENUES:</b>			
Product sales, net	\$2,887,442	\$1,836,102	\$895,518
Revenues under collaborative agreements	39,437,784	54,250,334	12,728,597
Total revenues	42,325,226	56,086,436	13,624,115
<b>OPERATING EXPENSES:</b>			
Cost of product sales	1,094,400	257,834	985,283
Research and development	70,044,073	57,563,470	51,773,504
Selling, general and administrative	24,812,199	18,104,073	15,122,960
Total operating expenses	95,950,672	75,925,377	67,881,747
<b>OPERATING LOSS</b>	<b>(53,625,446 )</b>	<b>(19,838,941 )</b>	<b>(54,257,632 )</b>
<b>OTHER INCOME (EXPENSE):</b>			
Interest income, net	59,028	63,530	49,015
Other income, net	14,416	5,560	966,967
Total other income, net	73,444	69,090	1,015,982
<b>NET LOSS</b>	<b>\$(53,552,002)</b>	<b>\$(19,769,851)</b>	<b>\$(53,241,650)</b>
Basic and diluted net loss per share	<b>\$(0.48 )</b>	<b>\$(0.19 )</b>	<b>\$(0.56 )</b>
Shares used in computing basic and diluted net loss per share	111,077,105	102,566,089	94,357,695
Comprehensive loss	<b>\$(53,552,002)</b>	<b>\$(19,769,851)</b>	<b>\$(53,241,650)</b>
See accompanying notes to consolidated financial statements.			

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HALOZYME THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2012	2011	2010
Operating activities:			
Net loss	\$(53,552,002)	\$(19,769,851)	\$(53,241,650)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	8,348,587	5,569,899	4,866,325
Depreciation and amortization	1,079,424	1,095,823	1,507,925
Long-term debt, non-cash interest expense	8,625	—	—
Loss (gain) on disposal of equipment	7,370	(1,566)	) 13,542
Changes in operating assets and liabilities:			
Accounts receivable, net	(13,440,622)	) 65,803	1,915,641
Inventories	(2,103,433)	) (373,841)	) 966,129
Prepaid expenses and other assets	(4,420,646)	) (4,611,346)	) (2,147,119)
Accounts payable and accrued expenses	(3,263,487)	) 711,777	3,437,089
Deferred rent	44,895	172,438	(314,747)
Deferred revenue	2,961,993	(17,209,561)	) (2,388,641)
Net cash used in operating activities	(64,329,296)	) (34,350,425)	) (45,385,506)
Investing activities:			
Purchases of property and equipment	(1,412,585)	) (828,508)	) (646,544)
Net cash used in investing activities	(1,412,585)	) (828,508)	) (646,544)
Financing activities:			
Proceeds from issuance of common stock, net	81,476,845	—	59,965,059
Proceeds from issuance of long-term debt, net	29,660,600	—	—
Proceeds from issuance of common stock under equity incentive plans, net	1,680,173	4,748,612	1,858,333
Net cash provided by financing activities	112,817,618	4,748,612	61,823,392
Net increase (decrease) in cash and cash equivalents	47,075,737	(30,430,321)	) 15,791,342
Cash and cash equivalents at beginning of period	52,825,527	83,255,848	67,464,506
Cash and cash equivalents at end of period	\$99,901,264	\$52,825,527	\$83,255,848
Supplemental disclosure of cash flow information:			
Interest paid	\$18,875	\$—	\$—
Supplemental disclosure of non-cash investing and financing activities:			
Capitalized property and liability associated with a build-to-suit lease arrangement	\$1,450,000	\$—	\$—
Accounts payable for purchases of property and equipment	\$153,623	\$189,898	\$13,806
See accompanying notes to consolidated financial statements.			

HALOZYME THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
BALANCE AT JANUARY 1, 2010	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	3,060,540	3,060	4,745,432	—	4,748,492
Issuance of restricted stock awards	347,883	349	(229 )	—	120
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
Share-based compensation expense	—	—	8,348,587	—	8,348,587
Issuance of common stock for cash, net	7,820,000	7,820	81,469,025	—	81,476,845
Issuance of common stock pursuant to exercise of stock options and vesting of restricted stock units, net	525,707	525	1,679,648	—	1,680,173
Issuance of restricted stock awards	374,195	374	(374 )	—	—
Net loss	—	—	—	(53,552,002 )	(53,552,002 )
BALANCE AT DECEMBER 31, 2012	112,709,174	\$112,709	\$347,314,658	\$(298,573,648)	\$48,853,719

See accompanying notes to consolidated financial statements.

Halozyme Therapeutics, Inc.

Notes to Consolidated Financial Statements

### 1. Organization and Business

Halozyme Therapeutics, Inc. is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding 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 technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

Our proprietary enzymes can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or to alter abnormal tissue structures for clinical benefit. We have chosen to exploit our technology and expertise in a balanced way to modulate both risk and spend by: (1) developing our own proprietary products in therapeutic areas with significant unmet medical needs, such as diabetes, oncology and dermatology, and (2) licensing our technology to biopharmaceutical companies to collaboratively develop products which combine our technology with the collaborators' proprietary compounds.

The majority of the product candidates in our current pipeline are based on rHuPH20, a patented human recombinant hyaluronidase enzyme. rHuPH20 temporarily breaks down hyaluronic acid - a naturally occurring substance that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. Our proprietary pipeline consists of multiple clinical stage products in diabetes, oncology and dermatology. We currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Pfizer Inc. (Pfizer), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma) and Intrexon Corporation (Intrexon), with three product candidates which have been submitted for regulatory approval in the U.S. and/or Europe as well as several others at various stages of development.

We were founded in 1998 and reincorporated from the State of Nevada to the State of Delaware in November 2007. Except where specifically noted or the context otherwise requires, the use of terms such as "Halozyme," "we," "our," and "us" in these Notes to Consolidated Financial Statements refers to Halozyme Therapeutics, Inc.

### 2. Summary of Significant Accounting Policies

#### Basis of Presentation

The consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and our 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 our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our 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.

#### 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 us to a significant concentration of credit risk consist of cash and cash equivalents and accounts receivable. We maintain our cash and cash equivalent balances with one major commercial bank. Deposits held with the bank exceed the amount of insurance provided on such deposits.

We have license and collaborative agreements with pharmaceutical companies under which we receive payments for license fees, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and supply of bulk formulation of rHuPH20. In addition, we sell Hylenex<sup>®</sup> 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 our 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, we recorded no allowance for doubtful accounts at December 31, 2012 and 2011. Approximately 86% of accounts receivable balance as of December 31, 2012 represents amounts due from Roche and Pfizer. Approximately 82% of the accounts receivable balance as of December 31, 2011 represents amounts due from Roche, Baxter and ViroPharma. For the years ended December 31, 2012, 2011 and 2010, 45%, 19% and 52% of total revenues were from Roche and 17%, 42% and 42% of total revenues were from Baxter, respectively. For the year ended December 31, 2012, 22% of total revenues were from Pfizer. 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, 2012, 2011 and 2010 consisted of domestic revenues of approximately \$22.7 million, \$44.9 million and \$6.0 million, respectively, and foreign revenues of approximately \$19.6 million, \$11.2 million and \$7.6 million, respectively. Of our total foreign revenues for the years ended December 31, 2012, 2011 and 2010, approximately \$18.9 million, \$10.4 million, \$7.2 million, respectively, were attributable to Switzerland. We attribute revenues under collaborative agreements to the individual countries where the collaborator is headquartered. We attribute revenues from product sales to the individual countries to which the product is shipped. For the years ended December 31, 2012, 2011 and 2010, we had no foreign based operations, and we had no long-lived assets located in foreign countries.

We rely 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 our collaborators' product candidates. Payments due to these suppliers represent 20% and 59% of the accounts payable balance at December 31, 2012 and 2011, respectively. We also rely on a third-party manufacturer for the fill and finish of Hylenex recombinant product under a contract we entered in June 2011. Payments due to this supplier represent 8.0% and 3.7% of the accounts payable balance at December 31, 2012 and 2011, respectively.

#### Accounts Receivable, Net

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, distribution fees and chargebacks. We recorded no allowance for doubtful accounts at December 31, 2012 and 2011, as the collectibility of accounts receivable is reasonably assured. Allowances for prompt payment discounts, distribution fees and chargebacks as of December 31, 2012 and 2011 were immaterial.

#### Inventories

Inventories are stated at lower of cost or market. Cost 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 we expect to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.



Raw materials inventories consist of raw materials used in the manufacture of our 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.

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 regulatory bodies such as the U.S. Food and Drug Administration ("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 as inventory.

#### Property and Equipment, Net

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. Leased buildings under build-to-suit lease arrangements are capitalized and included in property and equipment when we are involved in the construction of the structural improvements or take construction risk prior to the commencement of the lease. Upon occupancy of facilities under the build-to-suit leases, we assess whether those arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If we continue to be the deemed owner, the facilities would be accounted for as financing leases.

#### Impairment of Long-Lived Assets

We account 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, 2012 and 2011, there has been no impairment of the value of such assets.

#### Fair Value of Financial Instruments

We follow 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 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.

Our financial instruments include cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable, accrued expenses and long-term debt. Fair value estimates of these instruments are made at a specific point in time, based on

relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. . Further, based on the borrowing rates currently available to us for loans with similar terms, we believe the fair value of long-term debt approximates its carrying value. Cash equivalents of approximately \$98.4 million and \$51.8 million at December 31, 2012 and 2011, 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. We have 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 the lease. The difference between rent expense accrued and amounts paid under lease agreements 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 our net loss for all periods presented.

#### 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 supply of bulk rHuPH20, and/or royalties on sales of products resulting from collaborative arrangements. We recognize revenues in accordance with the authoritative guidance for revenue recognition. We recognize 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 FDA in December 2005. From 2005 through January 7, 2011, we granted Baxter the worldwide market rights for Hylenex recombinant under the terms of the amended and restated development and supply agreement with Baxter ("Hylenex Collaboration"). Baxter commercially launched Hylenex recombinant in October 2009. Effective January 7, 2011, we and Baxter mutually agreed to terminate the collaboration. 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.

In December 2011, we reintroduced Hylenex recombinant to the market, shipped initial orders to our wholesaler customers and began promoting Hylenex recombinant through our sales force. We sell Hylenex recombinant in the United States to wholesale pharmaceutical distributors, who 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 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 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 the product is 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 we can reliably estimate product returns and chargebacks from the wholesale distributors, 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 wholesale distributors and 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 adjustments 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. We expect our customers will take advantage of this discount; therefore, at the time the sale is made to the respective wholesale distributors, we accrue the entire prompt payment discount, based on the gross amount of each invoice, by reducing our accounts receivable and deferred revenue associated with such product sales.

**Chargebacks.** We provide discounts to end-user members of certain group purchasing organizations ("GPO") under collective purchasing contracts between us and the GPOs. We also provide discounts to certain hospitals, who are members of the GPOs with which we do not have contracts. The end-user members purchase products from the wholesale distributors at a contracted discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the end-users 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. We incur GPO fees for these transactions which are also recorded in the same period the related product sales revenue is recognized and are included in accrued expenses.

**Product Returns.** The product returns 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.

For the years ended December 31, 2012 and 2011, we recorded product sales revenue of approximately \$2.2 million and \$35,000, respectively, related to Hylenex recombinant, net of estimated distribution fees, prompt payment discounts, chargebacks and product returns totaling approximately \$1.1 million and \$8,000, respectively. We have a deferred revenue balance of approximately \$624,000 and \$167,000 at December 31, 2012 and 2011, respectively, for Hylenex recombinant shipments, which is net of estimated distribution fees, prompt pay discounts and product returns. In addition, inventory at December 31, 2012 and 2011 included a deferred cost of product sales of approximately \$178,000 and \$31,000, respectively, associated with Hylenex recombinant shipments to wholesalers. At the time we 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.

**Revenues under Collaborative Agreements.** We have license and collaboration agreements under which the collaborators obtained worldwide rights for the use of our proprietary rHuPH20 enzyme 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 specified milestones designated in the collaborative agreements, annual maintenance fees, 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. We analyze each element of our collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

Effective January 1, 2011, we adopted Accounting Standards Update ("ASU") No. 2009-13, Multiple-Deliverable Revenue Arrangements ("ASU 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 our 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 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, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are not contingent upon the delivery of additional items or meeting other specified performance conditions. 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.

Nonrefundable 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 collaborator is fixed or determinable and collectibility 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.

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 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.

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. Effective January 1, 2011, we adopted, on a prospective basis, ASU No. 2010-17, Revenue Recognition - Milestone Method ("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:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement
1. 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 vendor.

Prior to our adoption of 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.

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 reasonably assured. Revenue from the manufacture of rHuPH20 API is recognized when the API has met all specifications required for the collaborator's 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 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 30 to 90 days prior written notice to us. There are no performance, cancellation, termination or refund provisions in any of our collaborative agreements that contain material financial consequences to us.

Refer to Note 3, "Collaborative Agreements," and Note 5, "Deferred Revenue," for further discussion on our collaborative arrangements.

#### 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 Baxter Hylenex Collaboration in January 2011, we 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, 2012.

### Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trial expenses, 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 our research and development efforts and have no alternative future uses.

In accordance with certain research and development agreements, we are obligated to make certain upfront payments upon execution of the agreement. 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 we do not expect the goods to be delivered or services to be performed.

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 the 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 as incurred.

### Clinical Trial Expenses

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 progress of the clinical trials. 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 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, we have had no material changes in clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

### Share-Based Compensation

We record 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, 2012, 2011 and 2010 based on our historical experience for the years then ended.



Total share-based compensation expense related to share-based awards for the years ended December 31, 2012, 2011 and 2010 was comprised of the following:

	Year Ended December 31,		
	2012	2011	2010
Research and development	\$4,190,938	\$2,815,362	\$2,517,172
Selling, general and administrative	4,157,649	2,754,537	2,349,153
Share-based compensation expense	\$8,348,587	\$5,569,899	\$4,866,325
Net share-based compensation expense, per basic and diluted share	\$0.08	\$0.05	\$0.05
Share-based compensation expense from:			
Stock options	\$4,722,629	\$3,230,822	\$4,022,790
Restricted stock awards and restricted stock units	3,625,958	2,339,077	843,535
	\$8,348,587	\$5,569,899	\$4,866,325

Cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) are classified as cash inflows provided by financing activities and cash outflows used in operating activities. Due to our net loss position, no tax benefits have been recognized in the consolidated statements of cash flows.

#### Income Taxes

We provide for income taxes using the liability method. Under this method, deferred income tax assets and liabilities are determined based on the differences between the financial statement carrying amounts of existing assets and liabilities at each year end and their respective tax bases and are measured using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Deferred tax assets and other tax benefits are recorded when it is more likely than not that the position will be sustained upon audit. Valuation allowances have been established to reduce our net deferred tax assets to zero, as we believe that it is more likely than not that such assets will not be realized.

#### Other Income

Other income for the year ended December 31, 2010 consisted of one-time grants of approximately \$978,000 received under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code.

#### Net Loss Per Share

Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Stock options, unvested stock awards and restricted stock units are considered to be common equivalents and are only included in the calculation of diluted earnings per common share when their effect is dilutive. Because of our net loss, outstanding stock options, outstanding restricted stock units and unvested stock awards totaling 7,444,333, 6,365,667 and 8,095,365 were excluded from the calculation of diluted net loss per common share for the years ended December 31, 2012, 2011 and 2010, respectively, because their effect is anti-dilutive.

#### Segment Information

We operate our business in 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 the delivery of injected drugs and fluids or to alter abnormal tissue structures for clinical benefit. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaborative agreements with third parties and (ii) product sales of

Hylenex recombinant. The chief operating decision maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

#### Adoption of Recent Accounting Pronouncements

Effective January 1, 2012, we adopted Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income and ASU No. 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-5. In these updates, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in these updates are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU Nos. 2011-05 and 2011-12 did not have a material impact on our consolidated financial position or results of operations. We have presented comprehensive loss in our consolidated statements of comprehensive loss.

Effective January 1, 2012, we prospectively adopted FASB's ASU No. 2011-04, "Fair Value Measurement (Topic 820) - Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS". The amendments in ASU 2011-04 result in common fair value measurement and disclosure requirements in GAAP and International Financial Reporting Standards ("IFRS"). Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU No. 2011-04 did not have a material effect on our consolidated financial position or results of operations.

### 3. Collaborative Agreements

#### Roche Collaboration

In December 2006, we and Roche entered into a license and collaborative agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and up to thirteen Roche target compounds (the "Roche Collaboration"). As of December 31, 2012, Roche has elected a total of five exclusive targets and retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual maintenance fees to us. As of December 31, 2012, we have received \$61.75 million from Roche, including the \$20.0 million upfront license fee payment for the application of rHuPH20 to the initial three Roche exclusive targets, \$20.75 million in connection with Roche's election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets, \$13.0 million in clinical development milestone payments and \$8.0 million in regulatory milestone payments. We are also entitled to receive reimbursements for providing research and development services and rHuPH20 API to Roche at its request.

Under the terms of the Roche Collaboration, Roche will pay us a royalty on each product commercialized under the agreement consisting of a mid-single digit percent of the net sales of such product. Unless terminated earlier in accordance with its terms, the Roche Collaboration continues in effect until the expiration of Roche's obligation to pay royalties. Roche has the obligation to pay royalties with respect to each product in each country, during the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country. Pursuant

to the terms of the Roche Collaboration, we scaled up the production of rHuPH20 and identified a second source manufacturer that would help meet anticipated production obligations arising from the Roche Collaboration. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20), 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 Collaboration. Refer to Note 5 for a further discussion on deferred revenue associated with the Roche Collaboration. We determined that the clinical and regulatory milestones were substantive; therefore, we recognized the clinical and regulatory milestone payments as revenue upon achievement of such milestones.

For the years ended December 31, 2012 and 2011, we recognized \$8.0 million and \$5.0 million, respectively, as revenues under collaborative agreements in accordance with the Milestone Method related to the achievement of certain regulatory and clinical milestones pursuant to the terms of the Roche Collaboration. There were no milestone payments recognized as revenues under collaborative agreements under the Roche Collaboration for the year ended December 31, 2010.

#### Gammagard Collaboration

In September 2007, we entered into a license and collaborative agreement with Baxter, under which Baxter obtained a worldwide, exclusive license to develop and commercialize a product candidate (currently named HyQ) consisting of rHuPH20 combined with a current Baxter product, GAMMAGARD LIQUID™ (the “Gammagard Collaboration”). As of December 31, 2012, we have received \$13.0 million under the Gammagard Collaboration, including the \$10.0 million upfront license fee payment and a \$3.0 million regulatory milestone payment. Baxter will pay us a royalty on each product commercialized under the agreement consisting of a mid-single digit percent of the net sales of such product. The Gammagard Collaboration is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Collaboration, while we are responsible for the supply of rHuPH20 enzyme. We perform research and development activities and supply rHuPH20 enzyme at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Collaboration. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard Collaboration.

Unless terminated earlier in accordance with its terms, the Gammagard Collaboration continues in effect until the expiration of Baxter's obligation to pay royalties. Baxter has the obligation to pay royalties, with respect to each product in each country, during the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country.

Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), the upfront payment was deferred and is being recognized over the term of the Gammagard Collaboration. For the year ended December 31, 2011, we recognized \$3.0 million as revenues under collaborative agreements under the Gammagard Collaboration in accordance with the Milestone Method. There were no milestone payments recognized as revenues under collaborative agreements under the Gammagard Collaboration for the years ended December 31, 2012 and 2010.

#### Other Collaborations

In December 2012, we and Pfizer entered into a collaboration and license agreement, under which Pfizer has the worldwide license to develop and commercialize products combining rHuPH20 enzyme with Pfizer proprietary biologics directed to up to six targets (the “Pfizer Collaboration”). Targets may be selected on an exclusive or non-exclusive basis. As of December 31, 2012, we have recognized a nonrefundable upfront payment of \$9.5 million for the licenses to three specified exclusive targets and three additional targets which Pfizer has the right to elect in the future upon payment of additional fees. Unless terminated earlier in accordance with its terms, the Pfizer Collaboration continues in effect until the later of (i) expiration of the last to expire of the valid claims of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers a product developed under the collaboration, and (ii) expiration of the last to expire royalty term for a product developed



under the collaboration. The royalty term of a product developed under the Pfizer Collaboration, with respect to each country, consists of the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country. Pfizer may terminate the agreement prior to expiration for any reason in its entirety or on a target-by-target basis upon 30 days prior written notice to us. Upon any such termination, the license granted to Pfizer (in total or with respect to the terminated target, as applicable) will terminate, provided, however, that in the event of expiration of the agreement, the licenses granted will become perpetual, non-exclusive and fully-paid-up.

In May 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]) (the "ViroPharma Collaboration"). 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, 2012, we have received \$13.0 million from ViroPharma, including the \$9.0 million nonrefundable upfront license fee payment and a \$3.0 million clinical development milestone payment. We are entitled to receive a royalty on each product commercialized under the agreement consisting of ten percent of the net sales of such product. Unless terminated earlier in accordance with its terms, the ViroPharma Collaboration continues in effect until the later of (i) expiration of the last to expire of the valid claims of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers a product developed under the collaboration, and (ii) expiration of the last to expire royalty term for a product developed under the collaboration. The royalty term of a product developed under the ViroPharma Collaboration, with respect to each country, consists of the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country. 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 June 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) (the "Intrexon Collaboration"). In addition, the license provides Intrexon with exclusivity for a defined indication ("Exclusive Field"). As of December 31, 2012, we have received \$10.0 million from Intrexon, including a nonrefundable upfront license fee payment of \$9.0 million. We are entitled to receive a royalty on each product commercialized under the agreement consisting of a percentage of the net sales of such product ranging from mid-single digits up to a low double-digit percentage. Unless terminated earlier in accordance with its terms, the Intrexon Collaboration continues in effect until the later of (i) expiration of the last to expire of the valid claims of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers a product developed under the collaboration, and (ii) expiration of the last to expire royalty term for a product developed under the collaboration. The royalty term of a product developed under the Intrexon Collaboration, with respect to each country, consists of the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country. 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, chairman of its board of directors and major shareholder is also a member of our board of directors.

We identified the deliverables at the inception of the Pfizer, ViroPharma and Intrexon agreements 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 were 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

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services to be performed for the collaborators. The arrangement consideration was allocated to the deliverables based on the relative selling price method.

The amount allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions (the noncontingent amount). As such, we excluded from the allocable arrangement consideration the milestone payments, annual exclusivity fees and royalties regardless of the probability of receipt. Based on the results of our analysis, we allocated the \$9.5 million license fees from Pfizer, the \$9.0 million upfront license fee from ViroPharma and the \$9.0 million upfront license fee from Intrexon to the license fee deliverable under each of the arrangements. We determined that the upfront payments were earned upon the granting of the worldwide, exclusive right to our technology to the collaborators in these arrangements. As a result, we recognized the \$9.5 million license fee under the Pfizer Collaboration for the year ended December 31, 2012, the \$9.0 million upfront license fee received under the ViroPharma Collaboration and the \$9.0 million upfront license fee received under the Intrexon Collaboration for the year ended December 31, 2011, as revenues under collaborative agreements.

Pfizer, ViroPharma and Intrexon are each solely responsible for the development, manufacturing and marketing of any products resulting from their respective collaborations. We are entitled to receive payments for research and development services and supply of rHuPH20 API to these collaborators if requested by such collaborator. We recognize amounts allocated to research and development services as revenues under collaborative agreements as the related services are performed. We recognize amounts allocated to the sales of API as revenues under collaborative agreements when such API has met all required specifications by the collaborators and the related title and risk of loss and damages have passed to the collaborators. We cannot predict the timing of delivery of research and development services and API as they are at the collaborators' requests.

For the year ended December 31, 2011, we recognized a \$3.0 million milestone payment as revenues under collaborative agreements in accordance with the Milestone Method related to the achievement of a development milestone pursuant to the terms of the ViroPharma Collaboration. There were no milestone payments recognized as revenues under collaborative agreements associated with these collaborations for the year ended December 31, 2012. There were no milestone payments recognized as revenues under collaborative agreements associated with the Intrexon Collaboration for the years ended December 31, 2012 and 2011.

Pursuant to the terms of our existing collaborations collectively, we are entitled to receive additional milestone payments for the successful development of the elected targets in the aggregate of up to approximately \$58.5 million upon achievement of specified clinical development milestone events and up to approximately \$84.0 million upon achievement of specified regulatory milestone events in connection with specified regulatory filings and receipt of marketing approvals.

#### 4. Certain Balance Sheet Items

Inventories consist of the following:

	December 31, 2012	December 31, 2011
Raw materials	\$ 1,127,061	\$ 201,822
Work-in-process	792,257	290,647
Finished goods	751,378	74,794
	\$ 2,670,696	\$ 567,263

Property and equipment consists of the following:

	December 31, 2012	December 31, 2011
Research equipment	\$ 6,360,004	\$ 5,231,763
Computer and office equipment	1,432,975	1,266,041
Leasehold improvements	1,138,110	1,019,147
Building (1)	1,450,000	—
	10,381,089	7,516,951
Accumulated depreciation and amortization	(6,680,627 )	(5,745,903 )
	\$ 3,700,462	\$ 1,771,048

(1) Represents capitalized building under a build-to-suit lease arrangement where we are considered the owner (for accounting purposes only) during the construction period.

Depreciation and amortization expense was approximately \$1.1 million, \$1.1 million and \$1.5 million, for the years ended December 31, 2012, 2011 and 2010, respectively.

Accrued expenses consist of the following:

	December 31, 2012	December 31, 2011
Accrued outsourced research and development expenses	\$ 2,223,242	\$ 1,910,273
Accrued compensation and payroll taxes	4,053,590	3,223,936
Other accrued expenses	1,506,615	481,365
	\$ 7,783,447	\$ 5,615,574

#### 5. Deferred Revenue

Deferred revenue consists of the following:

	December 31, 2012	December 31, 2011
Collaborative agreements	\$ 43,222,473	\$ 40,716,806
Product sales	623,510	167,184
Total deferred revenue	43,845,983	40,883,990
Less current portion	8,891,017	4,129,407
Deferred revenue, net of current portion	\$ 34,954,966	\$ 36,754,583

Roche Collaboration. In December 2006, we and Roche entered into the Roche Collaboration under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and certain Roche target compounds. Under the terms of the Roche Collaboration, Roche paid \$20.0 million to us in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets.

Through December 31, 2012, Roche has paid an aggregate of \$20.75 million in connection with Roche's election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets. Roche currently retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual license maintenance fees to us.

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 Collaboration. We recognized revenue from the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Collaboration in the amounts of approximately \$2.0 million for each of the years ended December 31, 2012, 2011 and 2010. Deferred revenue relating to the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Collaboration was \$30.4 million and \$31.7 million as of December 31, 2012 and 2011, respectively.

During the year ended December 31, 2012, we received approximately \$7.0 million in deferred revenue relating to the manufacture of rHuPH20 API for Roche. We recognized approximately \$1.4 million as revenues under collaborative agreements from deferred revenue relating to the manufacture of rHuPH20 API for the year ended December 31, 2012. Deferred revenue relating to the manufacture of rHuPH20 API under the Roche Collaboration was \$5.6 million and zero as of December 31, 2012 and 2011, respectively.

**Baxter Gammagard Collaboration.** In September 2007, we and Baxter entered into the Gammagard Collaboration, under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID. Under the terms of the Gammagard Collaboration, Baxter paid us a nonrefundable upfront payment of \$10.0 million. Due to our continuing involvement obligations (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 Collaboration. We recognized revenue from the upfront payment under the Gammagard Collaboration in the amounts of approximately \$483,000, \$483,000 and \$521,000 for the years ended December 31, 2012, 2011 and 2010, respectively. Deferred revenue relating to the upfront payment under the Gammagard Collaboration was \$7.1 million and \$7.6 million as of December 31, 2012 and 2011, respectively.

**Baxter Hylenex Collaboration.** In February 2007, we and Baxter amended certain existing agreements for Hylenex recombinant and entered into the Hylenex Collaboration for kits and formulations with rHuPH20. Under the terms of the Hylenex Collaboration, Baxter paid us a nonrefundable upfront payment of \$10.0 million. In addition, Baxter would make payments to us based on sales of the products covered under the Hylenex Collaboration. Baxter had prepaid nonrefundable product-based payments totaling \$10.0 million in connection with the execution of the Hylenex Collaboration. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), the \$10.0 million upfront payment was initially deferred and was being recognized over the term of the Hylenex Collaboration. The prepaid product-based payments were also deferred and were being recognized as product sales revenues as we earned such revenues from the sales of Hylenex recombinant by Baxter.

In January 2011, we and Baxter mutually agreed to terminate the Hylenex Collaboration and the associated agreements. The termination of these agreements does not affect the other relationships between the parties, including the application of our Enhance technology to Baxter's GAMMAGARD LIQUID.

In July 2011, we and Baxter entered into an agreement (the "Transition Agreement") setting forth certain rights, data and assets to be transferred by Baxter to us during a transition period. Effective July 2011, we had no future performance obligations to Baxter in connection with the Hylenex Collaboration. 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 the deferred upfront payment from the Hylenex Collaboration as revenues under collaborative agreements for the year ended December 31, 2011. For the year ended December 31, 2010, we recognized revenues under the Hylenex Collaboration from the upfront payment in the amounts of approximately \$503,000, and from the product-based payments in the amounts of approximately \$332,000. There were no deferred revenues relating to the Hylenex Collaboration at December 31, 2012 and 2011. As a result of the termination of the Hylenex Collaboration, at December 31, 2010 we had recharacterized deferred revenue of approximately \$991,000 as a reserve for product returns for HYLENEX API previously delivered to Baxter that could be returned ("Delivered Products"). Pursuant to the terms of the Transition Agreement, Baxter no longer had the right to return the Hylenex recombinant API previously delivered to Baxter. 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.

#### 6. Long-Term Debt, Net

In December 2012, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (collectively, the "Lenders") for a \$30 million secured single-draw term loan facility with a maturity date, as amended, of January 1, 2017. On December 28, 2012, we drew down \$30 million under the Loan Agreement. The proceeds are to be used for working capital and general business requirements. The term loan bears a fixed interest rate of 7.55% per annum. The monthly repayment schedule includes interest only payments in arrears for the first year followed by equal principal and interest payments for the subsequent 36 months. The term loan requires a final payment of \$2.55 million which is due when the term loan becomes due or upon the prepayment of the facility. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 1% to 3% depending upon when the prepayment occurs.

In connection with the term loan, we received proceeds of \$29.7 million, net of debt offering costs. The debt offering costs have been recorded as debt discount on our consolidated balance sheet which together with the final \$2.55 million payment and fixed interest rate payments will be amortized to interest expense throughout the life of the term loan using the effective interest rate method.

The term loan facility is secured by substantially all of the assets of the Company and Halozyne, Inc., except that the collateral does not include any intellectual property (including all licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, as well as customary events of default and our indemnification obligations. One of the events of default is a material adverse change which is defined as a material adverse change in our business, operations, or condition (financial or otherwise); a material impairment of the prospect of repayment of any portion of the loan; or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. As of December 31, 2012, we were in compliance with all material covenants under the Loan Agreement and there was no material adverse change.

Future maturities and interest payments under the term loan as of December 31, 2012, are as follows:

2013	\$ 2,076,250
2014	10,461,382
2015	11,206,507
2016	11,206,507
2017	3,483,876
Total minimum payments	38,434,522
Less amount representing interest	(8,434,522 )
Gross balance of long-term debt	30,000,000
Less unamortized debt discount	(338,320 )
Present value of long-term debt	29,661,680
Less current portion of long-term debt, less discount	—
Long-term debt, less current portion and discount	\$ 29,661,680

Interest expense, including amortization of debt discount, related to the long-term debt for the year ended December 31, 2012 was \$28,000.

## 7. Stockholders' Equity

During 2012, we issued an aggregate of 444,637 shares of common stock, in connection with the exercises of stock options for cash in the aggregate amount of approximately \$2.0 million. In addition, we issued 374,195 shares of common stock, net of restricted stock awards canceled, in connection with the grants of restricted stock awards and 81,070 shares of common stock upon vesting of certain restricted stock units. The restricted stock unit holders surrendered 46,930 restricted stock units to pay for minimum withholding taxes totaling approximately \$347,000. In February 2012, we completed an underwritten public offering and issued 7,820,000 shares of common stock, including 1,020,000 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriter. All of the shares were offered at a public offering price of \$10.61 per share, generating approximately \$81.5 million in net proceeds. Of the 7,820,000 shares of common stock sold, Randal J. Kirk, a member of our board of directors, through his affiliates, purchased 1,360,000 shares of common stock in this offering at the public offering price of \$10.61 per share for a total of approximately \$14.4 million.

During 2011, we issued an aggregate of 3,045,540 shares of common stock in connection with the exercises of 3,137,056 shares of stock options for cash in the aggregate amount of approximately \$4.7 million. In addition, we issued 347,883 shares of common stock in connection with the grants of restricted stock awards and 15,000 shares of common stock upon vesting of certain restricted stock units.

In September 2010, we issued 8.3 million shares of common stock in a public offering at a public offering price of \$7.50 per share, generating approximately \$60.0 million in net proceeds. In connection with this financing, we granted to an underwriter an option to purchase 1,245,000 shares of common stock at a price of \$7.25 per share. The option was exercisable in the event that the underwriter sold more than 8.3 million shares of common stock. The option expired unexercised on October 8, 2010.

During 2010, we issued an aggregate of 479,093 shares of common stock in connection with the exercises of stock options, for cash in the aggregate amount of approximately \$1.9 million, and 120,000 shares of common stock for the grants of restricted stock awards.

## 8. Equity Incentive Plans

We have two equity incentive plans (the "Current Plans") under which we currently grant stock options, restricted stock awards and restricted stock units: the 2011 Stock Plan and the 2008 Outside Directors' Stock Plan. In May 2011, our stockholders approved our 2011 Stock Plan, which provides for the granting of up to a total of 6,000,000 shares of common stock (subject to certain limitations as described in the 2011 Stock Plan) to selected employees, consultants and non-employee members of our Board of Directors ("Outside Directors") as stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. The 2011 Stock Plan replaced our prior stock plans, consisting of our 2008 Stock Plan, 2006 Stock Plan and 2004 Stock Plan ("Prior Plans", collectively with the Current Plans, the "Plans"). The Prior Plans were terminated such that no additional awards could be granted under the Prior Plans, but the terms of the Prior Plans remain in effect with respect to outstanding awards until they are exercised, settled or canceled. The Plans were approved by the stockholders. Awards are subject to terms and conditions established by the Compensation Committee of our Board of Directors.

During the year ended December 31, 2012, we granted share-based awards under the 2011 Stock Plan and the 2008 Outside Directors' Stock Plan. At December 31, 2012, 7,062,013 shares were subject to outstanding awards and 2,730,059 shares were available for future grants of share-based awards. At the present time, management intends to issue new common shares upon the exercise of stock options, issuance of restricted stock awards and settlement of restricted stock units.

**Stock Options.** Options granted under each of the Plans must have an exercise price equal to at least 100% of the fair market value of our common stock on the date of grant. The options will generally have a maximum contractual term of ten years and vest at the rate of one-fourth of the shares on the first anniversary of the date of grant and 1/48 of the shares monthly thereafter. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans).

A summary of our stock option award activity as of and for the years ended December 31, 2012, 2011 and 2010 is as follows:

	Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value	
Outstanding at January 1, 2010	7,804,266	\$3.73			
Granted	1,332,714	\$5.94			
Exercised	(479,093 )	\$3.88			
Canceled/forfeited	(682,522 )	\$6.29			
Outstanding at December 31, 2010	7,975,365	\$3.87			
Granted	1,624,768	\$7.79			
Exercised	(3,137,056 )	\$1.71			
Canceled/forfeited	(593,293 )	\$6.72			
Outstanding at December 31, 2011	5,869,784	\$5.82			
Granted	1,215,442	\$9.90			
Exercised	(444,637 )	\$4.56			
Canceled/forfeited	(260,722 )	\$8.34			
Outstanding at December 31, 2012	6,379,867	\$6.59	6.5	\$7.4	million
Vested and expected to vest at December 31, 2012	6,086,988	\$6.49	6.3	\$7.4	million
Exercisable at December 31, 2012	3,958,125	\$5.34	5.1	\$6.8	million

The weighted average grant-date fair values of options granted during the years ended December 31, 2012, 2011 and 2010 were \$5.63 per share, \$4.57 per share and \$3.69 per share, respectively. As of December 31, 2012, approximately \$9.0 million of total unrecognized compensation costs related to non-vested stock option awards was expected to be recognized over a weighted average period of approximately 2.7 years. The intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was approximately \$2.9 million, \$16.6 million and \$1.8 million, respectively. Cash received from stock option exercises for the years ended December 31, 2012, 2011 and 2010 was approximately \$2.0 million, \$4.7 million and \$1.9 million, respectively.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ("Black-Scholes model") that uses the assumptions noted in the following table. Expected volatility is based on 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 rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The dividend yield assumption is based on the expectation of no future dividend payments by us. Assumptions used in the Black-Scholes model were as follows:

	Year Ended December 31,		
	2012	2011	2010
Expected volatility	64.0-69.2%	64.0-65.1%	65.8-70.8%
Average expected term (in years)	5.6	5.8	5.7
Risk-free interest rate	0.80-1.15%	1.14-2.55%	1.39-2.80%
Expected dividend yield	0	% 0	% 0

**Restricted Stock Awards.** Restricted stock awards are grants that entitle the holder to acquire shares of our common stock at zero or a fixed price, which is typically nominal. The shares covered by a restricted stock award cannot be sold, pledged, or otherwise disposed of until the award vests and any unvested shares may be reacquired by us for the original purchase price following the awardee's termination of service. Annual grants of restricted stock awards under the Outside Directors' Stock Plans typically vest in full the first day the awardee may trade our stock in compliance with our insider trading policy following the date immediately preceding the first annual meeting of stockholders following the grant date.

The following table summarizes our restricted stock award activity during the years ended December 31, 2012, 2011 and 2010:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2010	120,000	\$5.81
Granted	120,000	\$7.67
Vested	(120,000 )	\$5.81
Forfeited	—	\$—
Unvested at December 31, 2010	120,000	\$7.67
Granted	353,508	\$6.51
Vested	(120,000 )	\$7.67
Forfeited	(5,625 )	\$6.67
Unvested at December 31, 2011	347,883	\$6.51
Granted	380,158	\$10.29
Vested	(339,758 )	\$6.51
Forfeited	(5,963 )	\$10.81
Unvested at December 31, 2012	382,320	\$10.21

The fair value of the restricted stock awards is based on the market value of our common stock on the date of grant. The total grant-date fair value of restricted stock awards vested during the years ended December 31, 2012, 2011 and 2010 was approximately \$2.2 million, \$0.9 million and \$0.7 million, respectively. We recognized approximately \$2.1 million, \$1.7 million and \$0.8 million of share-based compensation expense related to the restricted stock awards for the years ended December 31, 2012, 2011 and 2010. As of December 31, 2012, total unrecognized compensation cost related to unvested shares was approximately \$2.0 million, which is expected to be recognized over a weighted-average period of approximately 2.2 years.

**Restricted Stock Units.** A restricted stock unit is a promise by us to issue a share of our common stock upon vesting of the unit. During the year ended December 31, 2012 and 2011, we granted 682,146 and 163,000 shares of restricted stock units, respectively, at no purchase price, to certain employees under the 2011 Stock Plan. Of the total 163,000 shares of restricted stock units granted during the year ended December 31, 2011, 148,000 shares were subject to percentage vesting based upon achievement of certain corporate goals and the employees' continuing services through May 2012. No restricted stock units were granted during the year ended December 31, 2010.

The following table summarizes our restricted stock unit activity during the years ended December 31, 2012 and 2011:

	Number of Shares	Weighted Average Purchase Price	Weighted Average Remaining Contractual Term (yrs)	Aggregate Intrinsic Value
Unvested at January 1, 2011	—	\$—		
Granted	163,000	\$—		
Vested	(15,000 )	\$—		
Forfeited	—	\$—		
Unvested at December 31, 2011	148,000	\$—		
Granted	682,146	\$—		
Vested	(128,000 )	\$—		
Forfeited	(20,000 )	\$—		
Unvested at December 31, 2012	682,146	\$—	2.03	\$4.6 million
Expected to vest at December 31, 2012	556,377	\$—	1.84	\$3.7 million

The estimated fair value of the restricted stock units was based on the market value of our common stock on the date of grant. The weighted average grant-date fair value of restricted stock units granted during the years ended December 31, 2012 and 2011 was \$10.61 and \$6.71 per share, respectively. The total intrinsic value of restricted stock units vested during the year ended December 31, 2012 and 2011 was approximately \$0.9 million and \$0.1 million, respectively. We recognized approximately \$1.5 million and \$0.7 million of share-based compensation expense related to the restricted stock units for the year ended December 31, 2012 and 2011, respectively. As of December 31, 2012, total unrecognized estimated unamortized compensation cost related to non-vested restricted stock units outstanding as of that date was approximately \$4.2 million, with a weighted average amortization period of approximately 3.9 years.

#### 9. Commitments and Contingencies

##### Operating Leases

Our administrative offices and research facilities are located in San Diego, California. We lease an aggregate of approximately 76,000 square feet of office and research space.

In June 2011, we entered into an amended and restated lease (the “11388 Lease”) with BMR-11388 Sorrento Valley Road LP for the office and research facilities located at 11388 Sorrento Valley Road, San Diego, California (“11388 Property”). The 11388 Lease commenced in June 2011 and continues through January 2018. The 11388 Lease supersedes the lease agreement with BC Sorrento, LLC entered into in July 2007. Under the terms of the 11388 Lease, the initial monthly rent payment was approximately \$38,000 net of costs and property taxes associated with the operation and maintenance of the leased facilities, commencing in December 2011 and increases to approximately \$65,000 starting in January 2013. Thereafter, the annual base rent is subject to approximately 2.5% annual increases each year throughout the term of the 11388 Lease. In addition, we received a cash incentive of approximately \$98,000, a tenant improvement allowance of \$300,000 and free and reduced rent totaling approximately \$744,000 under the terms of the 11388 Lease. Combined with the unamortized deferred rent under the Original Lease, unamortized deferred rent associated with the 11388 Lease of \$1.1 million and \$854,000 was included in deferred rent as of December 31, 2012 and 2011, respectively.

In July 2007, we entered into a sublease agreement (the “11404 Sublease”) with Avanir Pharmaceuticals, Inc. (“Avanir”) for Avanir’s excess leased facilities located at 11404 Sorrento Valley Road, San Diego, California for office and research space (“11404 Property”) for a monthly rent payment of approximately \$54,000, net of costs and property taxes associated with the operation and maintenance of the subleased facilities. The 11404 Sublease expires in January 2013. The annual base rent is subject

to approximately 4% annual increases each year throughout the terms of the 11404 Sublease. In addition, we received free rent totaling approximately \$492,000, of which approximately \$4,000 and \$149,000 was included in deferred rent as of December 31, 2012 and 2011, respectively.

In April 2009, we entered into a sublease agreement (the "11408 Sublease") with Avanir for office and research space located at 11408 Sorrento Valley Road, San Diego, California ("11408 Property"), which expires in January 2013. The monthly rent payments, which commenced in January 2010, were approximately \$21,000 and are subject to an annual increase of approximately 3%.

In June 2011, we entered into a lease agreement (the "11404/11408 Lease") with BMR-Sorrento Plaza LLC ("BMR-Sorrento") for the 11404 Property and 11408 Property commencing in January 2013 through January 2018. Pursuant to the terms of the 11404/11408 Lease, the initial monthly rent payment is approximately \$71,000 net of costs and property taxes associated with the operation and maintenance of the leased facilities, commencing in January 2013 and is subject to approximately 2.5% annual increases each year throughout the term of the 11404/11408 Lease.

In October 2012, we entered into a lease agreement (the "11436 Lease") with Cal-Sorrento, Ltd. for the 11436 Sorrento Valley Road, San Diego, California ("11436 Property"). The 11436 Lease requires the lessor to complete and pay for certain improvements on the building before the commencement of the lease which is estimated to be approximately May 2013. This lease expires in January 2018. Pursuant to the terms of the 11436 Lease, the initial monthly rent payment will be approximately \$24,300 net of costs and property taxes associated with the operation and maintenance of the leased facilities, commencing approximately May 2013 and will be subject to approximately 3% annual increases each year throughout the term of the 11436 Lease. In addition, we will receive free and reduced rent totaling approximately \$158,000. Under the terms of the 11436 Lease, we are the "deemed owner" (for accounting purposes only) of the facility during the construction period. As such, we recorded an asset of \$1.5 million, representing the fair value of the building with a corresponding long-term lease financing obligation.

We pay a pro rata share of operating costs, insurance costs, utilities and real property taxes incurred by the landlords for the subleased facilities.

Additionally, we lease certain office equipment under operating leases. Total rent expense was approximately \$1.6 million, \$1.5 million and \$1.5 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Approximate annual future minimum operating lease payments as of December 31, 2012 are as follows:

Year:	Operating Leases
2013	\$1,865,000
2014	2,052,000
2015	2,049,000
2016	2,073,000
2017	2,126,000
Thereafter	80,000
Total minimum lease payments	\$10,245,000
Other Commitments	

Under the terms of the Roche Collaboration, we were obligated to scale up the production of rHuPH20 and to identify a second source manufacturer that would help meet anticipated production obligations arising from the collaboration. To that end, during 2008, we entered into a Technology Transfer Agreement and a Clinical Supply Agreement with a second rHuPH20 manufacturer, Cook Pharmica LLC ("Cook"). Cook manufactures certain batches of the API that will be used in clinical trials of certain product candidates. Cook has the capacity to produce the quantities we were required to deliver under the terms of the

Roche Collaboration. The technology transfer was completed in 2008. In 2009, multiple batches of rHuPH20 were produced to support planned future clinical studies. In 2010, we initiated process validation activities in support of potential future commercialization. The process validation was completed in 2011.

In March 2010, we entered into a Commercial Supply Agreement with Cook (the "Cook Commercial Supply Agreement"). Under the terms of the Cook Commercial Supply Agreement, Cook will manufacture certain batches of the API that will be used for potential commercial supply of certain product candidates. Under the terms of the Cook Commercial Supply Agreement, we are committed to certain minimum annual purchases of API equal to four quarters of forecasted supply. At December 31, 2012, we have \$7.7 million minimum purchase obligation in connection with the Cook Commercial Supply Agreement.

In March 2010, we amended our Commercial Supply Agreement (the "March 2010 Avid Amendment") with Avid Bioservices, Inc. ("Avid") which was originally entered into in February 2005 and amended in December 2006. Under the terms of the March 2010 Avid Amendment, we are committed to certain minimum annual purchases of API equal to three quarters of forecasted supply. In addition, Avid has the right to manufacture and supply a certain percentage of the API that will be used in Hylenex recombinant. At December 31, 2012, we had a minimum purchase obligation of approximately \$217,000.

In March 2010, we entered into a second Commercial Supply Agreement with Avid (the "Avid Commercial Supply Agreement"). Under the terms of the Avid Commercial Supply Agreement, we are committed to certain minimum annual purchases of API equal to three quarters of forecasted supply. In addition, Avid has the right to manufacture and supply a certain percentage of the API that will be used in certain product candidates. At December 31, 2012, we had \$7.7 million minimum purchase obligation in connection with this agreement.

In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, under which Baxter provides the final fill and finish steps in the production process of Hylenex recombinant for a limited period of time. The initial term of the agreement with Baxter extends expires on December 31, 2013; however, upon regulatory approval of a second filling line, the initial term will automatically be extended to December 31, 2015, subject to further extensions in accordance with the terms and conditions of the agreement. At December 31, 2012, we had a minimum purchase obligation of approximately \$9.5 million.

In June 2011, we entered into a services agreement with another third party manufacturer for the technology transfer and manufacture of Hylenex recombinant. At December 31, 2012, we had no minimum purchase obligation in connection with this agreement.

#### Legal Contingencies

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.

#### 10. Income Taxes

Significant components of our net deferred tax assets at December 31, 2012 and 2011 are shown below. A valuation allowance of \$128.4 million and \$107.5 million has been established to offset the net deferred tax assets as of December 31, 2012 and 2011, respectively, as realization of such assets is uncertain.



	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	\$86,732,000	\$69,912,000
Deferred revenue	17,345,000	15,338,000
Research and development credits	20,286,000	19,270,000
Share-based compensation	2,975,000	2,122,000
Depreciation	179,000	76,000
Other, net	926,000	771,000
Total deferred tax assets	128,443,000	107,489,000
Valuation allowance for deferred tax assets	(128,443,000 )	(107,489,000 )
Net deferred tax assets	\$—	\$—

The provision for income taxes on earnings subject to income taxes differs from the statutory federal income tax rate at December 31, 2012, 2011 and 2010, due to the following:

	2012	2011	2010
Federal income tax at 34%	\$(18,208,000 )	\$(6,722,000 )	\$(18,102,000 )
State income tax, net of federal benefit	(3,023,000 )	(1,153,000 )	(3,106,000 )
Increase in valuation allowance	20,954,000	9,935,000	22,469,000
Tax effect on non-deductible expenses and other	1,293,000	1,671,000	2,118,000
Research and development credits	(1,016,000 )	(3,731,000 )	(3,379,000 )
	\$—	\$—	\$—

At December 31, 2012, we had federal and California tax net operating loss carryforwards of approximately \$245.3 million and \$247.0 million, respectively. Included in these amounts are federal and California net operating losses of approximately \$27.9 million attributable to stock option deductions of which the tax benefit will be credited to equity when realized. The federal and California tax loss carryforwards will begin to expire in 2018 and 2013, respectively, unless previously utilized.

At December 31, 2012, we also had federal and California research and development tax credit carryforwards of approximately \$14.3 million and \$9.0 million, respectively. The federal research and development tax credits will begin to expire in 2024 unless previously utilized. The California research and development tax credits will carryforward indefinitely until utilized.

The American Taxpayer Relief Act of 2012, which retroactively reinstated the United States federal research and development tax credit from January 1, 2012 through December 31, 2013, was not enacted into law until the first quarter of 2013. Therefore the deferred tax asset and corresponding increase in the valuation allowance for the amount of the credit generated in 2012 will not be reflected until 2013.

Pursuant to Internal Revenue Code Section 382, the annual use of the net operating loss carryforwards and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As a result of any such ownership change, portions of our net operating loss carryforwards and research and development tax credits are subject to annual limitations. We recently completed an updated Section 382 analysis regarding the limitation of the net operating losses and research and development credits as of December 31, 2012. Based upon the analysis, we determined that ownership changes occurred in prior years. However, the annual limitations on net operating loss and research and development tax credit carryforwards will not have a material impact on the future utilization of such carryforwards.

At December 31, 2012 and 2011, our unrecognized income tax benefits and uncertain tax positions were not material and would not, if recognized, affect the effective tax rate. Interest and/or penalties related to uncertain income tax positions are recognized

by us as a component of income tax expense. For the years ended December 31, 2012, 2011 and 2010, we recognized no interest or penalties.

We are subject to taxation in the U.S. and in various state jurisdictions. Our tax years for 1998 and forward are subject to examination by the U.S. and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

#### 11. Employee Savings Plan

We have an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. All employees are eligible to participate, provided they meet the requirements of the plan. We are not required to make matching contributions under the plan. However, we voluntarily contributed to the plan approximately \$508,000, \$355,000 and \$433,000 in the years ended December 31, 2012, 2011 and 2010, respectively.

#### 12. Restructuring Expense

In October 2010, we completed a corporate reorganization to focus our resources on advancing our core proprietary programs and supporting strategic alliances with Roche and Baxter. This reorganization resulted in a reduction in the workforce of approximately 25 percent primarily in the discovery research and preclinical areas. We recorded approximately \$1.3 million of severance pay and benefits expenses in connection with the reorganization, of which \$1.2 million and \$76,000 was included in research and development expense and selling, general and administrative expense, respectively, in the consolidated statement of comprehensive loss for the year ended December 31, 2010. No other restructuring charges were incurred. We made cash payments of \$1.2 million during the year ended December 31, 2010 and paid the remaining balance in full during the year ended December 31, 2011.

#### 13. Related Party Transactions

In June 2011, we and Intrexon entered into the Intrexon Collaboration, 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). Intrexon's chief executive officer and chairman of its board of directors, Randal J. Kirk, is also a member of our Board of Directors. The collaborative arrangement with Intrexon was reviewed and approved by our Board of Directors in accordance with our related party transaction policy. For the years ended December 31, 2012 and 2011, we recognized \$1.0 million and \$9.0 million, respectively, in revenue under collaborative agreements pursuant to the terms of the Intrexon Collaboration. See Note 3 for a further discussion of the Intrexon Collaboration.

Connie L. Matsui, a member of our Board of Directors, and her husband had a controlling ownership interest (and therefore a financial interest) in an entity that held a minority ownership position in BC Sorrento, an entity that leased the 11388 Property to us until September 2010. The transaction with BC Sorrento was reviewed and approved by our Board of Directors in accordance with our related party transaction policy. Effective September 2010, BC Sorrento sold the 11388 Property to an unrelated party. As such, we no longer had any business transactions with BC Sorrento effective September 2010. We paid BC Sorrento approximately \$982,000 for the year ended December 31, 2010. No payments were made to BC Sorrento for the years ended December 31, 2012 and 2011.

## 14. Summary of Unaudited Quarterly Financial Information

The following is a summary of our unaudited quarterly results for the years ended December 31, 2012 and 2011:

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2012 (Unaudited):				
Total revenues (a)	\$7,440,179	\$7,757,175	\$5,334,323	\$21,793,549
Total operating expenses	\$22,580,577	\$21,805,273	\$25,364,160	\$26,200,662
Net loss	\$(15,119,181 )	\$(14,021,119 )	\$(20,005,846 )	\$(4,405,856 )
Net loss per share, basic and diluted	\$(0.14 )	\$(0.13 )	\$(0.18 )	\$(0.04 )
Shares used in computing net loss per share, basic and diluted	107,589,514	112,063,665	112,305,002	112,323,056
2011 (Unaudited):				
Total revenues (b)	\$7,543,894	\$23,188,948	\$22,942,428	\$2,411,166
Total operating expenses	\$17,203,480	\$20,093,017	\$17,789,595	\$20,839,285
Net income (loss)	\$(9,635,717 )	\$3,116,288	\$5,165,193	\$(18,415,615 )
Net income (loss) per share, basic and diluted	\$(0.10 )	\$0.03	\$0.05	\$(0.18 )
Shares used in computing net income (loss) per share:				
Basic	100,927,402	102,671,410	103,223,352	103,406,407
Diluted	100,927,402	104,393,835	105,009,189	103,406,407

(a) Revenues for the quarter ended December 31, 2012 included \$9.5 million in revenue under collaborative agreements from the Pfizer Collaboration.

Revenues for the quarter ended June 30, 2011 included revenue under collaborative agreements totaling \$18.0 million from the ViroPharma and Intrexon Collaborations. Revenues for the quarter ended September 30, 2011

(b) included revenue from collaborative agreements totaling \$17.9 million related to recognition of unamortized deferred prepaid product-based payments and unamortized deferred upfront payment pursuant to the termination of the Hylenex Collaboration with Baxter in July 2011.

Exhibit Index

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)
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(28)
  - 10.20#      Form of Stock Option Agreement (2011 Stock Plan)(28)
  - 10.21#      Form of Stock Option Agreement for Executive Officers (2011 Stock Plan)(28)
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- 10.22# Form of Restricted Stock Units Agreement (2011 Stock Plan)(28)
- 10.23# Form of Restricted Stock Award Agreement (2011 Stock Plan)(28)
- 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 Change In Control Agreement with Gregory Frost, dated December 21, 2012
- 10.32# Form of Amended and Restated Change In Control Agreement with Officer
- 10.33# Form of Change In Control Agreement with Officer
- 10.34\* Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.35\* Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.36\* Enhance License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
- 10.37 Termination Agreement between Halozyne Inc., Baxter Healthcare Corporation and Baxter Healthcare S.A, effective January 7, 2011(27)
- 10.38\* Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(16)
- 10.39\* License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(12)
- 10.40 Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(15)
- 10.41 Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(15)
- 10.43 Amended and Restated Lease (11388 Sorrento Valley Road), effective as of June 10, 2011(29)

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- 10.44 Lease (11404 and 11408 Sorrento Valley Road), effective as of June 10, 2011(29)
  - 10.45 Lease (11436 Sorrento Valley Road), dated October 31, 2012
  - 10.46 Loan and Security Agreement and Disbursement Letter, dated December 28, 2012
  - 10.47 First Amendment to Loan and Security Agreement and Disbursement Letter, dated February 5, 2013
  - 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.INS\*\* Instance Document
- 101.SCH\*\* Taxonomy Extension Schema Document
- 101.CAL\*\* Taxonomy Extension Calculation Linkbase Document
- 101.DEF\*\* Taxonomy Extension Definition Linkbase Document
- 101.LAB\*\* Taxonomy Extension Label Linkbase Document
- 101.PRE\*\* Taxonomy Extension Presentation Linkbase Document

- (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).
- (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 January 10, 2011 (File No. 001-32335).
- (28) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed May 6, 2011 (File No. 001-32335).
- (29) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed June 16, 2011 (File No. 001-32335).

\* 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 applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These

\*\* interactive data files 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 Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

# Indicates management contract or compensatory plan or arrangement.