

HALOZYME THERAPEUTICS INC

Form 10-K

March 11, 2011

**Table of Contents**

**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, 2010**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from        to**

**Commission File Number: 001-32335**  
**Halozyme Therapeutics, Inc.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*  
**11388 Sorrento Valley Road,  
San Diego, California**  
*(Address of principal executive offices)*

**88-0488686**  
*(I.R.S. Employer  
Identification No.)*  
**92121**  
*(Zip Code)*

**(858) 794-8889**  
*(Registrant's Telephone Number, Including Area Code)*

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

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

**Securities registered under Section 12(g) of the Act:  
None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. 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, 2010 was approximately \$506.9 million based on the closing price on the NASDAQ Stock Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2011, there were 101,389,856 shares of the registrant's \$0.001 par value common stock issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the issuer's Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2011 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Parts II and III of this Annual Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the issuer's fiscal year ended December 31, 2010.

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## Table of Contents

		Page
<b><u>PART I</u></b>		
<u>Item 1.</u>	<u>Business</u>	1
<u>Item 1A.</u>	<u>Risk Factors</u>	12
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	23
<u>Item 2.</u>	<u>Properties</u>	23
<u>Item 3.</u>	<u>Legal Proceedings</u>	23
<u>Item 4.</u>	<u>Removed and Reserved</u>	23
<b><u>PART II</u></b>		
<u>Item 5.</u>	<u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	24
<u>Item 6.</u>	<u>Selected Financial Data</u>	26
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	37
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	37
<u>Item 9A.</u>	<u>Controls and Procedures</u>	37
<u>Item 9B.</u>	<u>Other Information</u>	40
<b><u>PART III</u></b>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	40
<u>Item 11.</u>	<u>Executive Compensation</u>	41
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	41
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	42
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	42
<b><u>PART IV</u></b>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	43
	<b><u>SIGNATURES</u></b>	46
	<u>EX-10.36</u>	
	<u>EX-23.1</u>	
	<u>EX-31.1</u>	
	<u>EX-31.2</u>	
	<u>EX-32</u>	

---

**Table of Contents**

**PART I**

**Item 1. Business**

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

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

**Overview**

We are a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. Our existing products and our products under development are based primarily on intellectual property covering the family of human enzymes known as hyaluronidases.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing products and a limited number of product candidates; and (iv) supporting the development of partnered product candidates. We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have multiple proprietary programs in various stages of research and development. In addition, we have entered into a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, to apply Enhance<sup>™</sup> Technology to Roche's biological therapeutic compounds for up to eight targets. We also have a key partnership with Baxter Healthcare Corporation, or Baxter, to apply Enhance Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID<sup>®</sup>. In January 2011, we and Baxter mutually agreed to terminate a partnership between Baxter and us, under which Baxter had worldwide marketing rights for HYLENEX<sup>®</sup>, a registered trademark of Baxter International, Inc. There are two marketed products that utilize our technology: HYLENEX, a hyaluronidase human injection used as an adjuvant to enhance the dispersion and absorption of other injected drugs and fluids, and Cumulase<sup>®</sup>, a product used for *in vitro* fertilization, or IVF. Currently, we have received only limited revenue from the sales of API to the third party that produces Cumulase, in addition to other revenues from our partnerships with Baxter and Roche.

In February 2007, we and Baxter amended certain existing agreements relating to HYLENEX and entered into a new agreement for kits and formulations with rHuPH20, or the HYLENEX Partnership. In October 2009, Baxter commenced the commercial launch of HYLENEX recombinant (hyaluronidase human injection). Because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. In May 2010, we delivered a notice of breach to Baxter due to Baxter's failure to manufacture HYLENEX in accordance with the terms of existing

**Table of Contents**

development and supply contracts. In August 2010, we announced the withdrawal, without prejudice, of the notice of breach to Baxter. We have been in communication with the U.S. Food and Drug Administration, or FDA, and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The termination of these agreements does not affect the other relationships between the parties, including the application of Halozyme's Enhance Technology to Baxter's GAMMAGARD LIQUID.

On August 12, 2010, we announced the issuance of United States Patent No. 7,767,429 (the 429 Patent) claiming recombinant human hyaluronidase. Claims to the human PH20 glycoprotein, PEGylated variants, the glycoprotein produced by recombinant methods, and pharmaceutical compositions with other agents, including antibodies, insulins, cytokines, anti-infectives and additional therapeutic classes were awarded in this patent and additional claims are in prosecution. This patent will not expire until September 23, 2027. A European counterpart patent, EP1603541, was also granted to us on November 11, 2009. On August 13, 2010, however, we learned that an opposition to this patent was filed with the European Patent Office. We plan on contesting the opposition with written submissions to the European Patent Office and we expect to obtain European patent protection that is equal or superior to the claims issued in the 429 patent. The European patent provides protection until March 5, 2024.

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.

On December 2, 2010, Jonathan E. Lim, M.D. resigned as President, Chief Executive Officer and a member of the Board of Directors (Board) of Halozyme. On December 2, 2010, the Board appointed Gregory I. Frost, Ph.D., our then Vice President and Chief Scientific Officer and Director, to serve as our President and Chief Executive Officer. On the same day, we appointed H. Michael Shepard, Ph.D., our then Vice President, Discovery Research, to serve as our Vice President and Chief Scientific Officer.

We and our partners have product candidates in the research, preclinical and clinical stages, but future revenues from the sales and/or royalties of these product candidates will depend on our partners' abilities and ours to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we and our partners are able to obtain regulatory approvals for these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$225.3 million as of December 31, 2010.

In January 2010, we filed a shelf registration statement on Form S-3 (Registration No. 333-164215) which allows us, from time to time, to offer and sell up to \$100.0 million of equity or debt securities. In September 2010, we sold approximately \$60.2 million of our common stock in an underwritten public offering at a net price of \$7.25 per share. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

We reincorporated from the State of Nevada to the State of Delaware in November 2007. Our principal offices and research facilities are located at 11388 Sorrento Valley Road, San Diego, California 92121. Our telephone number is

(858) 794-8889 and our e-mail address is [info@halozyme.com](mailto:info@halozyme.com). Additional information about the Company can be found on our website at [www.halozyme.com](http://www.halozyme.com), and in our periodic and current reports filed with the Securities and Exchange Commission, or SEC. Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and online at [www.sec.gov](http://www.sec.gov) and our website at [www.halozyme.com](http://www.halozyme.com).



## **Table of Contents**

### **Technology**

Our primary technology is based on our proprietary recombinant human PH20 enzyme, or rHuPH20, a human synthetic version of hyaluronidase. Hyaluronidases are enzymes (proteins) that break down hyaluronan, or HA, which is a naturally occurring space-filling, gel-like substance that is a major component of both normal tissues throughout the body, such as skin and cartilage, and abnormal tissues such as tumors. The PH20 enzyme is a naturally occurring enzyme that temporarily degrades HA, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. Our proprietary rHuPH20 technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones for the development of our own proprietary products. The rHuPH20 technology may also be applied to existing and developmental products of third parties through key partnerships and other collaborations.

### **Strategy**

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

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

- Develop our own proprietary products based on our PH20 enzyme and other new molecular entities;

- Seek partnerships for our Enhance Technology drug delivery platform;

- Support product development and commercialization under our Roche Enhance Technology collaboration;

- Support product development and commercialization under our Baxter BioScience Enhance Technology collaboration; and

- Reintroduce HYLENEX to the market.

**Table of Contents**

**Products and Product Candidates**

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

***Ultrafast Insulin Program***

Our lead proprietary program focuses on the formulation of rHuPH20 with prandial (mealtime) insulins for the treatment of diabetes mellitus. Diabetes mellitus is an increasingly prevalent, costly condition associated with substantial morbidity and mortality. Attaining and maintaining normal blood sugar levels to minimize the long-term clinical risks is a key treatment goal for diabetic patients. Combining rHuPH20 with regular insulin (such combinations are referred to as Insulin-PH20 ) or a rapid acting analog insulin, i.e., insulin lispro (Humalog<sup>®</sup>) insulin aspart (Novolog<sup>®</sup>) and insulin glulisine (Apidra<sup>®</sup>) (such combinations are referred to as Analog-PH20 ), facilitates faster insulin dispersion in, and absorption from, the subcutaneous space into the vascular compartment

## **Table of Contents**

leading to faster insulin response. By making mealtime insulin onset faster, i.e., providing earlier insulin to the blood and thus earlier glucose lowering activity, a combination of insulin with rHuPH20 may yield a better profile of insulin effect, more like that found in healthy, non-diabetic people.

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

In January 2011, we initiated an insulin pump study that utilizes rHuPH20 combined with two commercially available mealtime insulin analogs: insulin aspart and insulin glulisine. Patients with type 1 diabetes enrolled in these pump studies will receive the insulin analog alone and the Analog-PH20 combination for three days each. Data for pharmacokinetic and glucodynamic measures as well as safety and tolerability will be collected and compared for each treatment. The double-blind crossover pump study will enroll approximately 36 type 1 diabetes patients who already receive their insulin therapy with a pump. Patients will receive subcutaneous continuous infusions of either insulin aspart alone and insulin aspart with rHuPH20 for 72 hours each or insulin glulisine alone and insulin glulisine with rHuPH20 for 72 hours each. The primary endpoint of the study is a comparison of the early insulin exposure as measured by the area under the curve during the first 60 minutes following a bolus infusion of insulin delivered by a pump. Various pharmacokinetic and glucodynamic measures including  $C_{max}$ ,  $T_{max}$ , glucose infusion rates, glycemic response to standard meal challenges, and area under the curve at specified time intervals will also be measured. An evaluation of the safety and local tolerability of the analogs with and without rHuPH20 will also be performed. We currently expect that results from the study will be available for presentation at a scientific forum by mid-2011.

In January 2011, we completed patient enrollment for two randomized double-blind Phase 2 clinical trials that utilize our rHuPH20 in combination with the two leading commercially available mealtime analogs: insulin aspart and insulin lispro. Diabetes patients enrolled in these cross-over design studies receive an insulin analog alone and the Analog-PH20 treatment for 12 weeks each. Previous studies have demonstrated that the coinjection of rHuPH20 with an insulin analog results in a more physiologic fast-in, fast-out profile that enhances the mealtime glycemic control for each analog. These Phase 2 clinical trials, one in type 1 diabetes patients and the other in type 2 patients, will compare two ultrafast insulin analog products formulated with rHuPH20 to an active comparator, Humalog. Each study enrolled approximately 110 patients and began with a 4 to 6 week titration period where patients optimized their basal insulin dosing. Patients then randomized to receive either the Lispro-PH20 or Aspart-PH20 investigational study drugs and the active comparator three times daily for 12 weeks each in a random sequence. The primary endpoint of each study will be a comparison of improved glycemic control, as assessed by the change in glycemic control from baseline. Data regarding postprandial glucose levels, the proportion of patients that safely achieve glycemic control targets, rates of hypoglycemia, weight change and additional endpoints will be collected.

In August 2010, we completed a Phase 2 clinical trial to compare regular insulin with rHuPH20 to lispro alone. After a one-month observation period that included dose optimization, patients were randomized to regular insulin with rHuPH20 or lispro and treated for three months. At the end of three months, patients were crossed over to the other study treatment for another three months. This study was designed to evaluate the safety and efficacy of Insulin-PH20 relative to a standard of care therapy, Humalog. The results of this study were presented at the Tenth Annual Diabetes Technology Meeting, November 2010, in Bethesda, Maryland.

In March 2010, we completed a Phase 2 clinical study in patients with type 2 diabetes mellitus. This randomized cross-over design study was designed to compare the postprandial glycemic excursions

## **Table of Contents**

following a standardized test meal for three treatment regimens: insulin lispro with rHuPH20, regular insulin with rHuPH20 and lispro alone, each delivered at an individually optimized dose. The clinical trial results showed that injection of insulin lispro with rHuPH20 reduces both hyperglycemic excursions and incidence of hypoglycemia relative to insulin lispro alone, and that the optimum dose of insulin lispro was reduced when coinjected with rHuPH20. The results from this study were presented at the American Diabetes Association, or ADA, 70th Scientific Sessions in Orlando in June 2010 and at the 46th Annual Meeting of the European Association for the Study of Diabetes, or EASD, in Stockholm, Sweden in September 2010.

In February 2010, we completed a Phase 1 clinical study designed to assess the effects of three approved prandial insulin analogs administered with rHuPH20 compared to each of the analogs alone, each delivered at a standardized dose. This randomized, six-way cross-over design, euglycemic clamp study compared the postprandial pharmacokinetics and glucodynamics of the insulin analogs with and without rHuPH20. The clinical trial results showed that the addition of rHuPH20 to three different mealtime insulin analogs accelerated their absorption. The acceleration produced by the coadministration of rHuPH20 produced significantly more pronounced insulin action during the first two hours after injection followed by a more rapid diminution of insulin effects compared to the analogs alone. The coinjection of PH20 with lispro, aspart and glulisine results in a more physiologic fast-in, fast-out profile and accelerates the glucodynamic profile for each analog. The results from this study were also presented at the ADA 70th Scientific Sessions in Orlando in June 2010 and the 46th Annual Meeting of the EASD in Stockholm, Sweden in September 2010.

## ***PEGPH20***

We are investigating a PEGylated version of rHuPH20, or PEGPH20, a new molecular entity, as a candidate for the systemic treatment of tumors rich in HA. PEGylation refers to the attachment of polyethylene glycol to our rHuPH20 enzyme, which extends its half life in the blood from less than one minute to approximately 48-72 hours. An estimated 20% to 30% of solid tumors, including prostate, breast, pancreas and colon, accumulate significant amounts of HA that surrounds and cover the surface of the tumor cells. The quantity of HA produced by the tumor correlates with increased tumor growth and metastasis and has been linked with tumor progression in some studies.

In preclinical studies, PEGPH20 has been shown to deplete HA in cell culture and in animal models of human cancer. The PEGPH20-mediated depletion of HA in tumor models results in significant inhibition of tumor growth when used as a single agent, and it greatly enhances the impact of chemotherapy. The increased efficacy of chemotherapy results from a great influx of drug into tumor tissue as the HA is removed. This effect is specific for the tumor microenvironment, and is not observed in normal tissues. Repeat dosing with PEGPH20 produced a sustained depletion of HA in the tumor microenvironment. For tumor models that did not produce HA, the presence of PEGPH20 had no effect. Administration of the combination of PEGPH20 with docetaxel, liposomal doxorubicin and gemcitabine in HA-producing animal tumor models produced a significant survival advantage for the combination relative to either chemotherapeutic agent alone.

In the first quarter of 2009, we initiated a Phase 1 clinical trial for our PEGPH20 program. This first in human trial with PEGPH20 is a dose-escalation, multicenter, pharmacokinetic and pharmacodynamic, safety study, in which patients with advanced solid tumors are receiving intravenous administration of PEGPH20 as a single agent. Based on initial data from this trial, and after consultation with the FDA, lower doses of PEGPH20 are now employed at a lower dosing frequency. The study is actively enrolling and in a dose escalation phase. In July 2010, we initiated a second Phase 1 clinical trial with PEGPH20 in the treatment of solid tumors. This trial incorporates the use of oral dexamethasone as a pretreatment for all patients prior to receiving intravenous administration of PEGPH20. The second Phase 1 study is ongoing and actively enrolling.

## ***Enhance Technology***

Enhance Technology, a proprietary drug delivery enhancement platform using rHuPH20, is a broad technology that we have licensed to other pharmaceutical companies. When formulated with other injectable drugs, Enhance Technology can facilitate the subcutaneous dispersion and absorption of these drugs. Molecules as large as 200 nanometers may pass freely through the Matrix, which recovers its normal density within approximately 24 hours, leading to a drug delivery platform which does not permanently alter the architecture of the skin. The principal focus of our Enhance Technology platform is the use of rHuPH20 to facilitate subcutaneous route of administration

## **Table of Contents**

for large molecule biological therapeutics, some of which currently require intravenous administration. Potential benefits of subcutaneous administration of these biologics include life cycle management, patient convenience, reductions in infusion reactions and lower administration costs.

We currently have Enhance Technology partnerships with Roche and Baxter and we are currently pursuing additional partnerships with biopharmaceutical companies that market or develop drugs that could benefit from injection via the subcutaneous route of administration.

### ***Roche Partnership***

In December 2006, Halozyme and Roche entered into an Enhance Technology partnership, or the Roche Partnership. Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds resulting from the 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 an additional ten targets. Roche elected to add a fourth exclusive target in December 2008 and a fifth exclusive target in June 2009. In 2010 Roche did not pay the annual license maintenance fee on five of the remaining eight additional target slots. As a result, Roche currently retains the option to exclusively develop and commercialize rHuPH20 with an additional three targets through the payment of annual license maintenance fees. Pending the successful completion of various clinical, regulatory and sales events, Roche will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership.

Compounds directed at three of the Roche exclusive targets have previously commenced clinical trials. Two compounds (subcutaneous Herceptin<sup>®</sup> and subcutaneous MabThera<sup>®</sup>) are in Phase 3 clinical trials and one compound (subcutaneous Actemra<sup>®</sup>) has completed a Phase 1 clinical trial.

In October 2009, Roche commenced its first Phase 3 clinical trial for a compound directed at an exclusive target and in December 2010, the enrollment for this study was completed. This Phase 3 clinical trial is for a subcutaneously delivered version of Roche's anticancer biologic, Herceptin (trastuzumab). The study will investigate the pharmacokinetics, efficacy and safety of subcutaneous Herceptin in patients with HER2-positive breast cancer as part of adjuvant treatment. 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 one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 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 20-25% of women with breast cancer. Roche has stated that they expect to file for regulatory approval of subcutaneous Herceptin in 2012.

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab). The study will investigate pharmacokinetics, efficacy and safety of MabThera SC. Intravenously administered MabThera is approved for the treatment of non-Hodgkin's lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), types of cancer that affects lymphocytes, or white blood cells. An estimated 66,000 new cases of NHL were diagnosed in the U.S. in 2009 with approximately 125,000 new cases reported worldwide.

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

Additional information about the Phase 3 subcutaneous Herceptin and Phase 3 subcutaneous MabThera clinical trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.roche-trials.com](http://www.roche-trials.com).

***Baxter Gammagard Partnership***

GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, Halozyme and Baxter entered into an Enhance Technology partnership, or the Gammagard Partnership. Under the terms of this partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID, or HyQ. Pending the successful completion of various regulatory and



## **Table of Contents**

sales milestones, Baxter will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter is responsible for all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we will be responsible for the supply of the rHuPH20 enzyme. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard License. In January 2011, Baxter announced the completion of a Phase 3 clinical trial for HyQ. Baxter has stated that they expect to file for regulatory approval of HyQ in 2011.

### ***HYLENEX Partnership***

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, enhances the dispersion and absorption of other injected drugs or fluids. In February 2007, Halozyme and Baxter amended certain existing agreements relating to HYLENEX and entered into the HYLENEX Partnership for kits and formulations with rHuPH20. Pending the successful completion of a series of regulatory and sales events, Baxter would have been obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter was responsible for development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. We supplied Baxter with API for HYLENEX, and Baxter prepared, filled, finished and packaged HYLENEX and held it for subsequent distribution.

In October 2009, Baxter commenced the commercial launch of HYLENEX recombinant (hyaluronidase human injection) for use in pediatric rehydration at the 2009 American College of Emergency Physicians (ACEP) scientific assembly. In addition, under the HYLENEX Partnership, Baxter had a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with Baxter hydration fluids and generic small molecule drugs, with the exception of combinations with (i) bisphosphonates, (ii) cytostatic and cytotoxic chemotherapeutic agents and (iii) proprietary small molecule drugs, the rights to which had been retained by Halozyme.

Because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. In May 2010, we delivered a notice of breach to Baxter due to Baxter's failure to manufacture HYLENEX in accordance with the terms of existing development and supply contracts. The notice was sent after Baxter informed us that a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying agreements with Baxter. In August 2010, we announced the withdrawal, without prejudice, of the notice of breach to Baxter. We have been in communication with the FDA and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The termination of these agreements does not affect the other relationships between the parties, including the application of Halozyme's Enhance Technology to Baxter's GAMMAGARD LIQUID.

### ***Cumulase***

Cumulase is an *ex vivo* (used outside of the body) formulation of rHuPH20 to replace the bovine (bull) enzyme currently used for the preparation of oocytes (eggs) prior to IVF during the process of intracytoplasmic sperm injection (ICSI), in which the enzyme is an essential component. Cumulase strips away the HA that surrounds the oocyte, allowing the clinician to then perform the ICSI procedure.

## **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 nine issued patents, one granted European patent and a number of pending

## **Table of Contents**

patent applications. We are the exclusive licensee of the University of Connecticut under a patent covering the DNA sequence that encodes human hyaluronidase. This patent expires in 2015. We have a patent pertaining to recombinant human hyaluronidase which expires in 2027 and further 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 determined upon maturation to our issued patents). We believe our patent filings represent a barrier to entry for potential competitors looking to utilize these hyaluronidases.

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

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

## **Research and Development Activities**

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

Since our inception in 1998 through December 31, 2010, we have incurred research and development expenses of \$201.5 million. From January 1, 2008 through December 31, 2010, approximately 26% and 17% of our research and development expenses were associated with the development of our ultrafast insulin and PEGPH20 product candidates, respectively. Due to the uncertainty in obtaining the FDA and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

## **Manufacturing**

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

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

## **Table of Contents**

### **Sales and Marketing**

#### ***HYLENEX***

Resolution of the manufacturing issue discovered in a small number of vials of HYLENEX during a routine inspection is a top priority for us. The manufacturing problem resulted in a voluntary recall of the product in May 2010 and it has been off the market since that time. We have identified the issue and have proposed a solution to the FDA. Additional data requested by the agency is currently being generated. Upon confirmation of this data, Baxter will be able to resume its role as the provider of the final fill and finish steps in the production process. This should, pending regulatory review and approval, allow us to reintroduce the product in the second half of 2011. Future manufacturing plans for HYLENEX call for a shift of these activities to an alternate supplier with a new process that would allow more favorable pricing.

In January 2011, Baxter returned its worldwide marketing rights for HYLENEX to us. Upon its return to the market, we intend to take advantage of the initial marketing inroads achieved by Baxter. We are continuing to assess our commercial and strategic options for the product to address additional uses and geographic regions.

#### ***Cumulase***

We have an exclusive distribution agreement with a distributor of IVF reagents and media that sells directly to IVF clinics in both the United States and European markets. During 2010, sales of API for Cumulase were approximately \$466,000.

### **Competition**

#### ***HYLENEX***

Other manufacturers have FDA-approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc., with an ovine (ram) hyaluronidase, Vitrase<sup>®</sup>, and Amphastar Pharmaceuticals, Inc., with a bovine hyaluronidase, Amphadase<sup>™</sup>. In addition, some commercial pharmacies compound hyaluronidase preparations for institutions and physicians even though compounded preparations are not FDA-approved products. Some compounding pharmacies do not test every batch of product for drug concentration, sterility and lack of pyrogens. In addition, HYLENEX is priced at a significant premium compared to the animal-derived hyaluronidases currently in the marketplace. This price premium may slow market adoption of HYLENEX and make market penetration difficult.

#### ***Cumulase***

A key clinical selling point for Cumulase is that it may eliminate the risk of animal pathogen transmission and toxicity inherent in slaughterhouse preparations. The competing enzymes are of animal origin, creating an opportunity for a recombinant human enzyme alternative. Cumulase is priced at a premium compared to the animal-derived products sold by leading IVF suppliers, which may make market penetration difficult.

### **Government Regulations**

The FDA and comparable regulatory agencies in foreign countries regulate extensively the manufacture and sale of the pharmaceutical products that we have developed or currently are developing. The FDA has established guidelines and safety standards that are applicable to the laboratory and preclinical evaluation and clinical investigation of therapeutic products and stringent regulations that govern the manufacture and sale of these products. The process of

obtaining regulatory approval for a new therapeutic product usually requires a significant amount of time and substantial resources. The steps typically required before a product can be produced and marketed for human use include:

Animal pharmacology studies to obtain preliminary information on the safety and efficacy of a drug;

Laboratory and preclinical evaluation *in vitro* and *in vivo* including extensive toxicology studies.

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

## **Table of Contents**

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

Phase 1 investigations are generally conducted in healthy subjects. In certain instances, subjects with a life-threatening disease, such as cancer, may participate in Phase 1 studies that determine the maximum tolerated dose and initial safety of the product;

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, typically are submitted to the FDA in a new drug application, or NDA. 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, or CDER, must approve an NDA 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 (trademark statute) and other federal and state laws, including the federal anti-kickback statute.

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

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

**Product Liability Insurance**

We currently maintain product liability insurance on our products and clinical trials that provides coverage in the amount of \$10.0 million per incident and \$10.0 million in the aggregate.

**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.



## **Table of Contents**

### **Employees**

As of March 1, 2011, we had 102 full-time employees, including 77 engaged in research and clinical development activities. Included in our total headcount are 36 employees who hold Ph.D. or M.D. degrees. None of our employees are unionized and we believe our relationship with our employees is good.

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

#### **Risks Related To Our Business**

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

Relative to expenses incurred in our operations, we have generated only minimal revenue from product sales, licensing fees and milestone payments to date and we may never generate sufficient revenues from future product sales, licensing fees and milestone payments to offset expenses. Even if we ultimately do achieve significant revenues from product sales, licensing fees and/or milestone payments, we expect to incur significant operating losses over the next few years. We have never been profitable, and we may never become profitable. Through December 31, 2010, we have incurred aggregate net losses of approximately \$225.3 million.

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

Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States and the other countries in which we anticipate doing business have similar requirements. The process for obtaining FDA and other regulatory approvals is extensive, time-consuming and costly, and there is no guarantee that the FDA or other regulatory bodies will approve any applications that may be filed with respect to any of our proprietary or partnered product candidates, or that the timing of any such approval will be appropriate for the desired product launch schedule for a product candidate. We, and our partners, attempt to provide guidance as to the timing for the filing and acceptance of such regulatory approvals, but such filings and approvals may not occur on the originally anticipated timeline, or at all. There are no proprietary or partnered product candidates currently in the regulatory approval process, and we and our partners may not be successful in obtaining such approvals for any potential products in a timely manner, or at all (please also refer to the risk factor titled *Our proprietary and partnered 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 partners are unsuccessful in maintaining our regulatory approvals our ability to generate revenues would be adversely affected. For example, because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. We have been in communication with the FDA and have provided them materials relating to the root cause and remediation plans. While we are generating data requested by the FDA and currently expect that we could reintroduce the product in the second half of 2011, this expectation is dependent upon regulatory review and approval and, therefore, we cannot guaranty that we will be able to meet this timeline.

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

We have existing supply agreements with contract manufacturing organizations Avid and Cook to produce bulk API. These manufacturers each produce API under cGMP for clinical uses. In addition, Avid currently produces API for commercialized products. Avid and Cook will also provide support for the chemistry, manufacturing and controls sections for FDA and other regulatory filings. We rely on their ability to successfully manufacture these batches according to product specifications and Cook has relatively limited experience manufacturing our API. In addition, as a result of our contractual obligations to Roche, we will be required to significantly scale up our commercial API production at Cook during the next two years. If Cook is unable to obtain status as a cGMP-approved manufacturing facility, or if either Avid or Cook: (i) are unable to retain status as cGMP-

**Table of Contents**

approved manufacturing facilities; (ii) are unable to otherwise successfully scale up our API production; or (iii) fail to manufacture the API required by our proprietary and partnered products and product candidates for any other reason, our business will be adversely affected. We have not established, and may not be able to establish, favorable arrangements with additional API manufacturers and suppliers of the ingredients necessary to manufacture the API should the existing manufacturers and suppliers become unavailable or in the event that our existing manufacturers and suppliers are unable to adequately perform their responsibilities. We have attempted to mitigate the impact of supply interruption through the establishment of excess API inventory, but there can be no assurances that this safety stock will be maintained or that it will be sufficient to address any delays, interruptions or other problems experienced by Avid and/or Cook. Any delays, interruptions or other problems regarding the ability of Avid and/or Cook to supply API on a timely basis could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of proprietary or partnered product candidates; (ii) delay or prevent the effective commercialization of proprietary or partnered products and/or (iii) cause us to breach contractual obligations to deliver API to our partners. Such delays would likely damage our relationship with our partners under our key collaboration agreements and they would have a material adverse effect on our business and financial condition.

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

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

For example, because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. In January 2011, Halozyme and Baxter mutually agreed to terminate the HYLENEX Partnership and Halozyme reacquired all rights to HYLENEX. We are in communication with the FDA, and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011.

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

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

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

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

**Table of Contents**

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:

regulatory review may not find a product candidate safe or effective enough to merit either continued testing or final approval;

regulatory review may not find that the data from preclinical testing and clinical trials justifies approval, or they may require additional studies that would significantly delay or make continued pursuit of approval commercially unattractive;

a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;

the cost of a clinical trial may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a trial;

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

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

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

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

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

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

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

Our partners are responsible for providing certain proprietary materials that are essential components of our partnered product candidates. For example, Roche is responsible for producing the Herceptin and MabThera required for its subcutaneous product candidates and Baxter is responsible for producing the GAMMAGARD LIQUID for its product candidate. If a partner, or any applicable third party service provider of a partner, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of either components of the partnered product candidate or the partnered product candidate itself, such difficulties could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of partnered product candidates; and/or (ii) delay or prevent the effective commercialization of partnered products. Such delays could have a material adverse effect on our business and financial condition. For example, Baxter received a Warning Letter from the FDA in January 2010 regarding Baxter's GAMMAGARD LIQUID manufacturing facility in Lessines, Belgium. The FDA indicated in

**Table of Contents**

March 2010 that the issues raised in the Warning Letter had been addressed by Baxter and we do not expect these issues to impact the development of the GAMMAGARD LIQUID product candidate.

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

We rely on third parties to store and ship API on our behalf and to also prepare, fill, finish and package our products and product candidates prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are acceptable to us, or if the third parties we identify fail to perform their obligations, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. For example, because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. We are in communication with the FDA, and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011. Effective January 7, 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The Baxter facility is the only facility currently approved by the FDA to prepare, fill, finish and package HYLENEX. Any delay in reaching a new agreement with Baxter would likely delay our ability to reintroduce the product in the second half of 2011.

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

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

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

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

We may not be successful in marketing and promoting our existing product candidates or any other products we develop or acquire in the future. Our sales, marketing and distribution capabilities are very limited. In order to commercialize any products successfully, we must internally develop substantial sales, marketing and distribution

capabilities or establish collaborations or other arrangements with third parties to perform these services. We do not have extensive experience in these areas, and we may not be able to establish adequate in-house sales, marketing and distribution capabilities or engage and effectively manage relationships with third parties to perform any or all of such services. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, whose efforts may not meet our expectations or be successful. These third



## **Table of Contents**

parties would be largely responsible for the speed and scope of sales and marketing efforts, and may not dedicate the resources necessary to maximize product opportunities. Our ability to cause these third parties to increase the speed and scope of their efforts may also be limited. In addition, sales and marketing efforts could be negatively impacted by the delay or failure to obtain additional supportive clinical trial data for our products. In some cases, third party partners are responsible for conducting these additional clinical trials and our ability to increase the efforts and resources allocated to these trials may be limited.

For example, in 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period on mutually acceptable terms and conditions. We may not successfully negotiate favorable terms of such transition service agreements which may cause a delay in the reintroduction of HYLENEX to the market.

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

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

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

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

restrictions on our products or manufacturing processes;

warning letters;

withdrawal of the products from the market;

voluntary or mandatory recall;

finer;

suspension or withdrawal of regulatory approvals;

suspension or termination of any of our ongoing clinical trials;

refusal to permit the import or export of our products;

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

product seizure; or

injunctions or the imposition of civil or criminal penalties.

**Table of Contents**

For example, because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. We are in communication with the FDA, and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011.

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

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

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

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

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

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

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

the introduction of generic competitors; and

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

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

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

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

The testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product liability claims were to be made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could

materially and adversely affect our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us. In addition, since many of our partnered product candidates include the pharmaceutical products of a third party, we run the risk that problems with the third party pharmaceutical product will give rise to liability claims against us.

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

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our relatively small staff size relative to the number of programs currently under development, we depend substantially on our ability to hire, train, motivate and retain high quality personnel, especially our scientists and management team. If we are unable to retain existing personnel or identify or hire additional

## **Table of Contents**

personnel, we may not be able to research, develop, commercialize or market our product candidates as expected or on a timely basis and we may not be able to adequately support current and future alliances with strategic partners.

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

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

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

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

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

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

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

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

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

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

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

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

**Table of Contents**

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

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

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

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

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

**Risks Related To Ownership of Our Common Stock**

***Our stock price is subject to significant volatility.***

We participate in a highly dynamic industry which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low sales prices of our common stock during the twelve months ended December 31, 2010 were \$9.11 and \$5.22, respectively. We expect our stock price to continue to be subject to significant volatility and, in addition to the other risks and uncertainties described elsewhere in this annual report on Form 10-K and all other risks and uncertainties that are either not known to us at this time or which we deem to be immaterial, any of the following factors may lead to a significant drop in our stock price:

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

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

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

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

general negative conditions in the healthcare industry;

general negative conditions in the financial markets;

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

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

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

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

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

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

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

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

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

our failure to obtain financing on acceptable terms; or

a restructuring of our operations.



## **Table of Contents**

***Future sales of shares of our common stock pursuant to our universal shelf registration statement may negatively affect our stock price.***

We currently have the ability to offer and sell up to \$39.8 million of additional equity or debt securities under an effective universal shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into our common stock.

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

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

## **Risks Related To Our Industry**

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

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including ours, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, or DEA, and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storing, recordkeeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, we and our contract suppliers and manufacturers are subject to periodic inspection of our or their respective facilities, procedures and operations and/or the testing of products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that we and our contract suppliers and manufacturers are in compliance with all applicable regulations. The FDA also conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems, or our contract suppliers and manufacturers processes, are in compliance with cGMP and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

In addition, the FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceuticals including, but not limited to, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet.

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

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

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

our patents and pending patent applications cover products and/or technology that we invented first;

we were the first to file patent applications for these inventions;

others will not independently develop similar or alternative technologies or duplicate our technologies;

any of our pending patent applications will result in issued patents; and

any of our issued patents, or patent pending applications that result in issued patents, will be held valid and infringed in the event the patents are asserted against others.

## **Table of Contents**

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. For example, a European patent, EP1603541, claiming rHuPH20 was granted to us on November 11, 2009. Claims to the human PH20 glycoprotein, PEGylated variants, the glycoprotein produced by recombinant methods, and pharmaceutical compositions with other agents, including antibodies, insulins, cytokines, anti-infectives and additional therapeutic classes were awarded in this patent and additional claims are in prosecution. On August 13, 2010, however, we learned that an opposition to this patent was filed with the European Patent Office. We plan on contesting the opposition with written submissions to the European Patent Office and we expect to obtain European patent protection that is equal or superior to claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429). Any limitations in our patent portfolio could have a material adverse effect on our business and financial condition. In addition, if any of our pending patent applications do not result in issued patents, or result in issued patents with narrow or limited claims, this could 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 inventions. In addition, costly litigation could be necessary to protect our patent position.

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

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

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

Patent protection for protein-based therapeutic products is highly uncertain and involves complex legal and factual questions. In recent years, there have been significant changes in patent law, including the legal standards that govern the scope of protein and biotechnology patents. Standards for patentability of full-length and partial genes, and their corresponding proteins, are changing. Recent court decisions have made it more difficult to obtain patents, by making it more difficult to satisfy the requirement of non-obviousness, have decreased the availability of injunctions against infringers, and have increased the likelihood of challenging the validity of a patent through a declaratory judgment

action. Taken together, these decisions could make it more difficult and costly for us to obtain, license and enforce our patents. In addition, in recent years, several members of the United States Congress have made numerous proposals to change the patent statute. These proposals include measures that, among other things, would expand the ability of third parties to oppose United States patents, introduce the first to file standard to the United States patent system, and limit damages an infringer is required to pay. If the patent statute is changed, the scope, validity and enforceability of our patents may be significantly decreased.

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

## **Table of Contents**

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

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

Additional provisions of the Healthcare Reform Act, some of which become 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 (commonly known as the "donut hole"), we will also be required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. 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

## **Table of Contents**

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 partnered products under development.***

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

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

None.

### **Item 2. *Properties***

Our administrative offices and research facilities are currently located in San Diego, California. We lease an aggregate of approximately 58,000 square feet of office and research space for a monthly rent expense of approximately \$128,000, 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. *Removed and Reserved***



**Table of Contents****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:

	2010		2009	
	High	Low	High	Low
First Quarter	\$ 8.67	\$ 5.22	\$ 6.41	\$ 3.93
Second Quarter	\$ 9.11	\$ 6.08	\$ 8.09	\$ 5.07
Third Quarter	\$ 8.10	\$ 6.41	\$ 7.91	\$ 6.11
Fourth Quarter	\$ 8.31	\$ 6.68	\$ 7.86	\$ 5.22

On March 1, 2011, the closing sales price of our common stock on the NASDAQ Stock Market was \$6.81 per share. As of March 1, 2011, we had approximately 3,500 stockholders of record. We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2010:

Plan Category	Number of Shares to be Issued upon Exercise of Outstanding	Weighted-Average Exercise Price of Outstanding	Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Shares Reflected in Column (a))
	Options, Warrants and Rights (a)	Options, Warrants and Rights (b)	(c)
Equity compensation plans approved by stockholders(1)	7,975,365	\$ 3.87	3,246,559
Equity compensation plans not approved by stockholders			

Total	7,975,365	\$	3.87	3,246,559
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(1) Represents stock options under the 2008 Stock Plan, 2008 Outside Directors Stock Plan, 2006 Stock Plan, 2005 Outside Directors Stock Plan, 2004 Stock Plan and the 2001 Stock Plan. Options under the 2001 Stock Plan were assumed by Halozyme as part of the March 2004 merger between DeliaTroph Pharmaceuticals, Inc. ( 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.

**Table of Contents****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, 2005 to December 31, 2010. The historical stock price performance included in this graph is not necessarily indicative of future stock price performance.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
Among Halozyme Therapeutics Inc. The NASDAQ Composite Index  
And The NASDAQ Biotechnology Index

\* \$100 invested on 12/31/05 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

	12/05	12/06	12/07	12/08	12/09	12/10
<b>Halozyme Therapeutics, Inc.</b>	\$ 100.00	\$ 442.31	\$ 390.66	\$ 307.69	\$ 322.53	\$ 435.16
<b>NASDAQ Composite</b>	\$ 100.00	\$ 112.51	\$ 122.09	\$ 72.15	\$ 104.22	\$ 123.00
<b>NASDAQ Biotechnology</b>	\$ 100.00	\$ 99.85	\$ 103.25	\$ 96.48	\$ 105.99	\$ 122.16

**Table of Contents****Item 6. Selected Financial Data**

The selected consolidated financial data set forth below as of December 31, 2010 and 2009, and for the fiscal years ended December 31, 2010, 2009 and 2008, 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, 2008, 2007 and 2006, and for the fiscal years ended December 31, 2007 and 2006, 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 Operations Data:	Years Ended December 31,				
	2010	2009	2008	2007	2006
Total revenues	\$ 13,624,115	\$ 13,671,305	\$ 8,764,139	\$ 3,799,521	\$ 981,746
Net loss	(53,241,650)	(58,360,523)	(48,654,199)	(23,896,183)	(14,751,986)
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.67)	\$ (0.61)	\$ (0.32)	\$ (0.24)
Shares used in computing net loss per share, basic and diluted	94,357,695	86,700,094	79,843,707	74,317,930	62,610,265

Balance Sheet Data:	As of December 31,				
	2010	2009	2008	2007	2006
Cash and cash equivalents	\$ 83,255,848	\$ 67,464,506	\$ 63,715,906	\$ 97,679,085	\$ 44,189,403
Working capital	74,155,368	60,044,794	59,794,370	92,312,937	41,343,010
Total assets	91,345,333	77,149,759	76,562,713	103,460,374	46,091,320
Deferred revenues	58,093,551	60,482,192	49,448,456	39,269,491	19,981,537
Total liabilities	70,993,877	70,246,370	61,182,717	45,692,450	23,010,085
Stockholders' equity	20,351,456	6,903,389	15,379,996	57,767,924	23,081,235

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

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

**Overview**

We are a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. Our existing products and our products under development are based primarily on intellectual property covering the family of human enzymes known as hyaluronidases. Hyaluronidases are enzymes (proteins) that break down hyaluronan, or HA, which is a naturally occurring space-filling, gel-like substance that is a major component of both normal tissues throughout the body, such as skin and cartilage, and abnormal tissues such as

tumors. Our primary technology is based on our proprietary recombinant human PH20 enzyme, or rHuPH20, a human synthetic version of hyaluronidase. The PH20 enzyme is a naturally occurring enzyme that temporarily degrades HA, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. Our proprietary rHuPH20 technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones through the development of our own proprietary products. The rHuPH20 technology may also be applied to existing and developmental products of third parties through partnerships or other collaborations.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing

## **Table of Contents**

products and a limited number of product candidates; and (iv) supporting the development of partnered product candidates. We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have multiple proprietary programs in various stages of research and development. In addition, we have entered into a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, to apply Enhance™ Technology to Roche's biological therapeutic compounds for up to eight targets. We also have a key partnership with Baxter Healthcare Corporation, or Baxter, to apply Enhance Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID®. In January 2011, we and Baxter mutually agreed to terminate a partnership, under which Baxter had worldwide marketing rights for HYLENEX®, a registered trademark of Baxter International, Inc. There are two marketed products that utilize our technology: HYLENEX, a product used as an adjuvant to enhance the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, we have received only limited revenue from the sales of API to the third party that produces Cumulase, in addition to other revenues from our partnerships with Baxter and Roche.

We and our partners have product candidates in the research, preclinical and clinical stages, but future revenues from the sales and/or royalties of these product candidates will depend on our partners' abilities and ours to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we and our partners are able to obtain regulatory approvals for these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$225.3 million as of December 31, 2010.

In January 2010, we filed a shelf registration statement on Form S-3 (Registration No. 333-164215) which allows us, from time to time, to offer and sell up to \$100.0 million of equity or debt securities. In September 2010, we sold approximately \$60.2 million of our common stock in an underwritten public offering at a net price of \$7.25 per share. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

### ***Collaborative Partnerships***

#### ***Roche Partnership***

In December 2006, Halozyme and Roche entered into an Enhance Technology partnership, or the Roche Partnership. Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds resulting from the 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 an additional ten targets. Roche elected to add a fourth exclusive target in December 2008 and a fifth exclusive target in June 2009. In 2010 Roche did not pay the annual license maintenance fee on five of the remaining eight target slots. As a result, Roche currently retains the option to exclusively develop and commercialize rHuPH20 with an additional three targets through the payment of annual license maintenance fees. Pending the successful completion of various clinical, regulatory and sales events, Roche will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership.

Compounds directed at three of the Roche exclusive targets have previously commenced clinical trials. Two compounds (subcutaneous Herceptin® and subcutaneous MabThera®) are in Phase 3 clinical trials and one compound (subcutaneous Actemra®) has completed a Phase 1 clinical trial.

In October 2009, Roche commenced its first Phase 3 clinical trial for a compound directed at an exclusive target and in December 2010, the enrollment for this study was completed. This Phase 3 clinical trial is for a subcutaneously

delivered version of Roche's anticancer biologic, Herceptin (trastuzumab). The study will investigate the pharmacokinetics, efficacy and safety of subcutaneous Herceptin in patients with HER2-positive breast cancer as part of adjuvant treatment. 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 one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 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 20-25% of women with breast cancer. Roche has stated that they expect to file for regulatory approval of subcutaneous Herceptin in 2012.

## **Table of Contents**

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab). The study will investigate pharmacokinetics, efficacy and safety of MabThera SC. Intravenously administered MabThera is approved for the treatment of non-Hodgkin's lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), types of cancer that affects lymphocytes, or white blood cells. An estimated 66,000 new cases of NHL were diagnosed in the U.S. in 2009 with approximately 125,000 new cases reported worldwide.

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

Additional information about the Phase 3 subcutaneous Herceptin and Phase 3 subcutaneous MabThera clinical trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.roche-trials.com](http://www.roche-trials.com).

### ***Baxter Gammagard Partnership***

GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, Halozyyme and Baxter entered into an Enhance Technology partnership, or the Gammagard Partnership. Under the terms of this partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID, or HyQ. Pending the successful completion of various regulatory and sales milestones, Baxter will be obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter is responsible for all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we will be responsible for the supply of the rHuPH20 enzyme. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard License. In January 2011, Baxter announced the completion of a Phase 3 clinical trial for HyQ. Baxter has stated that they expect to file for regulatory approval of HyQ in 2011.

### ***HYLENEX Partnership***

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, enhances the dispersion and absorption of other injected drugs or fluids. In February 2007, Halozyyme and Baxter amended certain existing agreements relating to HYLENEX and entered into a new agreement for kits and formulations with rHuPH20, or the HYLENEX Partnership. Pending the successful completion of a series of regulatory and sales events, Baxter would have been obligated to make milestone payments to us, as well as royalty payments on the sales of products that result from the partnership. Baxter was responsible for development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. We supplied Baxter with API for HYLENEX, and Baxter prepared, filled, finished and packaged HYLENEX and held it for subsequent distribution.

In October 2009, Baxter commenced the commercial launch of HYLENEX recombinant (hyaluronidase human injection) for use in pediatric rehydration at the 2009 American College of Emergency Physicians (ACEP) scientific assembly. In addition, under the HYLENEX Partnership, Baxter had a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with Baxter hydration fluids and generic small molecule drugs, with the exception of combinations with (i) bisphosphonates, (ii) cytostatic and cytotoxic chemotherapeutic agents and (iii) proprietary small molecule drugs, the rights to which had been retained by Halozyyme.

Because a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. In May 2010, we delivered a



notice of breach to Baxter due to Baxter's failure to manufacture HYLENEX in accordance with the terms of existing development and supply contracts. The notice was sent after Baxter informed us that a portion of the HYLENEX manufactured by Baxter was not in compliance with the requirements of the underlying agreements with Baxter. In August 2010, we announced the withdrawal, without prejudice, of the notice of breach to Baxter. We have been in communication with the U.S. Food and Drug Administration, or FDA, and have provided them materials relating to the root cause and remediation plans. We are also generating data requested by the FDA and

## **Table of Contents**

currently expect, pending regulatory review and approval, that we could reintroduce the product in the second half of 2011.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The termination of these agreements does not affect the other relationships between the parties, including the application of Halozyme's Enhance Technology to Baxter's GAMMAGARD LIQUID.

## ***Revenues***

Revenues from product sales depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our products and product candidates.

Revenues from license and collaboration agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before they are earned. Nonrefundable upfront payments and license fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. Milestone payments are generally recognized as revenue upon the achievement of the milestones as specified in the underlying agreement, assuming we meet certain criteria. Royalty revenues from the sale of licensed products are recognized upon the sale of such products.

Elements of our collaborative partnerships include nonrefundable license fees, reimbursements of research and development services, various clinical, regulatory or sales milestones and future product-based or royalty payments, as applicable. Due to our ongoing involvement obligations under these partnerships, we recorded the nonrefundable license fees and annual license maintenance fees as deferred revenues. Such revenues are being recognized over the terms of the underlying agreements that define the terms of the partnerships.

## ***Costs and Expenses***

*Cost of Sales.* Cost of sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, and freight costs associated with the sales of Cumulase, API for Cumulase and the API for HYLENEX. Cost of sales also consists of the write-down of obsolete inventory.

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

Since our inception in 1998 through December 31, 2010, we have incurred research and development expenses of \$201.5 million. From January 1, 2008 through December 31, 2010, approximately 26% and 17% of our research and development expenses were associated with the development of our ultrafast insulin and PEGPH20 product candidates, respectively. Due to the uncertainty in obtaining the FDA and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

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

Product candidate completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable

## **Table of Contents**

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.

*Selling, General and Administrative.* Selling, general and administrative, or SG&A, expenses consist primarily of compensation and other expenses related to our corporate operations and administrative employees, accounting and legal fees, other professional services expenses, marketing expenses, as well as other expenses associated with operating as a publicly traded company.

### ***Critical Accounting Policies and Estimates***

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

### ***Revenue Recognition***

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

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

### ***Product Sales***

Revenues from the sales of Cumulase and API for Cumulase are recognized when the transfer of ownership occurs, which is upon shipment to our distributor. We are obligated to accept returns for product that does not meet product specifications. Historically, we have not had any product returns as a result of not meeting product specifications.

Under the terms of the HYLENEX Partnership, we supplied Baxter the API for HYLENEX at our fully burdened cost plus a margin. Baxter filled and finished HYLENEX and held it for subsequent distribution, at which time we ensured it met product specifications and released it as available for sale. Because of our continued involvement in the development and production process of HYLENEX, the earnings process was not considered to be complete. Accordingly, we deferred the revenue and related product costs on the API for HYLENEX until the product was filled, finished, packaged and released. Baxter could only return the API for HYLENEX to us if it did not conform to certain specified criteria set forth in the HYLENEX Partnership or upon termination of such agreement.

Effective January 7, 2011, we and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. As a result, we recorded a reserve for inventory obsolescence of approximately \$875,000 for HYLENEX API for the year ended December 31, 2010. In addition, we have recharacterized deferred revenue of approximately \$991,000 as a reserve for product returns for HYLENEX API previously delivered to Baxter that could be returned to us.

## **Table of Contents**

In addition, we received product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the HYLENEX Partnership. Product sales revenues were recognized as we earned such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts could be reasonably estimated. Baxter had prepaid \$10.0 million of non-refundable product-based payments. The prepaid product-based payments were initially deferred and were being recognized as product sales revenue as we earned such revenue from the sales of HYLENEX by Baxter through December 31, 2010. As a result of the HYLENEX Partnership termination, we will reassess the period over which the unamortized deferred revenue relating to the prepaid product-based payments totaling approximately \$9.3 million at December 31, 2010 will be recognized. The period over which this amount will be amortized will be based on the final outcome of the definitive agreement expected to be signed by April 7, 2011.

### *Revenues under Collaborative Agreements*

Revenues from collaborative and licensing agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before they are earned. Nonrefundable upfront payments and license fees, in which we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. We recognize milestone payments upon the achievement of specified milestones if: (1) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees are nonrefundable and (3) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Reimbursements of research and development services are recognized as revenue during the period in which the services are performed. Royalties to be received based on sales of licensed products by our collaborators incorporating our products are recognized as earned in accordance with the terms of the underlying agreements.

Under the terms of the HYLENEX Partnership, Baxter paid us a nonrefundable upfront payment of \$10.0 million in 2007. Due to our continuing involvement obligations (for example, support activities associated with rHuPh20 enzyme), the \$10.0 million upfront payment was deferred and was being recognized over the term of the HYLENEX Partnership. As a result of the termination of the HYLENEX Partnership in January 2011, we will reassess the period over which the unamortized deferred revenue relating to the upfront payment totaling approximately \$7.8 million at December 31, 2010 will be recognized. The period over which this amount will be amortized will be based on the final outcome of the definitive agreement expected to be signed by April 7, 2011.

### *Share-Based Payments*

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

If factors change and we employ different assumptions for determination of fair value in future periods, the share-based compensation expense that we record may differ significantly from what we have recorded in the current

period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our consolidated financial statements. Alternatively, values may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our consolidated

## **Table of Contents**

financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with authoritative guidance on stock compensation using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

### ***Research and Development Expenses***

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

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

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

### ***Inventory***

Inventory consists of raw materials used in production, work in process and finished goods inventory on hand related to our HYLENEX and Cumulase products. Inventory is valued at lower of cost or market (net realizable value) using the first-in, first-out method. Inventory is reviewed periodically for slow-moving or obsolete status. To the extent that its net realizable value is lower than cost, an impairment would be recorded. As a result of the termination of the HYLENEX Partnership in January 2011, we recorded a reserve for inventory obsolescence of approximately \$875,000 for HYLENEX API for the year ended December 31, 2010.



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

**Table of Contents**

**Results of Operations**

***Comparison of Years Ended December 31, 2010 and 2009***

***Product Sales*** Product sales were \$896,000 for the year ended December 31, 2010 compared to \$971,000 for the year ended December 31, 2009. The decrease of \$75,000, or 8%, was primarily due to the decreases in sales of Cumulase and HYLENEX. Based on the recall of HYLENEX in May 2010 and the termination of the HYLENEX Partnership in January 2011, we expect only product sales of Cumulase in future periods until HYLENEX is reintroduced to the market. As a result of the HYLENEX Partnership termination, we will reassess the period over which the unamortized deferred revenue relating to the prepaid product-based payments totaling approximately \$9.3 million at December 31, 2010 will be recognized. The period over which this amount will be amortized will be based on the final outcome of the definitive agreement expected to be signed by April 7, 2011.

***Revenues Under Collaborative Agreements*** Revenues under collaborative agreements were approximately \$12.7 million for the years ended December 31, 2010 and 2009. Revenues under collaborative agreements primarily consisted of the amortization of license fees and milestone payments received from Roche and Baxter of approximately \$3.0 million and \$10.1 million in 2010 and 2009, respectively. The decrease of \$7.1 million, or 70%, was due to the decrease in milestone payments. As a result of the termination of the HYLENEX Partnership in January 2011, we will reassess the periods over which the unamortized deferred revenue relating to the upfront payment totaling approximately \$7.8 million at December 31, 2010 will be recognized. The period over which this amount will be amortized will be based on the final outcome of the definitive agreement expected to be signed by April 7, 2011.

Revenues under collaborative agreements also included reimbursements for research and development services from Roche of \$5.2 million and \$1.4 million and Baxter of \$4.2 million and \$1.2 million in 2010 and 2009, respectively. Such reimbursements are for research and development services rendered by us at the request of Roche and Baxter and the amount of future revenues related to reimbursable research and development services is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to increase in future periods provided that our partners meet various clinical and regulatory milestones set forth in such agreements.

***Cost of Sales*** Cost of sales were \$985,000 for the year ended December 31, 2010 compared to \$312,000 for the year ended December 31, 2009. The increase was primarily due to a reserve for inventory obsolescence of \$875,000 for HYLENEX API in 2010 in connection with the termination of the HYLENEX Partnership in January 2011. The increase was offset in part by the decrease in the cost of sales due to a decrease in HYLENEX API sales in 2010. Based on the termination of the HYLENEX Partnership in January 2011, we expect only cost of product sales of Cumulase in future periods until HYLENEX is reintroduced to the market.

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

***Selling, General and Administrative*** SG&A expenses were \$15.1 million for the year ended December 31, 2010 compared to \$15.2 million for the year ended December 31, 2009. We expect SG&A expenses to increase in future periods as we plan to increase sales and marketing activities.

***Share-Based Compensation*** Total compensation cost for our share-based payments was \$4.9 million for the year ended December 31, 2010 compared to \$4.5 million for the year ended December 31, 2009. Research and development expenses included share-based compensation of approximately \$2.5 million and \$2.4 million in 2010 and 2009, respectively. SG&A expenses included share-based compensation of approximately \$2.3 million and \$2.1 million in 2010 and 2009, respectively. As of December 31, 2010, \$6.8 million of total unrecognized

**Table of Contents**

compensation costs related to non-vested stock options and restricted stock awards is expected to be recognized over a weighted average period of 2.5 years.

**Other Income, net** Other income consisted of one-time grants of approximately \$978,000 received in 2010 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, or QTDP. Other income, net also included interest income of \$49,000 for the year ended December 31, 2010 compared to \$101,000 for the year ended December 31, 2009. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2010 as compared to the same period in 2009.

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

***Comparison of Years Ended December 31, 2009 and 2008***

**Product Sales** Product sales were \$971,000 for the year ended December 31, 2009 compared to \$712,000 for the year ended December 31, 2008. The increase of \$259,000, or 36%, was primarily due to the increases in sales of HYLENEX and Cumulase.

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements were approximately \$12.7 million for the year ended December 31, 2009 compared to \$8.1 million for the year ended December 31, 2008, which represents an increase of \$4.6 million or 57%. Revenues under collaborative agreements primarily consisted of the amortization of license fees and milestone payments received from Roche and Baxter of approximately \$10.1 million and \$3.4 million in 2009 and 2008, respectively. The increase of \$6.7 million, or 197%, was primarily due to the increase in milestone payments. Revenues under collaborative agreements also included reimbursements for research and development services from Roche of \$1.4 million and \$1.7 million and Baxter of \$1.2 million and \$3.0 million in 2009 and 2008, respectively.

**Cost of Sales** Cost of sales were \$312,000 for the year ended December 31, 2009 compared to \$332,000 for the year ended December 31, 2008. The decrease of \$20,000, or 6%, was mainly due to the decrease in the cost of Cumulase sales in 2009.

**Research and Development** Research and development expenses were \$56.6 million for the year ended December 31, 2009 compared to \$44.2 million for the year ended December 31, 2008. The increase of \$12.4 million, or 28%, was primarily due to the increases in activities supporting our ultrafast insulin program of \$10.5 million and PEGPH20 program of \$2.9 million.

**Selling, General and Administrative** SG&A expenses were \$15.2 million for the year ended December 31, 2009 compared to \$14.6 million for the year ended December 31, 2008. The increase of approximately \$570,000, or 4%, was primarily due to the increase in compensation costs of \$1.0 million and legal expenses related to patent applications of \$845,000. The increase was partially offset by a decrease in other legal expenses of \$1.2 million.

**Share-Based Compensation** Total compensation cost for our share-based payments was \$4.5 million for the year ended December 31, 2009 compared to \$3.7 million for the year ended December 31, 2008. Research and development expenses included share-based compensation of approximately \$2.4 million and \$1.5 million in 2009 and 2008, respectively. SG&A expenses included share-based compensation of approximately \$2.1 million and \$2.2 million in 2009 and 2008, respectively. As of December 31, 2009, \$7.1 million of total unrecognized compensation costs related to non-vested stock options and restricted stock awards is expected to be recognized over a weighted average period of 2.7 years.

**Other Income, net** Other income, net consisted of interest income of \$101,000 for the year ended December 31, 2009 compared to \$1.7 million for the year ended December 31, 2008. The decrease in interest income was primarily due to lower cash and cash equivalent balances and lower interest rates in 2009 as compared to the same period in 2008.

**Net Loss** Net loss for the year ended December 31, 2009 was \$58.4 million, or \$0.67 per common share, compared to \$48.7 million, or \$0.61 per common share for the year ended December 31, 2008. The increase in net loss was primarily due to an increase in operating expenses, partially offset by increases in revenues.

## **Table of Contents**

### **Liquidity and Capital Resources**

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2010, we had cash and cash equivalents of approximately \$83.3 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 \$47.0 to \$52.0 million for the year ending December 31, 2011, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones under our existing collaborative agreements. We do not expect our revenues to be sufficient to fund operations for several years. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing collaborations and cash that we will 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.

In January 2010, we filed a shelf registration statement on Form S-3 (Registration No. 333-164215) which allows us, from time to time, to offer and sell up to \$100.0 million of equity or debt securities. In September 2010, we sold approximately \$60.2 million of our common stock in an underwritten public offering at a net price of \$7.25 per share. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

In June 2009, we sold approximately \$40.0 million of our common stock in a public offering at a price of \$6.50 per share under a prior shelf registration statement on Form S-3 (Registration No. 333-155787) which was filed in November 2008.

Our existing cash and cash equivalents will 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 will 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 as well as covenants that may restrict our ability to operate our business.

### ***Operating Activities***

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

Net cash used in operations was \$40.1 million during the year ended December 31, 2009 compared to \$35.4 million of net cash used in operations during the year ended December 31, 2008. This change was primarily due to increased

operating expenses of approximately \$12.9 million and timing of accounts payable and accrued expenses payments; partially offset by increased partnership payments of approximately \$15.1 million during 2009 as compared to 2008.

***Investing Activities***

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

**Table of Contents**

Net cash used in investing activities was \$1.5 million during the year ended December 31, 2009 compared to \$1.2 million during the year ended December 31, 2008. This was primarily due to an increase in purchases of property and equipment during 2009.

**Financing Activities**

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

Net cash provided by financing activities was \$45.4 million during the year ended December 31, 2009 compared to \$2.6 million during the year ended December 31, 2008. Net cash provided by financing activities during 2009 primarily consisted of net proceeds of \$38.2 million from the sale of our common stock in June 2009 and \$7.2 million from warrant and stock option exercises. Net cash provided by financing activities during 2008 primarily consisted of proceeds from warrant and stock option exercises.

**Off-Balance Sheet Arrangements**

As of December 31, 2010, 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, 2010, future minimum payments due under our contractual obligations are as follows:

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Payments Due by Period</b>			<b>More than 5 Years</b>
		<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	
Operating leases	\$ 4,603,757	\$ 2,217,810	\$ 2,385,428	\$ 519	\$
License payments	1,975,000	775,000	600,000	600,000	
Purchase obligations(1)	30,703,423	28,389,966	1,636,396	533,271	143,790
<b>Total</b>	<b>\$ 37,282,180</b>	<b>\$ 31,382,776</b>	<b>\$ 4,621,824</b>	<b>\$ 1,133,790</b>	<b>\$ 143,790</b>

- (1) Purchase obligations include outstanding purchase orders for outsourced research and development services for our various preclinical and clinical programs, for the manufacturing of our products for clinical and commercial use and other recurring purchases and services made in the normal course of business.



As of December 31, 2010, we had no long-term debt or capital lease obligations.

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

the rate of progress and cost of research and development activities;

the number and scope of our research activities;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

our ability to establish and maintain product discovery and development collaborations;

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.

**Table of Contents**

**Recent Accounting Pronouncements**

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

**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 that we invest in 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, 2010, we did not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions, and all of our cash and cash equivalents were in money market mutual funds and other investments that we believe to be highly liquid.

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

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

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

None.

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

**Evaluation of Disclosure Controls and Procedures**

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this

evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

### **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, 2010, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**Table of Contents**

**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, 2010. 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, 2010, 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, 2010. The report appears below.

**Table of Contents**

**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, 2010, 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, 2010, 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, 2010 and 2009, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2010 of Halozyme Therapeutics, Inc. and our report dated March 11, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 11, 2011

**Table of Contents****Item 9B. *Other Information***

None.

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

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

**Executive Officers**

*Gregory I. Frost, Ph.D. (39)*, President, Chief Executive Officer and Director. Dr. Frost was named Halozyme's President and Chief Executive Officer in December 2010. Dr. Frost was Vice President and Chief Executive Officer from 1999 through December 2010. He brought the founding enzyme technologies to Halozyme in 1999 and has spent more than fifteen years conducting research on the extracellular matrix. Over his eleven years at Halozyme, Dr. Frost has led the R&D efforts from discovery through FDA approval for a number of biotechnology products. Prior to Halozyme, he was a Scientist at the Sidney Kimmel Cancer Center. In the Department of Pathology at the University of California, San Francisco, his work led directly to the purification, cloning, and characterization of the human hyaluronidase gene family, and the discovery of several metabolic disorders. He has authored multiple scientific peer-reviewed and invited articles in the hyaluronidase field and is an inventor on several key patents. Dr. Frost is a member of the American Association for Cancer Research and the American Society of Clinical Oncology and he is registered to practice before the U.S. Patent and Trademark Office. Dr. Frost earned his B.A. in biochemistry and molecular biology from the University of California, Santa Cruz, and his Ph.D. in the Department of Pathology at the University of California, San Francisco.

*Kurt A. Gustafson (43)*, Vice President, Secretary and Chief Financial Officer. Mr. Gustafson joined Halozyme in 2009 with extensive operational and managerial experience in financial planning and analysis, accounting, treasury and international responsibility gained during his 18 years with Amgen Inc. In his most recent position, as Vice President, Manufacturing Finance, Mr. Gustafson had financial responsibility for each of Amgen's worldwide manufacturing sites and the Cost Accounting Group. He was responsible for the financial planning, cost accounting, capital planning and procurement activities at each of these sites from 2006 to 2009. From 2004 to 2006, Mr. Gustafson was Vice President, Finance and CFO of Amgen International, responsible for financial planning and accounting for Ex-US operations. Stationed in Switzerland, Mr. Gustafson was responsible for Amgen's International Operations, which spanned Europe, the Middle East, Eastern Europe, North Africa and Australia. From 2000 to 2004, Mr. Gustafson headed up Corporate Financial Planning and Analysis, most recently as Vice President, Corporate Financial Planning & Analysis. In this role, he was responsible for worldwide consolidation of the company's forecasts. He also led the Corporate Business Analysis group, which provided financial and decision support to the Product Strategy Teams. From 1991 to 2000, Mr. Gustafson held multiple positions in Amgen's Treasury group with increasing levels of responsibility, most recently serving as 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.

*William J. Fallon (54)*, Vice President, Manufacturing & Operations. Mr. Fallon joined Halozyme in 2006 as Vice President, Manufacturing & Operations. His responsibilities include oversight of all aspects of internal and external manufacturing and facilities operations, as well as bioprocess development. Prior to Halozyme, he served as President and Chief Executive Officer of Cytovance Biologics, a contract manufacturing organization that



**Table of Contents**

provides manufacturing and development services to the biotechnology industry. From 2001 to 2003, he was Vice President of Technical Operations at Genzyme Corporation, having held the same position at Novazyme Pharmaceuticals, Inc. prior to its acquisition by Genzyme in 2001. Mr. Fallon joined Novazyme from Transkaryotic Therapies, where he was Vice President of Manufacturing from 1998 to 2001. From 1993 to 1998, he was employed in several management positions for the Ares-Serono Group, including Vice President, U.S. Manufacturing Operations. In this role, he served as general manager, overseeing the production and distribution of all of Serono's approved biotechnology products in the United States. From 1990 to 1992, he was Director of Manufacturing for Centocor, Inc. His prior experience also includes various management and operational roles at Invitron Corporation and Travenol-Genentech Diagnostics. Mr. Fallon earned a B.S. in marine science and a B.A. in biology from Long Island University, and an M.S. in biology from Northeastern University.

*H. Michael Shepard, Ph.D. (61)*, 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.

*Michael J. LaBarre, Ph. D. (47)* Vice President, Product Development. Dr. LaBarre joined Halozyme in 2008 and oversees all of Halozyme's product development efforts, bringing strong expertise in chemistry, manufacturing and controls (CMC) based on his extensive experience in the biotechnology industry for both biologics and small molecules. In his previous role as Vice President of Product Development at Paramount BioSciences, LLC, Dr. LaBarre led the CMC efforts for all of the product development programs within Paramount's portfolio. Prior to joining Paramount, Dr. LaBarre served in various research and development positions from 1995 to 2006 at Biogen Idec (previously IDEC), where he had responsibility for analytical and formulation development, protein purification, and biochemical characterization supporting numerous IND and BLA submissions, including those for Rituxan® and Zevalin®. His last position with Biogen Idec was Director of Analytical and Protein Biochemistry. Prior to IDEC, Dr. LaBarre spent two years at Vical, Inc. in the analytical methods development group. He began his career at Hybritech, where he held positions in regulatory affairs and manufacturing technical support, focusing on radiolabeled antibody technologies and analytical chemistry. Dr. LaBarre received his B.S. in chemistry from Southampton College and his Ph.D. in bioinorganic chemistry from the University of Arizona.

**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 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.

**Table of Contents**

**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, and Director Independence* 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.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules****(a) Documents filed as part of this report.**

## 1. Financial Statements:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets at December 31, 2010 and 2009</u>	F-2
<u>Consolidated Statements of Operations for Each of the Years Ended December 31, 2010, 2009 and 2008</u>	F-3
<u>Consolidated Statements of Cash Flows for Each of the Years Ended December 31, 2010, 2009 and 2008</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for Each of the Years Ended December 31, 2010, 2009 and 2008</u>	F-5
<u>Notes to the Consolidated Financial Statements</u>	F-6

2. List of all Financial Statement schedules. All 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(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)

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- 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)

**Table of Contents**

10.19#	Form of Indemnity Agreement for Directors and Executive Officers(17)
10.20#	Outside Director Compensation Plan(21)
10.21#	2008 Senior Executive Incentive Structure(20)
10.22#	2009 Senior Executive Incentive Plan(23)
10.23#	2010 Senior Executive Incentive Plan(26)
10.24#	Change in Control Policy(20)
10.25#	Severance Policy(21)
10.26*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.27*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.28*	License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(14)
10.29	Termination Agreement between Halozyme Inc., Baxter Healthcare Corporation and Baxter Healthcare S.A, effective January 7, 2011(28)
10.30*	Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(16)
10.31*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(12)
10.32	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(15)
10.33	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(15)
10.34	Underwriting Agreement between Halozyme Therapeutics, Inc. and Jefferies & Company, Inc., dated June 23, 2009(27)
10.35	Underwriting Agreement between Halozyme Therapeutics, Inc. and Barclays Capital Inc., dated September 8, 2010(25)
10.36	Separation Agreement And General Release of All Claims between Halozyme Therapeutics, Inc. and Jonathan E. Lim
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

- (1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed November 20, 2007.
- (2) Incorporated by reference to the Registrant's definitive proxy statement filed with the SEC on Form DEF14A on October 11, 2007.
- (3) Incorporated by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on April 23, 2004.
- (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.

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- (5) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the Commission on October 26, 2004.
- (6) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 22, 2005.
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed July 6, 2005.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2006.
- (9) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.

**Table of Contents**

- (10) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.
- (11) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2006.
- (12) Incorporated by reference to the Registrant's Current Report on Form 8-K/A, filed December 15, 2006.
- (13) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 21, 2006.
- (14) Incorporated by reference to the Registrant's Current Report on Form 8-K/A, filed February 20, 2007.
- (15) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed July 31, 2007.
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed September 12, 2007.
- (17) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 20, 2007.
- (18) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed March 14, 2008.
- (19) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 19, 2008.
- (20) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed April 21, 2008.
- (21) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed May 9, 2008.
- (22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed November 7, 2008.
- (23) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 9, 2009.
- (24) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed June 23, 2009.
- (25) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2009.
- (26) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 8, 2010.
- (27) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed September 9, 2010.
- (28) Incorporated by reference to the Registrant's Current Report on Form 8-K, January 10, 2011.

\* 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.

# Indicates management contract or compensatory plan or arrangement.

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



**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on March 11, 2011.

Halozyme Therapeutics, Inc.,  
a Delaware corporation

By:  
/s/ Gregory I. Frost, Ph.D.

Date: March 11, 2011

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gregory I. Frost, Ph.D. Gregory I. Frost, Ph.D.	President and Chief Executive Officer (Principal Executive Officer), Director	March 11, 2011
/s/ Kurt A. Gustafson Kurt A. Gustafson	Vice President, Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2011
/s/ Kenneth J. Kelley Kenneth J. Kelley	Chairman of the Board of Directors	March 11, 2011
/s/ Robert L. Engler, M.D.	Director	March 11, 2011

Robert L. Engler, M.D.

/s/ Kathryn E. Falberg

Director

March 11, 2011

Kathryn E. Falberg

/s/ Randal J. Kirk

Director

March 11, 2011

Randal J. Kirk

/s/ Connie L. Matsui

Director

March 11, 2011

Connie L. Matsui

/s/ John S. Patton, Ph.D.

Director

March 11, 2011

John S. Patton, Ph.D.

**Table of Contents**

**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, 2010 and 2009, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

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, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 11, 2011

F-1

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**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 83,255,848	\$ 67,464,506
Accounts receivable	2,328,268	4,243,909
Inventory	193,422	1,159,551
Prepaid expenses and other assets	3,720,896	1,573,777
Total current assets	89,498,434	74,441,743
Property and equipment, net	1,846,899	2,708,016
Total Assets	\$ 91,345,333	\$ 77,149,759
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,820,368	\$ 2,820,491
Accrued expenses	8,605,569	6,083,854
Deferred revenue	2,917,129	5,492,604
Total current liabilities	15,343,066	14,396,949
Deferred revenue, net of current portion	55,176,422	54,989,588
Deferred rent, net of current portion	474,389	859,833
Commitments and contingencies (Note 11)		
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; 100,580,849 and 91,681,756 shares issued and outstanding at December 31, 2010 and 2009, respectively	100,581	91,682
Additional paid-in capital	245,502,670	178,821,852
Accumulated deficit	(225,251,795)	(172,010,145)
Total stockholders' equity	20,351,456	6,903,389
Total Liabilities and Stockholders' Equity	\$ 91,345,333	\$ 77,149,759

See accompanying notes to consolidated financial statements.



**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>REVENUES:</b>			
Product sales	\$ 895,518	\$ 970,847	\$ 711,937
Revenues under collaborative agreements	12,728,597	12,700,458	8,052,202
<b>Total revenues</b>	<b>13,624,115</b>	<b>13,671,305</b>	<b>8,764,139</b>
<b>OPERATING EXPENSES:</b>			
Cost of product sales	985,283	311,891	332,324
Research and development	51,773,504	56,614,266	44,232,936
Selling, general and administrative	15,122,960	15,203,408	14,633,581
<b>Total operating expenses</b>	<b>67,881,747</b>	<b>72,129,565</b>	<b>59,198,841</b>
<b>OPERATING LOSS</b>	<b>(54,257,632)</b>	<b>(58,458,260)</b>	<b>(50,434,702)</b>
<b>OTHER INCOME (EXPENSE):</b>			
Other income (expense)	966,967	(3,010)	(3,024)
Interest income, net	49,015	100,747	1,720,527
<b>Total other income, net</b>	<b>1,015,982</b>	<b>97,737</b>	<b>1,717,503</b>
<b>NET LOSS BEFORE INCOME TAXES</b>	<b>(53,241,650)</b>	<b>(58,360,523)</b>	<b>(48,717,199)</b>
Income tax benefit			(63,000)
<b>NET LOSS</b>	<b>\$ (53,241,650)</b>	<b>\$ (58,360,523)</b>	<b>\$ (48,654,199)</b>
Basic and diluted net loss per share	\$ (0.56)	\$ (0.67)	\$ (0.61)
Shares used in computing basic and diluted net loss per share	94,357,695	86,700,094	79,843,707

See accompanying notes to consolidated financial statements.

**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (53,241,650)	\$ (58,360,523)	\$ (48,654,199)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	4,866,325	4,526,030	3,695,842
Depreciation and amortization	1,507,925	1,443,738	1,047,878
Loss on disposal of equipment	13,542	2,685	4,729
Changes in operating assets and liabilities:			
Accounts receivable	1,915,641	3,020,501	(6,484,585)
Inventory	966,129	(718,228)	262,145
Prepaid expenses and other assets	(2,147,119)	1,017,372	(576,469)
Accounts payable and accrued expenses	3,437,089	(2,000,233)	4,788,346
Deferred rent	(314,747)	(113,343)	363,484
Deferred revenue	(2,388,641)	11,033,736	10,178,965
Net cash used in operating activities	(45,385,506)	(40,148,265)	(35,373,864)
<b>INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(646,544)	(1,461,021)	(1,159,744)
Net cash used in investing activities	(646,544)	(1,461,021)	(1,159,744)
<b>FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, net	59,965,059	38,174,371	
Proceeds from exercise of stock options, net	1,858,333	1,018,357	843,716
Proceeds from exercise of warrants, net		6,165,158	1,726,713
Net cash provided by financing activities	61,823,392	45,357,886	2,570,429
Net increase (decrease) in cash and cash equivalents	15,791,342	3,748,600	(33,963,179)
Cash and cash equivalents at beginning of period	67,464,506	63,715,906	97,679,085
Cash and cash equivalents at end of period	\$ 83,255,848	\$ 67,464,506	\$ 63,715,906
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Accounts payable for purchases of property and equipment	\$ 13,806	\$ 143,493	\$ 159,472

See accompanying notes to consolidated financial statements.





**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**Years Ended December 31, 2010, 2009 and 2008**

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Stockholders</b>
			<b>Capital</b>		<b>Equity</b>
BALANCE AT JANUARY 1, 2008	77,903,944	\$ 77,904	\$ 122,685,443	\$ (64,995,423)	\$ 57,767,924
Share-based compensation expense			3,695,842		3,695,842
Issuance of common stock pursuant to exercise of warrants, net	1,628,374	1,628	1,725,085		1,726,713
Issuance of common stock pursuant to exercise of stock options	1,828,836	1,829	841,887		843,716
Issuance of restricted stock awards	192,500	193	(193)		
Net loss				(48,654,199)	(48,654,199)
BALANCE AT DECEMBER 31, 2008	81,553,654	81,554	128,948,064	(113,649,622)	15,379,996
Share-based compensation expense			4,526,030		4,526,030
Issuance of common stock for cash, net	6,150,000	6,150	38,168,221		38,174,371
Issuance of common stock pursuant to exercise of warrants, net	3,140,780	3,141	6,162,017		6,165,158
Issuance of common stock pursuant to exercise of stock options	717,322	717	1,017,447		1,018,164
Issuance of restricted stock awards	120,000	120	73		193
Net loss				(58,360,523)	(58,360,523)
BALANCE AT DECEMBER 31, 2009	91,681,756	91,682	178,821,852	(172,010,145)	6,903,389
Share-based compensation expense			4,866,325		4,866,325
Issuance of common stock for cash, net	8,300,000	8,300	59,956,759		59,965,059
Issuance of common stock pursuant to exercise of stock	479,093	479	1,857,734		1,858,213

options					
Issuance of restricted stock awards	120,000	120			120
Net loss				(53,241,650)	(53,241,650)
<b>BALANCE AT DECEMBER</b>					
31, 2010	100,580,849	\$ 100,581	\$ 245,502,670	\$ (225,251,795)	\$ 20,351,456

See accompanying notes to consolidated financial statements.

F-5

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**Table of Contents**

**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements**

**1. Organization and Business**

Halozyme Therapeutics, Inc. ( Halozyme or the Company ) is a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. The Company's existing products and its products under development are based primarily on intellectual property covering the family of human enzymes known as hyaluronidases.

The Company's operations to date have involved: (i) organizing and staffing its operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing its technology; (iii) undertaking product development for its existing products and a limited number of product candidates; and (iv) supporting the development of partnered product candidates. The Company currently has multiple proprietary programs in various stages of research and development. In addition, the Company has a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. ( Roche ) to apply Enhanze™ Technology to Roche's biological therapeutic compounds for up to eight targets. The Company also has a key partnership with Baxter Healthcare Corporation ( Baxter ) to apply Enhanze Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID™. The Company also had a partnership with Baxter, under which Baxter had worldwide marketing rights for HYLENEX®, a registered trademark of Baxter International, Inc. ( HYLENEX Partnership ). In January 2011, the Company and Baxter mutually agreed to terminate the HYLENEX Partnership. There are two marketed products that utilize the Company's technology: HYLENEX, a hyaluronidase human injection used as an adjuvant to enhance the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization ( IVF ). Currently, the Company has received only limited revenue from the sales of API to the third party that produces Cumulase, in addition to other revenues from its partnerships with Baxter and Roche.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

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

***Use of Estimates***

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

***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***

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

The Company sells its products to established distributors in the pharmaceutical industry. Credit is extended based on an evaluation of the customer's financial condition. Approximately 100% and 97% of the accounts receivable balance as of December 31, 2010 and 2009, respectively, represents amounts due from two customers.

F-6

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**Table of Contents**

**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

Management evaluates the collectibility of the accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at December 31, 2010 and 2009. For the years ended December 31, 2010, 2009 and 2008, 52%, 76% and 44% of total revenues were from Roche and 42%, 20% and 51% of total revenues were from Baxter, respectively.

The Company relies on two third-party manufacturers for the supply of the active pharmaceutical ingredient in each of its current products. Payments due to these suppliers represent 32% and 4% of the accounts payable balance at December 31, 2010 and 2009, respectively.

***Accounts Receivable***

Accounts receivable is recorded at the invoiced amount and is non-interest bearing. Accounts receivable is recorded net of an allowance for doubtful accounts. Currently, the allowance for doubtful accounts is zero as the collectibility of accounts receivable is reasonably assured.

***Inventory***

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

Inventory at December 31, 2010 and 2009 consists of raw materials used in the manufacture of the Company's HYLENEX and Cumulase products. As a result of the termination of the HYLENEX Partnership in January 2011, the Company recorded a reserve for inventory obsolescence of approximately \$875,000 for HYLENEX API for the year ended December 31, 2010. As of December 31, 2010 and 2009, the reserve for inventory obsolescence was approximately \$875,000 and \$0, respectively.

***Property and Equipment***

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

***Impairment of Long-Lived Assets***

The Company accounts for long-lived assets in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. For the years ended December 31, 2010, 2009 and 2008, there has been no impairment of the value of such assets.

***Fair Value of Financial Instruments***

The carrying value of cash equivalents, accounts receivable, accounts payable and accrued expenses approximates fair value. See *Fair Value Measurements* below for further discussion of fair value.

***Fair Value Measurements***

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

F-7

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**Table of Contents**

**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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.

Cash equivalents of approximately \$79.8 million and \$65.3 million at December 31, 2010 and 2009, respectively, are carried at fair value and are classified within Level 1 of the fair value hierarchy because they are valued based on quoted market prices for identical securities. The Company has no instruments that are classified within Level 2 and Level 3.

***Deferred Rent***

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

***Comprehensive Income/Loss***

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

***Revenue Recognition***

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

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

***Product Sales*** Revenues from the sales of Cumulase and API for Cumulase are recognized when the transfer of ownership occurs, which is upon shipment to the Company's distributor. The Company is obligated to accept returns for product that does not meet product specifications. Historically, the Company has not had any product returns as a result of not meeting product specifications.

In accordance with the HYLENEX Partnership with Baxter, the Company supplied Baxter with API for HYLENEX at its fully burdened cost plus a margin. Baxter filled and finished HYLENEX and held it for subsequent distribution, at

which time the Company ensured it met product specifications and released it as available for sale. Because of the Company's continued involvement in the development and production process of HYLENEX, the earnings process was not considered to be complete. Accordingly, the Company deferred the revenue and related product costs on the API for HYLENEX until the product was filled, finished, packaged and released. Baxter might only return the API for HYLENEX to the Company if it did not conform to the specified criteria set forth in the HYLENEX Partnership or upon termination of such agreement. In addition, the Company received product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the HYLENEX Partnership. Product sales revenues were recognized as the Company earned such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts could be reasonably estimated. Effective January 7, 2011, the Company and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. See Note 5, Deferred Revenue, for further discussion.



**Table of Contents**

**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

*Collaborative Agreements* The Company analyzes each element of its collaborative agreements to determine the appropriate revenue recognition. The Company recognizes revenue on nonrefundable upfront payments and license fees in which it has an ongoing involvement or performance obligation over the period of significant involvement under the related agreements. The Company recognizes milestone payments upon the achievement of specified milestones if: (1) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees are nonrefundable and (3) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Reimbursements of research and development services are recognized as revenue during the period in which the services are performed. Royalties to be received based on sales of licensed products by the Company's collaborators incorporating the Company's products will be recognized as earned. See Note 5, *Deferred Revenue*, for further discussion.

***Cost of Sales***

Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs and freight costs associated with the sales of Cumulase, API for Cumulase and the API for HYLENEX. Cost of sales also consists of the write-down of obsolete inventory. As a result of the termination of the HYLENEX Partnership in January 2011, the Company recorded a reserve for inventory obsolescence of \$875,000 for HYLENEX API for the year ended December 31, 2010.

***Research and Development Expenses***

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

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

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

***Clinical Trial Expenses***

Expenses related to clinical trials are accrued based on the Company's estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and

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

F-9

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)*****Restructuring Expense***

In accordance with authoritative guidance for exit or disposal cost obligations, the Company records costs and liabilities associated with restructuring activities, mainly employee separation costs based on actual and estimates of fair value in the period the liabilities are incurred. In periods subsequent to initial measurement, liabilities are evaluated and adjusted as appropriate for changes in circumstances at least on a quarterly basis. Please refer to Note 11, Restructuring Expense, for further discussion.

***Share-Based Payments***

The Company records compensation expense associated with stock options and other share-based compensation in accordance with the authoritative guidance for stock compensation. The cost of employee services received in exchange for an award of 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, 2010, 2009 and 2008 based on the Company's historical experience and those of its peer group. Total share-based compensation expense related to share-based awards for the years ended December 31, 2010, 2009 and 2008 was comprised of the following:

	<b>Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Research and development	\$ 2,517,172	\$ 2,441,907	\$ 1,541,003
Selling, general and administrative	2,349,153	2,084,123	2,154,839
Share-based compensation expense	\$ 4,866,325	\$ 4,526,030	\$ 3,695,842
Net share-based compensation expense, per basic and diluted share	\$ 0.05	\$ 0.05	\$ 0.05
Share-based compensation expense from:			
Stock options	\$ 4,022,790	\$ 3,648,174	\$ 2,691,571
Restricted stock awards	843,535	877,856	1,004,271
	\$ 4,866,325	\$ 4,526,030	\$ 3,695,842

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 the Company's net loss position, no tax benefits have been recognized in the consolidated statements of cash flows.

The cost of non-employee services received in exchange for an award of equity instrument is measured based on either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The Company recognized approximately \$0, \$93,000 and \$0 in stock-based compensation expense related to stock options granted to non-employees for the years ended December 31, 2010, 2009 and 2008, respectively. There were no non-employee stock options outstanding at December 31, 2010 and 2009.

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)*****Income Taxes***

Income taxes are recorded in accordance with authoritative guidance for accounting for income taxes, which requires the recognition of deferred tax assets and liabilities to reflect the future tax consequences of events that have been recognized in the Company's consolidated financial statements or tax returns. Measurement of the deferred items is based on enacted tax laws. In the event the future consequences of differences between financial reporting bases and tax bases of the Company's assets and liabilities result in a deferred tax asset, an evaluation of the probability of being able to realize the future benefits indicated by such assets is required. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. Effective January 1, 2007, the Company adopted the authoritative guidance on accounting for uncertainty in income taxes, which prescribes a comprehensive model for how the Company should recognize, measure, present and disclose in its consolidated financial statements for uncertain tax positions that the Company has taken or expects to take on a tax return.

***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 warrants 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 the Company's net loss, all outstanding stock options, unvested stock awards and warrants were excluded from the calculation. The Company has excluded the following stock options, unvested stock awards and warrants from the calculation of diluted net loss per common share because their effect is anti-dilutive:

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Stock options and awards	8,095,365	7,924,266	7,447,285
Warrants			3,230,656
	8,095,365	7,924,266	10,677,941

***Segment Information***

The Company operates in one segment, which is the research, development and commercialization of human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. The chief operating decision-makers review the operating results on an aggregate basis and manage the operations as a single operating segment.

***Pending Adoption of Recent Accounting Pronouncement***

In April 2010, the FASB issued Accounting Standards Update ( ASU ) No. 2010-17, Revenue Recognition (Topic 605): *Milestone Method of Revenue Recognition*. ASU No. 2010-17 states that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. The guidance in ASU No. 2010-17 is effective for fiscal years beginning on or after June 15, 2010 and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. Early adoption is permitted provided that the revised guidance is retrospectively applied to the beginning of the year of adoption. The Company will adopt this guidance on January 1, 2011. The Company does not expect

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

the adoption of ASU No. 2010-17 to have a material impact on its consolidated financial position or results of operations.

In September 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605): *Multiple-Deliverable Revenue Arrangements*. ASU No. 2009-13 requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. ASU No. 2009-13 eliminates the use of the residual method of allocation and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue for an arrangement with multiple deliverables subject to Accounting Standards Code 605-25. The guidance in ASU No. 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of ASU No. 2009-13 to have a material impact on its consolidated financial position or results of operations.

**3. Property and Equipment**

Property and equipment consists of the following:

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Research equipment	\$ 4,308,654	\$ 3,838,307
Computer and office equipment	1,215,894	1,333,924
Leasehold improvements	998,368	981,140
	6,522,916	6,153,371
Accumulated depreciation and amortization	(4,676,017)	(3,445,355)
	\$ 1,846,899	\$ 2,708,016

Depreciation and amortization expense was approximately \$1.5 million, \$1.4 million and \$1.0 million, for the years ended December 31, 2010, 2009 and 2008, respectively.

**4. Accrued Expenses**

Accrued expenses consist of the following:

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Accrued outsourced research and development expenses	\$ 3,647,762	\$ 2,609,819
Accrued compensation and payroll taxes	3,045,950	2,945,498
Accrued expenses	1,911,857	528,537

	\$ 8,605,569	\$ 6,083,854
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## 5. Deferred Revenue

Deferred revenue consists of the following:

	<b>December 31, 2010</b>	<b>December 31, 2009</b>
Collaborative agreements	\$ 48,761,361	\$ 50,390,400
Product sales	9,332,190	10,091,792
Total deferred revenue	58,093,551	60,482,192
Less current portion	2,917,129	5,492,604
Deferred revenue, net of current portion	\$ 55,176,422	\$ 54,989,588

F-12

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

*Roche Partnership* In December 2006, the Company and Roche entered into a license and collaborative agreement for Enhance Technology (the Roche Partnership). Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, the Company's proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid \$20.0 million to the Company in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. Through December 31, 2010, Roche paid an aggregate of \$19.25 million in connection with Roche's selection of two additional exclusive targets and annual license fees for the right to designate the remaining targets as exclusive targets. In 2010 Roche did not pay the annual license maintenance fees on five of the remaining eight target slots. As a result, Roche currently retains the option to exclusively develop and commercialize rHuPH20 with an additional three targets through the payment of annual license maintenance fees.

Due to the Company's continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), revenues from the upfront payment, exclusive designation fees and annual license maintenance fees were deferred and are being recognized over the term of the Roche Partnership. The Company recognized revenue from the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Partnership in the amounts of approximately \$2.0 million, \$1.9 million and \$1.2 million for the years ended December 31, 2010, 2009 and 2008, respectively. Deferred revenue relating to the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Partnership was \$32.9 million and \$32.6 million as of December 31, 2010 and 2009, respectively.

*Baxter Partnerships* In September 2007, the Company and Baxter entered into an Enhance Technology License and Collaboration Agreement (the Gammagard Partnership). Under the terms of the Gammagard Partnership, Baxter paid the Company a nonrefundable upfront payment of \$10.0 million. Due to the Company's 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 Partnership. The Company recognized revenue from the upfront payment under the Gammagard Partnership in the amounts of approximately \$521,000 for the year ended December 31, 2010 and \$606,000 for the years ended December 31, 2009 and 2008. Deferred revenue relating to the upfront payment under the Gammagard Partnership was \$8.1 million and \$8.6 million as of December 31, 2010 and 2009, respectively.

In February 2007, the Company and Baxter amended certain existing agreements for HYLENEX and entered into the HYLENEX Partnership for kits and formulations with rHuPH20. Under the terms of the HYLENEX Partnership, Baxter paid the Company a nonrefundable upfront payment of \$10.0 million. Due to the Company's continuing involvement obligations (for example, support activities associated with rHuPh20 enzyme), the \$10.0 million upfront payment was deferred and was being recognized over the term of the HYLENEX Partnership. The Company recognized revenue from the upfront payment under the HYLENEX Partnership in the amounts of approximately \$503,000 for the year ended December 31, 2010 and \$586,000 for the years ended December 31, 2009 and 2008. Deferred revenue relating to the upfront payment under the HYLENEX Partnership was \$7.8 million and \$8.3 million as of December 31, 2010 and 2009, respectively.

In addition, Baxter would make payments to the Company based on sales of the products covered under the HYLENEX Partnership. Baxter had prepaid nonrefundable product-based payments totaling \$10.0 million in connection with the execution of the HYLENEX Partnership. The prepaid product-based payments were initially deferred and were being recognized as product sales revenues as the Company earned such revenues from the sales of

HYLENEX by Baxter. The Company recognized revenue from the product-based payments in the amounts of approximately \$332,000, \$204,000 and \$116,000 for the years ended December 31, 2010, 2009 and 2008, respectively. Deferred revenue relating to the product-based payments was \$9.3 million and \$9.7 million as of December 31, 2010 and 2009, respectively.

Effective January 7, 2011, the Company and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a

**Table of Contents**

**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The termination of these agreements does not affect the other relationships between the parties, including the application of Halozyme's Enhance Technology to Baxter's GAMMAGARD LIQUID. As a result, the Company has recharacterized deferred revenue of approximately \$991,000 as a reserve for product returns for HYLENEX API previously delivered to Baxter that could be returned. In addition, the Company will reassess the periods over which the unamortized deferred revenue relating to the prepaid product-based payments totaling approximately \$9.3 million and the unamortized deferred revenue relating to the upfront payment totaling approximately \$7.8 million at December 31, 2010 will be recognized. The periods over which these amounts will be amortized will be based on the final outcome of the definitive agreement expected to be signed by April 7, 2011.

**6. Stockholders' Equity**

*Issuance of Common Stock* In September 2010, the Company issued 8.3 million shares of common stock in a public offering at a net price of \$7.25 per share, generating approximately \$60.0 million in net proceeds. In connection with this financing, the Company 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, the Company issued an aggregate of 599,093 shares of common stock in connection with the exercises of stock options (479,093 shares at a weighted average exercise price of \$3.88 per share) and restricted stock awards (120,000 shares at an exercise price of \$0.001 per share) for cash in the aggregate amount of approximately \$1.9 million.

In June 2009, the Company issued 6,150,000 shares of common stock in a public offering at a price of \$6.50 per share, generating approximately \$38.2 million in net proceeds.

During 2009, the Company issued an aggregate of 3,978,102 shares of common stock in connection with the exercises of stock purchase warrants (3,140,780 shares at a weighted average exercise price of \$2.05 per share), stock options (717,322 shares at a weighted average exercise price of \$1.42 per share) and restricted stock awards (120,000 shares at an exercise price of \$0.001 per share) for cash in the aggregate amount of approximately \$7.2 million.

During 2008, the Company issued an aggregate of 3,649,710 shares of common stock in connection with the exercises of stock purchase warrants (1,628,374 shares at a weighted average exercise price of \$1.06 per share), stock options (1,828,836 shares at a weighted average exercise price of \$0.55 per share) and restricted stock awards (192,500 shares at an exercise price of \$0.001 per share) for cash in the aggregate amount of approximately \$2.6 million.

**7. Equity Incentive Plans**

The Company currently has six equity incentive plans (the "Plans"): the 2008 Stock Plan, the 2008 Outside Directors Stock Plan, the 2006 Stock Plan, the 2005 Outside Directors' Stock Plan, the 2004 Stock Plan and the 2001 Stock Plan. All of the Plans were approved by the stockholders.

During the year ended December 31, 2010, the Company granted share-based awards under the 2008 Stock Plan and the 2008 Outside Directors' Stock Plan. The Company had an aggregate of 18,100,000 shares of common stock

reserved for issuance as of December 31, 2010. Of those shares, 7,975,365 shares were subject to outstanding options and 3,246,559 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 and restricted stock awards.

*Stock Options.* Options are subject to terms and conditions established by the Compensation Committee of the Company's Board of Directors. Options have a term of ten years and generally vest at the rate of 25% one year from the grant date and monthly thereafter until the options are fully vested over four years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans).

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

A summary of the Company's stock option award activity as of and for the years ended December 31, 2010, 2009 and 2008 is as follows:

	<b>Shares Underlying Stock Options</b>	<b>Weighted Average Exercise Price per Share</b>	<b>Weighted Average Remaining Contractual Term (yrs)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at January 1, 2008	7,809,979	\$ 2.03		
Granted	1,513,650	\$ 5.76		
Exercised	(1,857,478)	\$ 0.55		
Cancelled/forfeited	(211,366)	\$ 7.60		
Outstanding at December 31, 2008	7,254,785	\$ 3.02		
Granted	1,519,405	\$ 6.41		
Exercised	(717,322)	\$ 1.42		
Cancelled/forfeited	(252,602)	\$ 6.11		
Outstanding at December 31, 2009	7,804,266	\$ 3.73		
Granted	1,332,714	\$ 5.94		
Exercised	(479,093)	\$ 3.88		
Cancelled/forfeited	(682,522)	\$ 6.29		
Outstanding at December 31, 2010	7,975,365	\$ 3.87	4.4	\$ 32.7 million
Vested and expected to vest at December 31, 2010	7,730,469	\$ 3.80	4.3	\$ 32.3 million
Exercisable at December 31, 2010	5,824,507	\$ 3.05	3.3	\$ 28.7 million

The weighted average grant-date fair values of options granted during the years ended December 31, 2010, 2009 and 2008 were \$3.69 per share, \$3.72 per share and \$3.39 per share, respectively. As of December 31, 2010, approximately \$6.5 million of total unrecognized compensation costs related to non-vested stock option awards is expected to be recognized over a weighted average period of approximately 2.5 years. The intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was approximately \$1.8 million, \$3.9 million and \$9.9 million, respectively. Cash received from stock option exercises for the years ended December 31, 2010, 2009 and 2008 was approximately \$1.9 million, \$1.0 million and \$844,000, 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 the Company's common stock. Due to insufficient data of the Company's common stock, expected volatility in 2009 and 2008 was based on the Company's common stock and its peer group. 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 the Company. Assumptions used in the Black-Scholes model were as follows:

	<b>Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Expected volatility	65.8-70.8%	65.0%	65.0%
Average expected term (in years)	5.7	5.5	5.5
Risk-free interest rate	1.39-2.80%	1.65-2.73%	1.26-3.14%
Expected dividend yield	0%	0%	0%

F-15

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

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

In May 2008, the Company granted certain employees 87,500 performance-based restricted stock awards ( Performance Awards ), for a purchase price of \$0.001 per share, under the 2008 Stock Plan. All of the Performance Awards became fully vested upon achievement of certain development performance milestone criteria in September 2009. No performance-based awards were granted during the years ended December 31, 2010 and 2009. The Company recognized approximately \$231,000 and \$201,000 of share-based compensation expense related to the Performance Awards during the year ended December 31, 2009 and 2008, respectively.

During the years ended December 31, 2010, 2009 and 2008, the Company issued restricted stock awards under the 2008 Stock Plan, 2008 Outside Directors' Stock Plan and 2005 Outside Directors' Stock Plan. The following table summarizes the Company's unvested restricted stock activity during the years ended December 31, 2010, 2009 and 2008:

	<b>Number of Shares</b>		<b>Weighted Average Grant Date Fair Value</b>
Unvested at January 1, 2008	105,000	\$	10.37
Granted	192,500	\$	4.94
Vested	(105,000)	\$	10.37
Forfeited		\$	
Unvested at December 31, 2008	192,500	\$	4.94
Granted	120,000	\$	5.81
Vested	(192,500)	\$	4.94
Forfeited		\$	
Unvested at December 31, 2009	120,000	\$	5.81
Granted	120,000	\$	7.67
Vested	(120,000)	\$	5.81
Forfeited		\$	
Unvested at December 31, 2010	120,000	\$	7.67

The total grant-date fair value of restricted stock awards vested during the years ended December 31, 2010, 2009 and 2008 was approximately \$697,000, \$951,000 and \$1.1 million, respectively. As of December 31, 2010, total unrecognized compensation cost related to unvested shares was approximately \$324,000, which is expected to be recognized over a weighted-average period of approximately 4.4 months.

## **8. Commitments and Contingencies**

*Operating Leases* The Company's administrative offices and research facilities are located in San Diego, California. The Company leases an aggregate of approximately 58,000 square feet of office and research space.

In July 2007, the Company entered into a sublease agreement with Avanir Pharmaceuticals, Inc. ( *Avanir* ) for Avanir's excess leased facilities located at 11388 Sorrento Valley Road, San Diego, California ( *11388 Property* ) (the *11388 Sublease* ) for 27,575 square feet of office and research space. The 11388 Sublease expired in August 2008. As a result, in July 2007, the Company entered into a lease agreement (the *Lease* ) with BC Sorrento, LLC



**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

( BC Sorrento ) for these facilities through January 2013. Effective September 2010, BMR-11388 Sorrento Valley Road LLC acquired the 11388 Property and became the new landlord of the 11388 Property. Payment obligations under the Lease commenced in September 2008 after the obligations in the short-term 11388 Sublease had concluded. Under the terms of the Lease, the initial monthly rent payment was approximately \$37,000 net of costs and property taxes associated with the operation and maintenance of the leased facilities, commencing in September 2008 and increased to approximately \$73,000 starting in March 2009. Thereafter, the annual base rent is subject to approximately 4% annual increases each year throughout the term of the Lease. Under terms of the Lease and 11388 Sublease, the Company recorded a tenant improvement allowance of approximately \$276,000 and free rent totaling approximately \$794,000 as deferred rent, of which approximately \$545,000 and \$758,000 was included in deferred rent as of December 31, 2010 and 2009, respectively.

In July 2007, the Company also entered into a sublease agreement with Avanir for Avanir's excess leased facilities located at 11404 Sorrento Valley Road, San Diego, California (the 11404 Sublease ) for 21,184 square feet of office and research space 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, the Company received free rent totaling approximately \$492,000, of which approximately \$266,000 and \$355,000 was included in deferred rent as of December 31, 2010 and 2009, respectively.

In January 2009, the Company entered into a sub-sublease agreement with Sirion Therapeutics, Inc. ( Sirion ), a subtenant of Avanir, for Sirion's excess subleased facilities located at 11408 Sorrento Valley Road, San Diego, California (the Sub-Sublease ) for 2,000 square feet of office and research space. The Sub-Sublease expired in September 2009 with monthly rent payments of approximately \$6,000 commencing in April 2009. As a result, in April 2009, the Company entered into a sublease agreement with Avanir for 9,187 square feet of this facility (the 11408 Sublease ), 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%. Under terms of the 11408 Sublease, the Company received a tenant improvement allowance of \$75,000, of which approximately \$49,000 and \$62,000 was included in deferred rent at December 31, 2010 and 2009, respectively.

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

Additionally, the Company leases certain office equipment under operating leases. Total rent expense was approximately \$1.5 million, \$1.4 million and \$1.4 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Approximate annual future minimum operating lease payments as of December 31, 2010 are as follows:

<b>Year:</b>	<b>Operating Leases</b>
2011	\$ 1,926,000
2012	1,999,000
2013	83,000

2014	1,000
Total minimum lease payments	\$ 4,009,000

*Material Agreements* In September 2007, the Company entered into the Gammagard Partnership with Baxter. Under the terms of the Gammagard Partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, with a current Baxter product, GAMMAGARD LIQUID. Under the terms of the Gammagard Partnership, Baxter paid the Company a nonrefundable upfront payment of \$10.0 million. Due to the Company's continuing involvement obligations, the \$10.0 million upfront payment was deferred and is being recognized over the term of the Gammagard Partnership. Pending successful completion of a

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37.0 million to the Company. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard Partnership is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while the Company is responsible for the supply of the rHuPH20 enzyme. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard Partnership.

In February 2007, the Company and Baxter amended certain existing agreements relating to HYLENEX and entered into the HYLENEX Partnership for kits and formulations with rHuPH20. Under the terms of the HYLENEX Partnership, Baxter paid a nonrefundable upfront payment of \$10.0 million and, pending the successful completion of a series of regulatory and sales events, Baxter would have been obligated to make milestone payments to the Company which could potentially reach a value of up to \$25.0 million. In addition, Baxter would make payments to the Company based on the sales of products covered under the HYLENEX Partnership. Baxter had prepaid a total of \$10.0 million of such product-based payments. Baxter also assumed all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. The Company continued to supply Baxter with the API for HYLENEX, and Baxter filled and finished HYLENEX and held it for subsequent distribution. In addition, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with Baxter hydration fluids and generic small molecule drugs, with the exception of combinations with (i) bisphosphonates, (ii) cytostatic and cytotoxic chemotherapeutic agents and (iii) proprietary small molecule drugs, the rights to which have been retained by the Company. Due to the Company's continuing involvement obligations, the \$10.0 million upfront payment was deferred and was being recognized over the term of the HYLENEX Partnership. Effective January 7, 2011, the Company and Baxter mutually agreed to terminate the HYLENEX Partnership and the associated agreements. In addition, the parties agreed to endeavor in good faith to negotiate, by April 7, 2011, one or more definitive agreements setting forth the services to be provided by the respective parties during a transition period including, without limitation, Baxter's manufacture of an interim supply of Standalone Product (as defined in the HYLENEX Development and Supply Agreement), all on mutually acceptable terms and conditions. The termination of these agreements does not affect the other collaborative relationships between the parties, including the application of Halozyme's Enhance Technology to Baxter's GAMMAGARD LIQUID.

In December 2006, the Company and Roche entered into the Roche Partnership for Enhance Technology. Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and up to thirteen Roche target compounds resulting from the partnership. Roche paid \$20.0 million as an initial upfront license fee for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory and sales events, Roche will pay the Company further milestones which could potentially reach a value of up to \$111.0 million. In addition, Roche will pay the Company royalties on product sales for these first three targets. Through December 31, 2010, Roche has elected two additional exclusive targets. In 2010 Roche did not pay the annual license maintenance fee on five target slots. As a result, Roche has an option to select only three additional targets under the Roche partnership agreement, provided that Roche continues to pay annual exclusivity maintenance fees to the Company. For each of the additional five targets, Roche may pay the Company further upfront and milestone payments of up to \$47.0 million per target, as well as royalties on product sales for each of these additional five targets. Additionally, Roche will obtain access to the Company's expertise in developing and applying rHuPH20 to Roche targets. Under the terms of the Roche Partnership, the Company was 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 partnership. To that end, during 2008, the

Company entered into a Technology Transfer Agreement and a Clinical Supply Agreement with a second rHuPH20 manufacturer, Cook Pharmica LLC ( Cook ). Cook has the capacity to produce the quantities the Company was required to deliver under the terms of the Roche Partnership. The technology transfer was completed in 2008. In 2009, multiple batches

F-18

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

of rHuPH20 were produced to support planned future clinical studies. In 2010, the Company initiated process validation activities in support of potential future commercialization.

In August 2008, the Company entered into a Clinical Supply Agreement (the Cook Clinical Supply Agreement) with Cook. Under the terms of the Cook Clinical Supply Agreement, Cook will manufacture certain batches of the API that will be used in clinical trials of certain product candidates.

In March 2010, the Company 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, the Company is committed to certain minimum annual purchases of API equal to four quarters of forecasted supply. At December 31, 2010, the Company has a minimum purchase obligation of approximately \$5.4 million.

In March 2010, the Company amended its 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, the Company is 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 the Company's HYLENEX and Cumulase products. At December 31, 2010, the Company has a minimum purchase obligation of approximately \$308,000.

In March 2010, the Company entered into a second Commercial Supply Agreement with Avid (the Avid Commercial Supply Agreement). Under the terms of the Avid Commercial Supply Agreement, the Company is 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, 2010, the Company has a minimum purchase obligation of approximately \$408,000.

*Legal Contingencies* From time to time the Company is involved in legal actions arising in the normal course of its business. The Company is not presently subject to any material litigation nor, to management's knowledge, is any litigation threatened against the Company that collectively is expected to have a material adverse effect on the Company's consolidated cash flows, financial condition or results of operations.

**9. Income Taxes**

Significant components of the Company's net deferred tax assets at December 31, 2010 and 2009 are shown below. A valuation allowance of \$97.6 million and \$75.1 million has been established to offset the net deferred tax assets as of December 31, 2010 and 2009, respectively, as realization of such assets is uncertain.

	2010	2009
Deferred tax assets:		
Net operating loss carryforwards	\$ 57,035,000	\$ 42,253,000
Deferred revenue	22,248,000	18,370,000
Research and development credits	15,540,000	12,175,000

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Share-based compensation	1,449,000	1,171,000
Depreciation	533,000	327,000
Other, net	749,000	789,000
Total deferred tax assets	97,554,000	75,085,000
Valuation allowance for deferred tax assets	(97,554,000)	(75,085,000)
Net deferred tax assets	\$	\$

F-19

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

The provision for income taxes on earnings subject to income taxes differs from the statutory federal income tax rate at December 31, 2010, 2009 and 2008, due to the following:

	2010	2009	2008
Federal income tax rate of 34%	\$ (18,102,000)	\$ (19,843,000)	\$ (16,544,000)
State income tax, net of federal benefit	(3,106,000)	(3,405,000)	(2,839,000)
Research and development credits	(3,379,000)	(4,464,000)	(3,099,000)
Tax effect on non-deductible expenses and other	2,118,000	2,186,000	2,445,000
Increase in valuation allowance	22,469,000	25,526,000	20,037,000
Benefit due to refundable R&D credit			(63,000)
	\$	\$	\$ (63,000)

At December 31, 2010, the Company had federal and California tax net operating loss carryforwards of approximately \$159.0 million and \$165.0 million, respectively. Included in these amounts are federal and California net operating losses of approximately \$16.8 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 2012, respectively, unless previously utilized.

At December 31, 2010, the Company also had federal and California research and development tax credit carryforwards of approximately \$11.4 million and \$6.3 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.

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 the Company's net operating loss carryforwards and research and development tax credits are subject to annual limitations. The Company completed a Section 382 analysis regarding the limitation of the net operating losses and research and development credits as of December 31, 2010. Based upon the analysis, the Company 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, 2010 and 2009, the Company's 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 the Company as a component of income tax expense. For the years ended December 31, 2010 and 2009, the Company did not recognize any interest or penalties.

The Company is subject to taxation in the U.S. and in various state jurisdictions. The Company's 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.

**10. Employee Savings Plan**

The Company has an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. The plan allows participating employees to deposit into tax deferred investment accounts up to 90% of their salary, subject to annual limits. The Company is not required to make matching contributions under the plan. However, the Company voluntarily contributed to the plan approximately \$433,000, \$374,000 and \$0 in the years ended December 31, 2010, 2009 and 2008, respectively.

**11. Restructuring Expense**

In October 2010, the Company completed a corporate reorganization to focus its resources on advancing its 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.



**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

The Company 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 operations for the year ended December 31, 2010. No other restructuring charges were incurred. As of December 31, 2010, a balance of \$117,000 is included in current accrued expenses and is expected to be paid in 2011.

The following table summarizes the restructuring accrual activity:

	<b>Employee Severance and Benefits</b>
Balance, January 1, 2010	\$
Accruals during the year	1,321,579
Cash payments	(1,204,902)
Balance, December 31, 2010	\$ 116,677

**12. Management Changes**

On December 2, 2010, Jonathan E. Lim, M.D. resigned as President, Chief Executive Officer and a member of the Board of Directors ( Board ) of Halozyme. On December 2, 2010, the Board appointed Gregory I. Frost, Ph.D., our then Vice President and Chief Scientific Officer and Director, to serve as our President and Chief Executive Officer. On December 2, 2010, the Company appointed H. Michael Shepard, Ph.D., the Company's current Vice President, Discovery Research, to serve as the Company's Vice President and Chief Scientific Officer.

In connection with Dr. Lim's resignation from the Company, the Company and Dr. Lim entered into a Separation Agreement and Release (the Lim Separation Agreement ). Pursuant to the terms of the Lim Separation Agreement, in exchange for a release of claims and Dr. Lim's assistance (when reasonably requested by the Company) through March 31, 2011 in the transition of his responsibilities to Dr. Frost, the Company agreed to provide Dr. Lim with salary continuation for a period of one year and reimburse Dr. Lim for twelve months of healthcare coverage. In addition, Dr. Lim's outstanding options will continue to vest until March 31, 2011 under the original terms of Dr. Lim's option grants. The Company recorded a liability and expense of approximately \$448,000 in severance expenses for the year ended December 31, 2010, of which \$35,000 was paid as of December 31, 2010. A balance of \$413,000 is included in current accrued expenses as of December 31, 2010 and is expected to be paid by the end of 2011. In addition, 46,667 shares of Dr. Lim's options will become vested and exercisable during December 3, 2010 through March 31, 2011. The Company recognized approximately \$50,000 in incremental compensation costs associated with the modification to Dr. Lim's stock options for the year ended December 31, 2010.

**13. Related Party Transactions**

Connie L. Matsui, a director of the Company, 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 the Company until September 2010. The transaction with BC Sorrento was reviewed and approved by the Company's Board of Directors in accordance with the Company's related party transaction policy. Effective September 2010, BC Sorrento sold the 11388 Property to an unrelated party. As such, the Company no longer has any business transactions with BC Sorrento effective September 2010. The Company paid BC Sorrento approximately \$982,000, \$1.2 million and \$281,000 for the years ended December 31, 2010, 2009 and 2008, respectively.

In December 2006, Halozyme entered into a license agreement with a related party, Nektar Therapeutics AL, Corporation ( Nektar ) under which the Company obtained a license to certain intellectual property rights and proprietary technology of Nektar. Dr. John Patton, a member of the Company's Board of Directors, was an employee and director of Nektar at the time this agreement was executed. Effective January 1, 2009, Dr. Patton was

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)**

no longer an employee or director of Nektar. The Company paid Nektar approximately \$0, \$0 and \$73,000 for the year ended December 31, 2010, 2009 and 2008.

**14. Summary of Unaudited Quarterly Financial Information**

The following is a summary of the Company's unaudited quarterly statement of operations data derived from unaudited consolidated financial statements included in the Quarterly Reports on Form 10-Q:

<b>2010 (Unaudited):</b>	<b>Quarters Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Total revenues	\$ 3,441,731	\$ 3,213,353	\$ 3,396,507	\$ 3,572,524
Total operating expenses	\$ 15,229,877	\$ 15,365,431	\$ 15,830,148	\$ 21,456,291
Net loss	\$ (11,787,477)	\$ (12,150,923)	\$ (12,409,576)	\$ (16,893,674)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.13)	\$ (0.13)	\$ (0.17)
Shares used in computing net loss per share, basic and diluted	91,610,830	91,766,799	93,626,893	100,337,075

<b>2009 (Unaudited):</b>	<b>Quarters Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Total revenues	\$ 2,772,371	\$ 1,426,156	\$ 3,028,885	\$ 6,443,893
Total operating expenses	\$ 17,531,113	\$ 18,509,876	\$ 16,968,485	\$ 19,120,091
Net loss	\$ (14,725,364)	\$ (17,060,025)	\$ (13,910,282)	\$ (12,664,852)
Net loss per share, basic and diluted	\$ (0.18)	\$ (0.21)	\$ (0.16)	\$ (0.14)
Shares used in computing net loss per share, basic and diluted	82,429,868	82,990,107	89,570,540	91,488,388

F-22