

HALOZYME THERAPEUTICS INC

Form 10-K

March 12, 2010

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-K**

- þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2009**
- OR**
- o 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:  
None**

**Securities registered under Section 12(g) of the Act:  
Common Stock, Par Value \$.001  
*(Title of Class)***

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

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

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, 2009 was approximately \$487.4 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, 2010, there were 91,712,381 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 2010 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, 2009.

---

**Table of Contents**

	<b>Page</b>
<b><u>PART I</u></b>	
<u>Item 1.</u> <u>Business</u>	1
<u>Item 1A.</u> <u>Risk Factors</u>	10
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	21
<u>Item 2.</u> <u>Properties</u>	21
<u>Item 3.</u> <u>Legal Proceedings</u>	21
<u>Item 4.</u> <u>Removed and Reserved</u>	21
<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>	22
<u>Item 6.</u> <u>Selected Financial Data</u>	24
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	24
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	34
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	34
<u>Item 9A.</u> <u>Controls and Procedures</u>	34
<u>Item 9B.</u> <u>Other Information</u>	37
<b><u>PART III</u></b>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	37
<u>Item 11.</u> <u>Executive Compensation</u>	39
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	39
<u>Item 13.</u> <u>Certain Relationships and Related Transactions, and Director Independence</u>	39
<u>Item 14.</u> <u>Principal Accounting Fees and Services</u>	39
<b><u>PART IV</u></b>	
<u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>	40
<b><u>SIGNATURES</u></b>	43
<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 products targeting the extracellular matrix, or Matrix, for the endocrinology, oncology, dermatology and drug delivery markets. 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 organizing and staffing our operating subsidiary, Halozyme, Inc., acquiring, developing and securing our technology and undertaking product development for our existing products and a limited number of 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 Enhanze™ Technology to Roche's biological therapeutic compounds for up to 13 targets. We have also entered into two key partnerships with Baxter Healthcare Corporation, or Baxter, to apply Enhanze Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID™ and to develop and supply active pharmaceutical ingredient, or API, 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 increase the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, we receive only limited revenue from the sales of HYLENEX and from the sales of API to the third party that produces Cumulase, in addition to other revenues from our partnerships with Baxter and Roche.

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

We have product candidates in the research, preclinical and clinical stages, but future revenues from the sales of these product candidates will depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we 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 \$172.0 million as of December 31, 2009.

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. We may utilize this

## **Table of Contents**

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.

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).

## **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.

## **Strategy**

We are dedicated to the development and commercialization of both proprietary and partnered products targeting the Matrix for the endocrinology, oncology, dermatology and drug delivery markets. By expanding upon our scientific expertise in the 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. While rHuPH20 is the underlying drug delivery technology of both HYLENEX for generic small molecules and fluids, and Enhance Technology for proprietary small and large molecules, we are seeking ways to combine rHuPH20 with previously approved small molecule 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

Support Baxter's commercialization of HYLENEX.



**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 product and product candidates as well as our partnered product and 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 (such combinations are referred to as Analog-PH20 ) facilitates faster insulin dispersion in, and absorption from, the subcutaneous space into the vascular compartment leading to faster insulin response. By making mealtime insulin onset faster, i.e., providing

## **Table of Contents**

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 that participate in the growing \$3 billion prandial insulin market. We are developing Insulin-PH20 and Analog-PH20 in parallel to explore a maximum range of value creating opportunities. 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 are ongoing or planned, that will investigate the various attributes of our insulin product candidates. We plan on initiating additional studies with both Insulin-PH20 and Analog-PH20. The status and/or results from some of these trials are summarized below:

In November 2009, we announced results from our Phase 1 clinical study that demonstrated reduced intrasubject absorption variability for the combination of lispro (Humalog®), a mealtime analog insulin, plus rHuPH20 compared to subcutaneous injection of lispro alone. The results demonstrated that timing and degree of early insulin absorption between doses administered to the same subjects on different occasions were more consistent when combined with rHuPH20 than lispro administered alone. Intersubject variability for pharmacokinetic and glucodynamic measures in the study showed a favorable trend for the combination lispro with rHuPH20 compared to lispro alone. The study was not designed to test statistical significance for intersubject variability. Intrasubject variability for glucodynamic measures in the study also demonstrated favorable trends for the combination of lispro with rHuPH20 compared to lispro alone, and one endpoint measure, the percent of total glucose administered to keep glucose levels constant during the first four hours, reached statistical significance. Co-administration of rHuPH20 with both regular insulin (Humulin® R) and lispro was well tolerated. The study enrolled 22 healthy subjects who received two doses of three different treatments: insulin lispro alone, regular insulin with rHuPH20, and insulin lispro with rHuPH20 in a euglycemic glucose clamp trial design. All subjects underwent six clamp procedures. We presented these study results at the Diabetes Technology Society meeting in San Francisco in November 2009.

In November 2009, we also announced results from our Phase 1 clinical study which investigated the optimal insulin/rHuPh20 ratios. The results demonstrated faster insulin absorption and increased peak insulin concentrations after co-administration of rHuPH20 with insulin lispro and regular human insulin compared to insulin lispro and regular human insulin alone. The enhanced absorption effects were observed at clinically relevant insulin doses across a broad range of rHuPH20 concentrations. In addition, study results showed accelerated insulin action as measured by glucose infusion rates in this euglycemic glucose clamp study. Results of this study have been used to identify an optimal rHuPH20 dose for accelerating insulin absorption. We presented these study results at the Diabetes Technology Society meeting in San Francisco in November 2009. The initial study results were presented at the International Diabetes Federation Congress in Montreal in October 2009.

In September 2009, we also announced results from our Phase 2 clinical study in type 1 diabetic patients comparing lispro with and without rHuPH20 and regular insulin with and without rHuPH20. These results demonstrated faster insulin absorption and increased peak insulin concentrations after co-administration of rHuPH20 with lispro and rHuPH20 with regular insulin. Study results also showed a significant reduction in postprandial blood glucose levels following administration of a standardized test meal, with improvements in both peak and total hyperglycemic excursions compared to lispro and regular insulin alone. Mean glucose levels after the meal challenge remained within current treatment targets throughout the eight hour post meal observation period. We presented these results at the European Association for the Study of Diabetes in Vienna

in September 2009. The preliminary results from the study of lispro with and without rHuPH20 were presented at the American Diabetes Association (ADA) 69th Scientific Sessions in New Orleans in June 2009.

In September 2009, we initiated a Phase 1 clinical study that will assess the effects of three approved prandial insulin analogs administered with rHuPH20 compared to each of the analogs alone, each delivered at a

## **Table of Contents**

standardized dose. This randomized, six-way cross-over design, euglycemic clamp study will compare the postprandial pharmacokinetics and glucodynamics of the insulin analogs with and without rHuPH20.

In July 2009, we initiated 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 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. This randomized, double blind Phase 2 study will also investigate the pharmacokinetics of each treatment.

In May 2009, we initiated a Phase 2 clinical trial to compare regular insulin with rHuPH20 to lispro alone. After a one-month observation period that includes 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. The study will evaluate safety and efficacy.

## ***PEGPH20***

We are investigating 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 40% of solid tumors including prostate, breast, pancreas and colon produce significant amounts of HA that forms a halo-like coating over the surface of the tumor cell. The quantity of HA produced by the tumor cells 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 remove the HA coating surrounding several tumor cell lines. Treatment of PC3 (a prostate cancer cell line that produces HA) tumor-bearing mice with PEGPH20 as a single agent demonstrated a slowing of tumor growth relative to controls. 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 or with liposomal doxorubicin in HA producing animal tumor models produced a significant survival advantage for the combination relative to either chemotherapeutic agent alone.

Additional studies have demonstrated that PEGPH20 can significantly reduce tumor interstitial fluid pressure (IFP) in an animal cancer model in a dose dependent fashion, achieving more than 85% reduction in IFP following IV administration. Elevated tumor IFP has been associated with poor patient prognosis and resistance to chemotherapeutic regimens. Therefore, based on these animal studies and other tests conducted by Halozyme, PEGPH20 may represent a potentially innovative treatment approach against tumors that produce HA.

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 dose frequency.

## ***Chemophase***

Chemophase is an investigative drug being developed for potential use in the treatment of patients with superficial bladder cancer. Our Chemophase program combines our rHuPH20 enzyme with mitomycin C, a cytotoxic drug, for direct administration into the bladder immediately after transurethral resection of bladder tumors, a standard surgical treatment for the disease. Many bladder tumor cells produce high quantities of HA and thus treatment to remove the

HA coating could increase their exposure to mitomycin C. This may lead to a lower recurrence of the cancer and a better prognosis for patients.

During the first quarter of 2009, we decided to reallocate certain resources previously budgeted for Chemophase to other higher priority programs, such as our ultrafast insulin and PEGPH20 programs. We do not plan on initiating any new clinical trials with Chemophase and we are currently exploring strategic alternatives that will allow the Chemophase program to continue its clinical development.

## **Table of Contents**

### ***Enhance Technology***

Enhance Technology, a proprietary drug delivery enhancement approach 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 by temporarily opening flow channels under the skin. Molecules as large as 200 nanometers may pass freely through the extracellular 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 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 benefits to payors.

We currently have Enhance Technology partnerships with Roche and Baxter and we are currently pursuing additional partnerships with pharmaceutical 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 to the three original exclusive targets in December 2008 and a fifth exclusive target in June 2009.

Compounds directed at three of the Roche exclusive targets are currently in clinical trials. Two compounds are in Phase 1 clinical trials, and the third compound is in a Phase 3 clinical trial. In October 2009, we announced the commencement of the first Phase 3 clinical trial for a compound directed at an exclusive target. 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.

In September 2009, Roche began a Phase 1 clinical trial for a subcutaneous formulation of MabThera® (rituximab). The study will investigate the pharmacokinetics and tolerability of subcutaneous MabThera in patients with follicular lymphoma as part of maintenance treatment. Intravenously administered MabThera is approved for the treatment of non-Hodgkin's lymphoma (NHL), a type 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.

Additional information about the Phase 3 subcutaneous Herceptin and Phase 1 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).

Roche retains the option to exclusively develop and commercialize rHuPH20 with an additional eight 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.

***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

## **Table of Contents**

partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID. 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 of 2009, we announced the commencement of a Phase 3 clinical trial for GAMMAGARD LIQUID with rHuPH20, and in July 2009, we announced the completion of enrollment for this study.

### ***HYLENEX Partnership***

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, facilitates 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 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 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 development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. We will continue to supply Baxter with API for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. In October 2009, Baxter announced 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 (Boston). In addition, under the HYLENEX Partnership, Baxter has 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 Halozyme.

### ***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 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 patent applications pertaining to recombinant human hyaluronidase and their methods of manufacture which, if issued, would expire in 2024. 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

## **Table of Contents**

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, 2009, we have incurred research and development expenses of \$149.7 million. From January 1, 2007 through December 31, 2009, approximately 20% and 15% 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 U.S. Food and Drug Administration, or FDA, and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

## **Manufacturing**

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce bulk active pharmaceutical ingredient, or API. These manufacturers each produce API under 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 few 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.

## **Sales and Marketing**

### ***HYLENEX***

Baxter is responsible for execution of HYLENEX clinical development, sales and marketing strategy. Baxter has indicated that it intends to build a strong clinical foundation with post-marketing trials and to educate the market on the concept of difficult venous access. Post-marketing clinical trials are continuing to explore the potential of HYLENEX in additional medical settings. Examples of the trials include the completed INFUSE-Pediatric Rehydration study, completed INFUSE-LR study and completed INFUSE-Morphine study. In addition, Baxter recently completed enrollment of patients in a second INFUSE-Pediatric Rehydration Study, which is designed to

evaluate the rehydration success rate (efficacy) and safety in children treated with HYLENEX-augmented subcutaneous fluid infusion compared to intravenous hydration. In October 2009, Baxter completed 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 (Boston) in conjunction with publication of data from the INFUSE-Pediatric Rehydration study in PEDIATRICS. Continued roll out of HYLENEX in the major hospital market by a Baxter sales force will occur in 2010.

## **Table of Contents**

### ***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 2009, sales of Cumulase and API for Cumulase were approximately \$514,000.

### **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.

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;

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

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

## **Table of Contents**

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 current Good Manufacturing Practices, or 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.

## **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.

## **Employees**

As of March 1, 2010, we had 139 full-time employees, including 110 engaged in research and clinical development activities. Included in our total headcount are 51 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

**Table of Contents**

losses over the next few years. We have never been profitable, and we may never become profitable. Through December 31, 2009, we have incurred aggregate net losses of approximately \$172.0 million.

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

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce bulk API. These manufacturers each produce API under current Good Manufacturing Practices, or cGMP, for clinical uses. In addition, 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 few years. If Cook is unable to obtain status as a cGMP-approved manufacturing facility, or if either Avid or Cook: (i) are unable to retain status as cGMP-approved manufacturing facilities; (ii) are unable to otherwise successfully scale up our API production; or (iii) fail to manufacture the API required by our proprietary and partnered products and product candidates for any other reason, our business will be adversely affected. We have not established, and may not be able to establish, favorable arrangements with additional API manufacturers and suppliers of the ingredients necessary to manufacture the API should the existing manufacturers and suppliers become unavailable or in the event that our existing manufacturers and suppliers are unable to adequately perform their responsibilities. We have attempted to mitigate the impact of supply interruption through the establishment of excess API inventory, but there can be no assurances that this safety stock will be maintained or that it will be sufficient to address any delays, interruptions or other problems experienced by Avid and/or Cook. Any delays, interruptions or other problems regarding the ability of Avid and/or Cook to supply API on a timely basis could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of proprietary or partnered product candidates; and (ii) delay or prevent the effective commercialization of proprietary or partnered products. 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.

***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. In January 2010, Baxter received a Warning Letter from the FDA regarding observations made by the agency following inspections of Baxter's manufacturing facility in Lessines, Belgium. The Warning Letter identified a number of issues associated with certain fill and finish processes and controls relating to GAMMAGARD LIQUID therapy. We understand that Baxter is working with the FDA to address these issues and we do not expect these issues to impact the development of the GAMMAGARD LIQUID product candidate.





**Table of Contents**

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

We have entered into key 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.

***We may wish to raise funds in the next twelve months, and there can be no assurance that such funds will be available.***

During the next twelve months, we may wish to raise additional capital to continue the development of our product candidates or for other corporate purposes. Our current cash position and expected revenues during the next few years will 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 expect to raise additional capital in the future through one or more financing vehicles that may be available to us. These financing vehicles currently include: (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.

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, we may 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.

We depend upon the efforts of third parties, such as Baxter for HYLENEX, to promote and sell our current products, but there can be no assurance that the efforts of these third parties will meet our expectations or result in any significant product sales. While these third parties are largely responsible for the speed and scope of sales and marketing efforts, they may not dedicate the resources necessary to maximize product opportunities and our ability to

cause these third parties to increase the speed and scope of their efforts may 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.

## **Table of Contents**

***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, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a subsidiary of Baxter to prepare, fill, finish and package HYLENEX under a development and supply agreement. We rely on its ability to successfully manufacture HYLENEX batches according to product specifications. Any delays or interruptions in Baxter's ability to manufacture HYLENEX batches in amounts necessary to meet product demand could have a material adverse impact on our business and financial condition.

***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., 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.

***If our proprietary and partnered product candidates do not receive and maintain regulatory approvals, they will not be commercialized, and this failure would substantially impair our ability to generate revenues.***

Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States. Most other countries in which we may do business have similar requirements. To date, two of our product candidates have received regulatory approval from the FDA.

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 new drug applications, or NDAs, 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 our desired product launch schedule and other business priorities, which are subject to change. There are no proprietary or partnered product candidates currently in the NDA approval process, and we and our partners may not be successful in obtaining such approvals for any potential products.

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

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

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

FDA review may not find that the data from preclinical testing and clinical trials justifies approval, or they may require additional studies that would make it commercially unattractive to continue pursuit of approval;

the FDA may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;

**Table of Contents**

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

the FDA may not approve our manufacturing processes or facilities, or the processes or facilities of our key partners, our contract manufacturers or our raw material suppliers;

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

the FDA may change its formal or informal approval requirements and policies, act contrary to previous guidance, or adopt new regulations; or

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

If the FDA does not approve a proprietary or partnered product candidate 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 many of the same 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.

***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 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.

**Table of Contents**

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

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

***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

**Table of Contents**

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 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, particularly Jonathan Lim, M.D., our President and Chief Executive Officer, or Gregory Frost, Ph.D., our Chief Scientific Officer, then 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. Lim and 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

## **Table of Contents**

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;

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, 2009 were \$8.09 and \$3.93, 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;

**Table of Contents**

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 approved by the FDA, the failure of the FDA to approve such products in a timely manner consistent with the FDA's historical approval process;

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

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

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

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

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

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

our failure to obtain financing on acceptable terms; or

a restructuring of our operations.

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

We currently have the ability to offer and sell up to \$100.0 million of additional equity or debt securities under a currently 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

## **Table of Contents**

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.

We currently own or license several U.S. 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. Such 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 to determine the priority 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

## **Table of Contents**

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 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

## **Table of Contents**

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. 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. For example, for HYLENEX, such competitors include, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc. and Amphastar Pharmaceuticals, Inc. among others. For our Insulin-PH20 and Analog-PH20 product candidates, such competitors may include Bionin 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:

	2009		2008	
	High	Low	High	Low
First Quarter	\$ 6.41	\$ 3.93	\$ 7.25	\$ 4.19
Second Quarter	\$ 8.09	\$ 5.07	\$ 6.62	\$ 4.75
Third Quarter	\$ 7.91	\$ 6.11	\$ 8.26	\$ 5.35
Fourth Quarter	\$ 7.86	\$ 5.22	\$ 7.29	\$ 2.60

On March 1, 2010, the closing sales price of our common stock on the NASDAQ Stock Market was \$6.63 per share. As of March 1, 2010, 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, 2009:

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)	7,804,266	\$ 3.73	4,026,751
Equity compensation plans not approved by stockholders			

Total	7,804,266	\$	3.73	\$
-------	-----------	----	------	----

- (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. No additional options will be granted under the 2001 Stock Plan.

**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, 2004 to December 31, 2009. 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 12/31/04 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

	<b>12/04</b>	<b>12/05</b>	<b>12/06</b>	<b>12/07</b>	<b>12/08</b>	<b>12/09</b>
<b>Halozyme Therapeutics, Inc.</b>	\$ 100.00	\$ 82.73	\$ 365.91	\$ 323.18	\$ 254.55	\$ 266.82
<b>NASDAQ Composite</b>	\$ 100.00	\$ 101.33	\$ 114.01	\$ 123.71	\$ 73.11	\$ 105.61
<b>NASDAQ Biotechnology</b>	\$ 100.00	\$ 117.54	\$ 117.37	\$ 121.37	\$ 113.41	\$ 124.58

**Recent Sales of Unregistered Securities**

During the quarter ended December 31, 2009, holders of various outstanding warrants exercised their rights to purchase 492,857 common shares for gross proceeds of approximately \$1.1 million. The shares and underlying warrants were purchased for investment in a private placement exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.



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

The selected consolidated financial data set forth below as of December 31, 2009 and 2008, and for the fiscal years ended December 31, 2009, 2008 and 2007, 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, 2007, 2006 and 2005, and for the fiscal years ended December 31, 2006 and 2005, 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,				
	2009	2008	2007	2006	2005
Total revenues	\$ 13,671,305	\$ 8,764,139	\$ 3,799,521	\$ 981,746	\$ 127,209
Net loss	(58,360,523)	(48,654,199)	(23,896,183)	(14,751,986)	(13,275,373)
Net loss per share, basic and diluted	\$ (0.67)	\$ (0.61)	\$ (0.32)	\$ (0.24)	\$ (0.26)
Shares used in computing net loss per share, basic and diluted	86,700,094	79,843,707	74,317,930	62,610,265	50,317,021

Balance Sheet Data:	As of December 31,				
	2009	2008	2007	2006	2005
Cash and cash equivalents	\$ 67,464,506	\$ 63,715,906	\$ 97,679,085	\$ 44,189,403	\$ 19,132,194
Working capital	60,044,794	59,794,370	92,312,937	41,343,010	17,802,804
Total assets	77,149,759	76,562,713	103,460,374	46,091,320	20,510,255
Deferred revenues	60,482,192	49,448,456	39,269,491	19,981,537	254,138
Total liabilities	70,246,370	61,182,717	45,692,450	23,010,085	2,303,368
Stockholders' equity	6,903,389	15,379,996	57,767,924	23,081,235	18,206,887

**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 products targeting the extracellular matrix for the endocrinology, oncology, dermatology and drug delivery markets. Our existing products and our products under development are based 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 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.

## **Table of Contents**

Our operations to date have involved organizing and staffing our operating subsidiary, Halozyme, Inc., acquiring, developing and securing our technology and undertaking product development for our existing products and a limited number of 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 Enhanze™ Technology to Roche's biological therapeutic compounds for up to 13 targets. We have also entered into two key partnerships with Baxter Healthcare Corporation, or Baxter, to apply Enhanze Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID™ and to develop and supply active pharmaceutical ingredient, or API, 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 increase the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, we receive only limited revenue from the sales of HYLENEX and 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 have product candidates in the research, preclinical and clinical stages, but future revenues from the sales of these product candidates will depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we 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 \$172.0 million as of December 31, 2009.

We currently have an effective universal shelf registration statement which allows us to offer and sell up to \$100.0 million of equity or debt securities and 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 Enhanze 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 to the three original exclusive targets in December 2008 and a fifth exclusive target in June 2009.

Compounds directed at three of the Roche exclusive targets are currently in clinical trials. Two compounds are in Phase 1 clinical trials, and the third compound is in a Phase 3 clinical trial. In October 2009, we announced the commencement of the first Phase 3 clinical trial for a compound directed at an exclusive target. 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.

In September 2009, Roche began a Phase 1 clinical trial for a subcutaneous formulation of MabThera® (rituximab). The study will investigate the pharmacokinetics and tolerability of subcutaneous MabThera in patients with follicular lymphoma as part of maintenance treatment. Intravenously administered MabThera is approved for the treatment of non-Hodgkin's lymphoma (NHL), a type 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.

## **Table of Contents**

Additional information about the Phase 3 subcutaneous Herceptin and Phase 1 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).

Roche retains the option to exclusively develop and commercialize rHuPH20 with an additional eight 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.

### ***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. 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 of 2009, we announced the commencement of a Phase 3 clinical trial for GAMMAGARD LIQUID with rHuPH20, and in July 2009, we announced the completion of enrollment for this study.

### ***HYLENEX Partnership***

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, facilitates 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 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 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 development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. We will continue to supply Baxter with API for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. In October 2009, Baxter announced 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 (Boston). In addition, under the HYLENEX Partnership, Baxter has 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 Halozyme.

### ***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

## **Table of Contents**

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.

*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, 2009, we have incurred research and development expenses of \$149.7 million. From January 1, 2007 through December 31, 2009, approximately 20% and 15% 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 U.S. Food and Drug Administration, or FDA, and other regulatory approvals, our reliance on third parties and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our proprietary product candidates for commercialization. However, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

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

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



## **Table of Contents**

### ***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 and 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 supply Baxter the API for HYLENEX at our fully burdened cost plus a margin. Baxter fills and finishes HYLENEX and holds it for subsequent distribution, at which time we ensure it meets product specifications and release it as available for sale. Because of our continued involvement in the development and production process of HYLENEX, the earnings process is not considered to be complete. Accordingly, we defer the revenue and related product costs on the API for HYLENEX until the product is filled, finished, packaged and released. Baxter may only return the API for HYLENEX to us if it does not conform to certain specified criteria set forth in the HYLENEX Partnership or upon termination of such agreement. We have historically demonstrated that the API shipped to Baxter has consistently met the specified criteria; therefore, no allowance for product returns has been established. In addition, we receive product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the HYLENEX Partnership. Product sales revenues are recognized as we earn such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts can be reasonably estimated. Baxter has prepaid \$10.0 million of product-based payments. The prepaid product-based payments were initially deferred and are being recognized as product sales revenue as the Company earns such revenue from the sales of HYLENEX by Baxter.

### ***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.

### ***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.

## **Table of Contents**

Expected volatilities are based on the historical volatility of our common stock and our peer group. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience.

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

## ***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.

## **Table of Contents**

### ***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.

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

### **Results of Operations**

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

***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. 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. 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 we meet various clinical and regulatory milestones set forth in such agreements.

***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. Based upon Baxter's launch of HYLENEX in the fourth quarter of 2009 and potential supply shortages for similar products, we expect product sales to increase in future periods due to increased HYLENEX sales.

***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. We expect cost of sales to increase as product sales also increase.

***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. We expect research and development costs to increase in future periods as we increase our research efforts, expand our clinical trials and continue to develop and manufacture our product candidates.

***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

**Table of Contents**

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.

**Interest Income** Interest income was \$98,000 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 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.

***Comparison of Years Ended December 31, 2008 and 2007***

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements were approximately \$8.1 million for the year ended December 31, 2008 compared to \$3.2 million for the year ended December 31, 2007, which represents an increase of \$4.9 million or 153%. Revenues under collaborative agreements primarily consisted of the amortization of license fees and milestone payments received from Baxter and Roche of approximately \$3.4 million and \$1.9 million in 2008 and 2007, respectively. Revenues under collaborative agreements also included reimbursements for research and development services from Baxter of \$3.0 million and \$543,000 and Roche of \$1.7 million and \$749,000 in 2008 and 2007, respectively.

**Product Sales** Product sales were \$712,000 for the year ended December 31, 2008 compared to \$640,000 for the year ended December 31, 2007. The increase of \$72,000, or 11%, was primarily due to the increase in sales of HYLENEX and the API for HYLENEX.

**Cost of Sales** Cost of sales were \$332,000 for the year ended December 31, 2008 compared to \$240,000 for the year ended December 31, 2007. The increase of \$92,000, or 38%, was due to the increase in sales of the API for HYLENEX and an increase in the cost of Cumulase sales in 2008.

**Research and Development** Research and development expenses were \$44.2 million for the year ended December 31, 2008 compared to \$20.6 million for the year ended December 31, 2007. The increase of \$23.6 million, or 115%, was primarily due to the increase in outsourced research and development costs of \$10.6 million, related to our various preclinical programs and the manufacturing scale-up of our rHuPH20 enzyme, and increased compensation costs of \$6.6 million, of which \$878,000 related to increased share-based compensation, primarily due to the increase in our research and development headcount. At December 31, 2008, our headcount for research and development functions totaled 96 employees, compared with 56 employees at December 31, 2007. Additionally, our clinical trial expenses increased by \$3.0 million, research supplies expenses increased by \$1.3 million and facilities expenses increased by \$1.2 million resulting from leasing larger facilities effective July 2007 to accommodate the increase in headcount in 2008 as compared to 2007.

**Selling, General and Administrative** SG&A expenses were \$14.6 million for the year ended December 31, 2008 compared to \$11.2 million for the year ended December 31, 2007. The increase of approximately \$3.4 million, or 30%, was primarily due to the increase in compensation costs of \$2.0 million, of which \$237,000 related to share-based compensation. At December 31, 2008, our headcount for SG&A functions totaled 34 employees, compared with 27 employees at December 31, 2007. Legal expenses also increased during this period by \$955,000, of which \$576,000 related to patent applications and \$635,000 related to the settlement of an arbitration matter. Facilities expenses also increased by \$246,000 and insurance expenses increased by \$273,000 in 2008 as compared to 2007.

**Share-Based Compensation** Total compensation cost for our share-based payments was \$3.7 million for the year ended December 31, 2008 compared to \$2.6 million for the year ended December 31, 2007. Research and development expense included share-based compensation of approximately \$1.5 million and \$663,000 in 2008 and 2007, respectively. SG&A expenses included share-based compensation of approximately \$2.2 million and \$1.9 million in 2008 and 2007, respectively. As of December 31, 2008, \$6.5 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 2.8 years.



## **Table of Contents**

**Interest Income** Interest income was \$1.7 million for the year ended December 31, 2008 compared to \$4.3 million for the year ended December 31, 2007. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2008 as compared to the same period in 2007.

**Net Loss** Net loss for the year ended December 31, 2008 was \$48.7 million, or \$0.61 per common share, compared to \$23.9 million, or \$0.32 per common share for the year ended December 31, 2007. The increase in net loss was primarily due to an increase in operating expenses, partially offset by increases in revenues.

## **Liquidity and Capital Resources**

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2009, we had cash and cash equivalents of approximately \$67.5 million. We will continue to have significant cash requirements to support our 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 \$40.0 to \$45.0 million for the year ending December 31, 2010, 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 at least 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. 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 \$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 payments; partially offset by increased partnership payments of approximately \$18.1 million during 2009 as compared to 2008.

Net cash used in operations was \$35.4 million during the year ended December 31, 2008 compared to \$148,000 of net cash used in operations during the year ended December 31, 2007. This change was primarily due to increased operating expenses of approximately \$27.2 million as well as reduced receipts from partnership payments of approximately \$10.2 million during 2008 as compared to 2007.

**Table of Contents****Investing Activities**

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.

Net cash used in investing activities was \$1.2 million during the year ended December 31, 2008 compared to \$2.4 million during the year ended December 31, 2007. This was primarily due to a decrease in purchases of property and equipment during 2008.

**Financing Activities**

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.

Net cash provided by financing activities was \$2.6 million during the year ended December 31, 2008 compared to \$56.0 million during the year ended December 31, 2007. Net cash provided by financing activities during 2008 primarily consisted of proceeds from warrant and stock option exercises. Net cash provided by financing activities during 2007 primarily consisted of approximately \$52.0 million in proceeds, net of issuance costs, from sales of our common stock and approximately \$4.0 million in proceeds from warrant and stock option exercises.

*Off-Balance Sheet Arrangements* As of December 31, 2009, 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, 2009, future minimum payments due under our contractual obligations are as follows:

Contractual Obligations:	Total	Payments Due by Period			More than 5 Years
		Less than 1 Year	1-3 Years	4-5 Years	
Operating leases	\$ 6,733,297	\$ 2,148,743	\$ 4,495,328	\$ 89,226	\$
License payments	1,580,000	305,000	610,000	610,000	55,000
Purchase obligations(1)	11,940,181	10,533,931	1,312,500	93,750	
Total	\$ 20,253,478	\$ 12,987,674	\$ 6,417,828	\$ 792,976	\$ 55,000

(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, 2009, 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;

## **Table of Contents**

the effect of competing technological and market developments;

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

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

## **Recent Accounting Pronouncements**

See Note 2, *Summary of Significant Accounting Policies – 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, 2009, 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.

**Table of Contents**

**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, 2009, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. 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, 2009, 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, 2009. 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, 2009, 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, 2009, 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, 2009 and 2008, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2009 and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 12, 2010





**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 2010 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**

*Jonathan E. Lim, M.D. (38)*, President, Chief Executive Officer and Director. Dr. Lim became employee number five when he joined Halozyme in May 2003 as President and CEO. He was elected to the Board of Directors in October 2003 and served as Chairman from April 2004 to December 2005. Under Dr. Lim's leadership, Halozyme has raised over \$225 million from financings and corporate partnerships, signed major alliances with Roche and Baxter, received two FDA approvals, for HYLENEX and Cumulase, and transitioned into a NASDAQ listed company with approximately 140 employees. From 2001 to 2003, Dr. Lim was a management consultant at McKinsey & Company, where he specialized in the health care industry, serving a wide range of companies from start-ups to Fortune 500 multinationals in the biopharmaceutical, medical products and payor/provider segments. From 1999 to 2001, Dr. Lim was a National Institutes of Health Postdoctoral Fellow conducting clinical outcomes research at Harvard Medical School. Dr. Lim's professional experience also includes clinical training in general surgery at the New York Hospital-Cornell Medical Center and Memorial Sloan-Kettering Cancer Center; Founder and President of a health care technology start-up; Founding Editor-in-Chief of the McGill Journal of Medicine; basic science and clinical research at the Salk Institute for Biological Studies and the Massachusetts Eye and Ear Infirmary; and membership on the strategic planning committee of the American Medical Association from 2002 to 2005. Dr. Lim earned his B.S., with honors, and M.S. in molecular biology from Stanford University, his M.D. from McGill University and his M.P.H. in health care management from Harvard University.

*Gregory I. Frost, Ph.D. (38)*, Vice President, Chief Scientific Officer and Director. Dr. Frost co-founded Halozyme in 1999 and has spent more than fifteen years conducting research on the extracellular matrix. Over his ten 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 (SKCC), where he focused much of his work studying tumor physiology and developing enzyme platform technologies. His research in the Department of Pathology at the University of California, San Francisco, 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 matrix biology 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. Dr. Frost is registered to practice before the U.S. Patent and Trademark Office, and 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 (42)*, Vice President, Chief Financial Officer. Mr. Gustafson joined Halozyme in 2009 with extensive operational and managerial experience in financial planning and analysis, accounting, treasury and international responsibility gained during his 18 years with Amgen Inc. In his most recent position, as Vice President, Manufacturing Finance, Mr. Gustafson had financial responsibility for each of Amgen's worldwide

**Table of Contents**

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 Europe, responsible for financial planning and accounting for European 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.

*Jonathan A. Leff, M.D. (52)*, Vice President, Chief Medical Officer. Dr. Leff joined Halozyme in 2009 with extensive experience in clinical development and medical affairs, and a proven track record in pharmaceutical product development from early stage molecules through global filing, approval and launch. From 2007 to 2009, Dr. Leff served at Hoffmann-La Roche, Inc. as Vice President and Global Head, Inflammation Clinical Development and Disease Biology Leadership Team member. While at Roche, he helped lead the development of products for inflammation, including managing the clinical development department on a global basis for inflammation products in registration phase development, such as MabThera®/Rituxan®, ocrelizumab, and Actemra®. From 2002 to 2007, Dr. Leff was at Amgen Inc., where he served most recently as Vice President, North American Medical Affairs. His responsibilities included leadership of a department of 500 people, and the oversight of 5 therapeutic areas, 8 marketed products and 4 late stage pipeline products, which involved the support and growth of 5 blockbuster brands: Neupogen®, Neulasta®, Epogen®, Aranesp®, and Enbrel®. In his prior role at Amgen, Dr. Leff was Senior Medical Director and Department Head of Osteoporosis Research, where he was responsible for conducting Phase 2 and 3 osteoporosis clinical trials for denosumab in over 10,000 patients, including a 7,800 patient fracture study. From 1994 to 2002, Dr. Leff was at Merck & Co., where he performed Phase 1 through Phase 4 clinical research studies for Singulair®, a leukotriene receptor antagonist, which resulted in a global filing and regulatory approval. From 1990 to 1994, Dr. Leff was a faculty member in the Pulmonary Division of the University of Colorado School of Medicine, with responsibilities for patient care, teaching and basic research. Dr. Leff received board certification in Internal Medicine, Pulmonary Medicine and Critical Care Medicine. He received his B.A. in chemistry and M.D. from the University of Pennsylvania.

*Robert L. Little (60)*, Vice President, Chief Commercial Officer. Mr. Little joined Halozyme in 2006 with extensive experience in the pharmaceutical industry in general management, commercial operations, sales and marketing and business development. From 2003 to 2006, Mr. Little was Senior Vice President of Commercial Operations at Neurocrine Biosciences, where he was responsible for building and managing the sales and marketing functions. During his tenure, Mr. Little put in place a fully integrated commercial organization, including a marketing team, a 200-person CNS sales force and full logistical and infrastructure support in order to co-detail Zolofit® with Pfizer and in preparation for the introduction of Indiplon®. From 1985 to 2003, Mr. Little was at Pharmacia, Inc. where his most recent position was Group Vice President, Diversified Products. His responsibilities included managing Pharmacia's Diversified Products business, as well as forming a new global business unit merging pricing, reimbursement and health outcomes groups to focus on current industry issues, pricing and drug values. From 1999 to 2001, Mr. Little was Group Vice President, Specialty Products and worldwide head of a \$2.5 billion, global specialty products business (ophthalmology, endocrinology, neurology and others). Mr. Little previously held a number of positions within Pharmacia, including President and Managing Director of Pharmacia in Milan, Italy, President of Pharmacia & UpJohn in Canada and President of Pharmacia, Inc. in Canada. Prior to joining Pharmacia, he held positions at Adria Laboratories and Miles Laboratories/Bayer AG in the United Kingdom, Italy and the United States. Mr. Little earned

his degree in economics and finance from the West London Business School, Ealing Technical College.

*William J. Fallon (53)*, 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

**Table of Contents**

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

*David A. Ramsay (45)*, Vice President, Corporate Development. Mr. Ramsay joined Halozyme in 2003. Mr. Ramsay was Chief Financial Officer from 2003 through May 2009. He has over 20 years of corporate financial experience spanning several industries. From 2000 to 2003, he was Vice President, Chief Financial Officer of Lathian Systems, a provider of technology-based sales solutions for the life sciences industry. Prior to Lathian, Mr. Ramsay was Vice President, Treasurer of ICN Pharmaceuticals, now called Valeant Pharmaceuticals International, a multinational, specialty pharmaceutical company. Mr. Ramsay joined ICN in 1998 from ARCO, where he spent four years in various financial roles, most recently serving as Manager of Financial Planning & Analysis for the company's 1,700-station West Coast Retail Marketing Network. Prior to ARCO, he served as Vice President, Controller for Security Pacific Asian Bank, a subsidiary of Security Pacific Corporation. He began his career as an auditor at Deloitte & Touche, where he obtained his CPA license. Mr. Ramsay served as Chairman of the Audit Committee and on the Board of Directors for Axxora Life Sciences, Inc., a privately held, worldwide research reagent company which was acquired by Enzo Biochem in 2007. Mr. Ramsay graduated from the University of California, Berkeley, with a B.S. in business administration and earned his M.B.A. with a dual major in finance and strategic management from The Wharton School at the University of Pennsylvania.

**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.

**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, 2009 and 2008</u>	F-2
<u>Consolidated Statements of Operations for Each of the Years Ended December 31, 2009, 2008 and 2007</u>	F-3
<u>Consolidated Statements of Cash Flows for Each of the Years Ended December 31, 2009, 2008 and 2007</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for Each of the Years Ended December 31, 2009, 2008 and 2007</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# Halozyyme Therapeutics, Inc. 2005 Outside Directors' Stock Plan(7)
- 10.9# Form of Stock Option Agreement (2005 Outside Directors' Stock Plan)(11)



Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

- 10.10# Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan)(11)
- 10.11# Halozyme Therapeutics, Inc. 2006 Stock Plan(10)
- 10.12# Form of Stock Option Agreement (2006 Stock Plan)(11)
- 10.13# Form of Restricted Stock Agreement (2006 Stock Plan)(11)

**Table of Contents**

10.14#	Halozyme Therapeutics, Inc. 2008 Stock Plan(19)
10.15#	Form of Stock Option Agreement (2008 Stock Plan)(25)
10.16#	Form of Restricted Stock Agreement (2008 Stock Plan)(25)
10.17#	Halozyme Therapeutics, Inc. 2008 Outside Directors Stock Plan(19)
10.18#	Form of Restricted Stock Agreement (2008 Outside Directors Stock Plan)(25)
10.19#	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*	Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(16)
10.30*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(12)
10.31	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(15)
10.32	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(15)
10.33	Underwriting Agreement between Halozyme Therapeutics, Inc. and Jefferies & Company, Inc., dated June 23, 2009(24)
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.
- (5)

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

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.

**Table of Contents**

- (9) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.
  - (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.
- \* 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 12, 2010.

Halozyme Therapeutics, Inc.,  
a Delaware corporation

By: /s/ Jonathan E. Lim, M.D.

Jonathan E. Lim, M.D.  
President and Chief Executive Officer

Date: March 12, 2010

**POWER OF ATTORNEY**

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Jonathan E. Lim 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/ Jonathan E. Lim, M.D. Jonathan E. Lim, M.D.	President and Chief Executive Officer (Principal Executive Officer), Director	March 12, 2010
/s/ Kurt A. Gustafson Kurt A. Gustafson	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2010
/s/ Gregory I. Frost, Ph.D. Gregory I. Frost, Ph.D.	Vice President and Chief Scientific Officer, Director	March 12, 2010
/s/ Kenneth J. Kelley	Chairman of the Board of Directors	March 12, 2010

Kenneth J. Kelley

/s/ Robert L. Engler, M.D.

Director

March 12, 2010

Robert L. Engler, M.D.

/s/ Kathryn E. Falberg

Director

March 12, 2010

Kathryn E. Falberg

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Randal J. Kirk Randal J. Kirk	Director	March 12, 2010
/s/ Connie L. Matsui Connie L. Matsui	Director	March 12, 2010
/s/ John S. Patton, Ph.D. John S. Patton, Ph.D.	Director	March 12, 2010

**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, 2009 and 2008, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 12, 2010

F-1

---



**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 67,464,506	\$ 63,715,906
Accounts receivable	4,243,909	7,264,410
Inventory	1,159,551	441,323
Prepaid expenses and other assets	1,573,777	2,591,149
 Total current assets	 74,441,743	 74,012,788
Property and equipment, net	2,708,016	2,549,925
 Total Assets	 \$ 77,149,759	 \$ 76,562,713
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,820,491	\$ 6,668,791
Accrued expenses	6,083,854	3,995,897
Deferred revenue	5,492,604	3,553,730
 Total current liabilities	 14,396,949	 14,218,418
Deferred revenue, net of current portion	54,989,588	45,894,726
Deferred rent, net of current portion	859,833	1,069,573
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock \$0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding		
Common stock \$0.001 par value; 150,000,000 shares authorized; 91,681,756 and 81,553,654 shares issued and outstanding at December 31, 2009 and 2008, respectively	91,682	81,554
Additional paid-in capital	178,821,852	128,948,064
Accumulated deficit	(172,010,145)	(113,649,622)
 Total stockholders' equity	 6,903,389	 15,379,996
 Total Liabilities and Stockholders' Equity	 \$ 77,149,759	 \$ 76,562,713

See accompanying notes to consolidated financial statements.

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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>REVENUES:</b>			
Revenues under collaborative agreements	\$ 12,700,458	\$ 8,052,202	\$ 3,159,931
Product sales	970,847	711,937	639,590
Total revenues	13,671,305	8,764,139	3,799,521
<b>OPERATING EXPENSES:</b>			
Cost of product sales	311,891	332,324	240,429
Research and development	56,614,266	44,232,936	20,554,105
Selling, general and administrative	15,203,408	14,633,581	11,155,194
Total operating expenses	72,129,565	59,198,841	31,949,728
<b>OPERATING LOSS</b>	(58,458,260)	(50,434,702)	(28,150,207)
Interest income	97,737	1,717,503	4,254,024
<b>NET LOSS BEFORE INCOME TAXES</b>	(58,360,523)	(48,717,199)	(23,896,183)
Income tax benefit		(63,000)	
<b>NET LOSS</b>	\$ (58,360,523)	\$ (48,654,199)	\$ (23,896,183)
Basic and diluted net loss per share	\$ (0.67)	\$ (0.61)	\$ (0.32)
Shares used in computing basic and diluted net loss per share	86,700,094	79,843,707	74,317,930

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>2009</b>	<b>2008</b>	<b>2007</b>
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (58,360,523)	\$ (48,654,199)	\$ (23,896,183)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	4,526,030	3,695,842	2,580,204
Depreciation and amortization	1,443,738	1,047,878	576,491
Loss on disposal of equipment	2,685	4,729	3,289
Changes in operating assets and liabilities:			
Accounts receivable	3,020,501	(6,484,585)	(416,260)
Inventory	(718,228)	262,145	(260,976)
Prepaid expenses and other assets	1,017,372	(576,469)	(1,416,590)
Accounts payable and accrued expenses	(2,000,233)	4,788,346	2,529,348
Deferred rent	(113,343)	363,484	865,063
Deferred revenue	11,033,736	10,178,965	19,287,954
Net cash used in operating activities	(40,148,265)	(35,373,864)	(147,660)
<b>INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(1,461,021)	(1,159,744)	(2,365,326)
Net cash used in investing activities	(1,461,021)	(1,159,744)	(2,365,326)
<b>FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, net	38,174,371		51,989,488
Proceeds from exercise of warrants, net	6,165,158	1,726,713	2,305,843
Proceeds from exercise of stock options, net	1,018,357	843,716	1,707,337
Net cash provided by financing activities	45,357,886	2,570,429	56,002,668
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,748,600</b>	<b>(33,963,179)</b>	<b>53,489,682</b>
<b>CASH AND CASH EQUIVALENTS at beginning of period</b>	<b>63,715,906</b>	<b>97,679,085</b>	<b>44,189,403</b>
<b>CASH AND CASH EQUIVALENTS at end of period</b>	<b>\$ 67,464,506</b>	<b>\$ 63,715,906</b>	<b>\$ 97,679,085</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Accounts payable for purchases of property and equipment	\$ 143,493	\$ 159,472	\$

See accompanying notes to consolidated financial statements.

F-4

---

**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**Years Ended December 31, 2009, 2008 and 2007**

	<b>Common Stock</b>		<b>Additional</b>		<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Accumulated</b>	<b>Stockholders</b>
			<b>Capital</b>	<b>Deficit</b>	<b>Equity</b>
BALANCE AT JANUARY 1, 2007	68,736,993	\$ 68,737	\$ 64,111,738	\$ (41,099,240)	\$ 23,081,235
Share-based compensation expense			2,580,204		2,580,204
Issuance of common stock for cash, net	5,570,394	5,570	51,983,918		51,989,488
Issuance of common stock pursuant to exercise of warrants, net	1,783,852	1,784	2,304,059		2,305,843
Issuance of common stock pursuant to exercise of stock options	1,707,705	1,708	1,705,629		1,707,337
Issuance of restricted stock awards	105,000	105	(105)		
Net loss				(23,896,183)	(23,896,183)
<b>BALANCE AT DECEMBER 31, 2007</b>	<b>77,903,944</b>	<b>77,904</b>	<b>122,685,443</b>	<b>(64,995,423)</b>	<b>57,767,924</b>
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)
<b>BALANCE AT DECEMBER 31, 2008</b>	<b>81,553,654</b>	<b>81,554</b>	<b>128,948,064</b>	<b>(113,649,622)</b>	<b>15,379,996</b>
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	3,140,780	3,141	6,162,017		6,165,158

warrants, net					
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)
<b>BALANCE AT DECEMBER 31, 2009</b>	91,681,756	\$ 91,682	\$ 178,821,852	\$ (172,010,145)	\$ 6,903,389

See accompanying notes to consolidated financial statements.

F-5

---

**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 products targeting the extracellular matrix for the endocrinology, oncology, dermatology and drug delivery markets. The Company's existing products and products under development are based on intellectual property covering the family of human enzymes known as hyaluronidases.

The Company's operations to date have involved organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for its existing products and a limited number of product candidates. The Company currently has multiple proprietary programs in various stages of research and development. In addition, the Company has entered into a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. ( Roche ) to apply Enhance Technology to Roche's biological therapeutic compounds for up to 13 targets. The Company has also entered into two key partnerships with Baxter Healthcare Corporation ( Baxter ) to apply Enhance Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID<sup>®</sup> and to develop and supply active pharmaceutical ingredient ( API ) for HYLENEX, a registered trademark of Baxter International, Inc. Baxter is responsible for the execution of HYLENEX clinical development, sales and marketing strategy. There are two marketed products that utilize the Company's technology: HYLENEX, a product used as an adjuvant to increase the dispersion and absorption of other injected drugs and fluids, and Cumulase<sup>®</sup>, a product used for *in vitro* fertilization. Currently, the Company receives only limited revenue from the sales of HYLENEX and 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 us 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. Deposits held with the bank 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 97% and 99% of the accounts receivable balance as of December 31, 2009 and 2008, respectively, represents amounts due from two customers.

F-6

---



**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, 2009 and 2008. For the years ended December 31, 2009, 2008 and 2007, 76%, 44% and 50% of total revenues were from Roche and 20%, 51% and 36% 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 4% and 39% of the accounts payable balance at December 31, 2009 and 2008, 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. The Company is obligated to accept returns for product that does not meet product specifications. Historically, the Company has not had any product returns; therefore, no allowance for product returns has been established.

***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.

***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 year ended December 31, 2009, 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

---

**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 \$65.3 million at December 31, 2009 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.

***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.

***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 and 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 Amended and Restated Development and Supply Agreement (the HYLENEX Partnership) with Baxter, the Company supplies Baxter with API for HYLENEX at its fully burdened cost plus a margin. Baxter fills and finishes HYLENEX and holds it for subsequent distribution, at which time the Company ensures it meets product specifications and releases it as available for sale. Because of the Company's continued involvement in the development and production process of HYLENEX, the earnings process is not considered to be complete. Accordingly, the Company defers the revenue and related product costs on the API for HYLENEX until the product is filled, finished, packaged and released. Baxter may only return the API for HYLENEX to the Company if it does not

conform to the specified criteria set forth in the HYLENEX Partnership or upon termination of such agreement. The Company has historically demonstrated that the API shipped to Baxter has consistently met the specified criteria, therefore, no allowance for product returns has been established. In addition, the Company receives product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the HYLENEX Partnership. Product sales revenues are recognized as the Company earns such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts can be reasonably estimated.

*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

**Table of Contents**

**Halozyme Therapeutics, Inc.**

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

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.

***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.

***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.

***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

F-9

---

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

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, 2009, 2008 and 2007 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, 2009, 2008 and 2007 was comprised of the following:

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Research and development	\$ 2,441,907	\$ 1,541,003	\$ 662,690
Selling, general and administrative	2,084,123	2,154,839	1,917,514
Share-based compensation expense before taxes	4,526,030	3,695,842	2,580,204
Related income tax benefits			
Share-based compensation expense	\$ 4,526,030	\$ 3,695,842	\$ 2,580,204
Net share-based compensation expense, per basic and diluted share	\$ 0.05	\$ 0.05	\$ 0.03
Share-based compensation expense from:			
Stock options	\$ 3,648,174	\$ 2,691,571	\$ 1,857,249
Restricted stock awards	877,856	1,004,271	722,955
	\$ 4,526,030	\$ 3,695,842	\$ 2,580,204

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 \$93,000, \$0 and \$0 in stock-based compensation expense related to stock options granted to non-employees for the years ended December 31, 2009, 2008 and 2007, respectively. There were no non-employee stock options outstanding at December 31, 2009.

***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



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

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. Management has considered future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. In the event the Company were to determine that it would be able to realize the deferred tax assets in the future in excess of their net recorded amounts, an adjustment to the deferred tax assets would increase the income in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of the net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to income in the period such determination was made.

In July 2006, the Financial Accounting Standards Board ( FASB ) issued additional guidance which requires the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the provisions under this guidance also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions under this guidance on January 1, 2007. The adoption of these provisions had no impact on the Company's consolidated financial position or results of operations. At December 31, 2009 and 2008, the Company's unrecognized income tax benefits and uncertain tax provisions were not material and would not, if recognized, affect the effective tax rate.

***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:

	2009	2008	2007
Stock options and awards	7,924,266	7,447,285	7,914,979
Warrants		3,230,656	4,859,030
	7,924,266	10,677,941	12,774,009

***Segment Information***

The Company operates in one segment, which is the research, development and commercialization of products based on the extracellular matrix for the endocrinology, oncology, dermatology and drug delivery markets. The chief operating decision-makers review the operating results on an aggregate basis and manage the operations as a single operating segment.

***Adoption of Recent Accounting Pronouncements***

In June 2009, the FASB approved *The FASB Accounting Standards Codification* (the Codification ) as the single source of authoritative U.S. GAAP for all non-governmental entities, with the exception of the SEC and its staff. The Codification, which launched on July 1, 2009, changes the referencing and organization of accounting guidance and became effective for interim and annual periods ending after September 15, 2009. The Codification is now the single official source of authoritative U.S. GAAP (other than guidance issued by the SEC), superseding existing FASB, American Institute of Certified Public Accountants, Emerging Issues Task Force ( EITF ), and related literature. Only one level of authoritative U.S. GAAP now exists. All other literature is considered non-authoritative. The Codification does not change U.S. GAAP. The Company adopted the Codification effective

F-11

---

**Table of Contents**

**Halozyme Therapeutics, Inc.**

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

July 1, 2009. The adoption of the Codification did not have a material impact on the Company's consolidated financial position or results of operations.

Effective April 1, 2009, the Company adopted authoritative guidance for subsequent events, which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The guidance sets forth the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements. The adoption of the guidance for subsequent events did not have a material impact on the Company's consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted FASB's new guidance on accounting for collaborative arrangements. This statement focuses on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the statement of operations and certain related disclosure questions. The adoption of the new guidance on accounting for collaborative arrangements did not have a material impact on the Company's consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted new authoritative guidance for business combinations. This new guidance replaces prior guidance on the subject and requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at fair value. Additionally, it also requires transaction costs related to the business combination to be expensed as incurred. The adoption of the new guidance for business combinations did not have a material effect on the Company's consolidated financial condition and results of operations.

Effective January 1, 2009 the Company adopted FASB's new guidance on determining whether instruments granted in shared-based payment transactions are participating securities. The new guidance clarified that all outstanding unvested share-based payment awards that contain rights to nonforfeitable dividends participate in undistributed earnings with common shareholders. Awards of this nature are considered participating securities and the two-class method of computing basic and diluted earnings per share must be applied. The adoption of this new guidance did not have a material impact on the Company's consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted FASB's new guidance on determining whether an instrument (or an embedded feature) is indexed to an entity's own stock. The guidance provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. The adoption of this new guidance did not have a material impact on the Company's consolidated financial position or results of operations.

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

In September 2009, the FASB issued Accounting Standards Update (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.

F-12

---

**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)****3. Inventory**

Inventory consists of the following as of December 31, 2009 and 2008:

	<b>2009</b>	<b>2008</b>
Raw materials	\$ 1,159,551	\$ 435,386
Finished goods		5,937
	<b>\$ 1,159,551</b>	<b>\$ 441,323</b>

Inventory is used in the manufacture of the Company's HYLENEX and Cumulase products and is stated at the lower of cost or market.

**4. Property and Equipment**

Property and equipment consists of the following as of December 31, 2009 and 2008:

	<b>2009</b>	<b>2008</b>
Research equipment	\$ 3,838,307	\$ 2,699,706
Computer and office equipment	1,333,924	1,079,034
Leasehold improvements	981,140	814,067
	6,153,371	4,592,807
Accumulated depreciation and amortization	(3,445,355)	(2,042,882)
	<b>\$ 2,708,016</b>	<b>\$ 2,549,925</b>

Depreciation and amortization expense was approximately \$1.4 million, \$1.0 million and \$576,000, for the years ended December 31, 2009, 2008 and 2007, respectively.

**5. Accrued Expenses**

Accrued expenses consist of the following as of December 31, 2009 and 2008:

<b>2009</b>	<b>2008</b>
-------------	-------------

Accrued compensation and payroll taxes	\$ 2,945,498	\$ 2,060,866
Accrued outsourced research and clinical trial expenses	2,609,819	1,543,321
Accrued expenses	528,537	391,710
	\$ 6,083,854	\$ 3,995,897

## 6. Deferred Revenue

Deferred revenue consists of the following as of December 31, 2009 and 2008:

	<b>2009</b>	<b>2008</b>
Collaborative agreements	\$ 50,390,400	\$ 44,905,031
Product sales	10,091,792	4,543,425
Total deferred revenue	60,482,192	49,448,456
Less current portion	5,492,604	3,553,730
Deferred revenue, net of current portion	\$ 54,989,588	\$ 45,894,726

**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, 2009, Roche paid an aggregate of \$13.5 million in connection with Roche's election of two additional exclusive targets and annual license fees for the right to designate the remaining targets as exclusive targets. In addition, at December 31, 2009 the Company was entitled to receive \$3.5 million, which is included in deferred revenue at December 31, 2009, in connection with annual license maintenance fees for the remaining Roche targets.

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 \$1.9 million, \$1.2 million and \$1.2 million for the years ended December 31, 2009, 2008 and 2007, 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 \$606,000 for the years ended December 31, 2009 and 2008 and \$192,000 for the year ended December 31, 2007.

In February 2007, the Company and Baxter amended certain existing agreements for HYLENEX and entered into a new agreement for kits and formulations with rHuPH20 (the HYLENEX Partnership). 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 is 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 \$586,000 for the years ended December 31, 2009 and 2008 and \$516,000 for the year ended December 31, 2007.

In addition, Baxter will make payments to the Company based on sales of the products covered under the HYLENEX Partnership. Baxter has prepaid a total of \$10.0 million of such product-based payments in connection with the execution of the HYLENEX Partnership. The prepaid product-based payments are deferred and are being recognized as product sales revenues as the Company earns such revenues from the sales of HYLENEX by Baxter.

**7. Stockholders Equity**

*Issuance of Common Stock* 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 price of \$2.05 per share), stock options (717,322 shares at a weighted average price of \$1.42 per share) and restricted stock awards (120,000 shares at a 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 price of \$1.06 per share), stock options



**Table of Contents**

**Halozyme Therapeutics, Inc.**

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

(1,828,836 shares at a weighted average price of \$0.55 per share) and restricted stock awards (192,500 shares at a price of \$0.001 per share) for cash in the aggregate amount of approximately \$2.6 million.

In April 2007, the Company entered into a definitive stock purchase agreement (the *Purchase Agreement*) with New River Management V, LP ( *New River* ). Under the terms of the Purchase Agreement, New River purchased 3,500,000 newly-issued shares of the Company's common stock for an aggregate price of approximately \$32.1 million. The sale of the shares was completed in May 2007. The Company has agreed to file a registration statement upon demand with the SEC covering the resale of these shares.

In February 2007, an affiliate of Baxter purchased 2,070,394 shares of the Company's common stock for an aggregate price of approximately \$20.0 million.

During 2007, the Company issued an aggregate of 3,596,557 shares of common stock in connection with the exercises of stock purchase warrants (1,783,852 shares at a weighted average price of \$1.29 per share), stock options (1,707,705 shares at a weighted average price of \$1.00 per share) and restricted stock awards (105,000 shares at a price of \$0) for cash in the aggregate amount of approximately \$4.0 million.

*Warrants* In connection with the October 2004 private placement, the Company issued warrants to purchase 2,709,542 shares of common stock at an exercise price of \$2.25 per share. These warrants were exercisable until October 12, 2009. As of December 31, 2009 and 2008, 0 and 1,927,715, respectively, of these warrants were outstanding.

In connection with the January 2004 private placement, the Company issued warrants to purchase 8,094,829 shares of common stock at an exercise price of \$1.75 per share, as amended. These warrants were exercisable until January 28, 2009 and were callable by the Company under certain conditions. As of December 31, 2009 and 2008, 0 and 1,302,941, respectively, of these warrants were outstanding.

**8. 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, 2009, 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, 2009. Of those shares, 7,804,266 shares were subject to outstanding options and 4,026,751 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, 2009, 2008 and 2007 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, 2007	8,637,322	\$ 1.12		
Granted	1,029,881	\$ 8.08		
Exercised	(1,732,567)	\$ 1.11		
Cancelled/forfeited	(124,657)	\$ 1.81		
Outstanding at December 31, 2007	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	6.4	\$ 19.7 million
Vested and expected to vest at December 31, 2009	7,526,580	\$ 3.63	6.3	\$ 19.7 million
Exercisable at December 31, 2009	5,202,944	\$ 2.48	5.2	\$ 19.0 million

The weighted average grant-date fair values of options granted during the years ended December 31, 2009, 2008 and 2007 were \$3.72 per share, \$3.39 per share and \$4.94 per share, respectively. As of December 31, 2009, approximately \$6.8 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 2.7 years. The intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was approximately \$3.9 million, \$9.9 million and \$13.5 million, respectively. Cash received from stock option exercises for the years ended December 31, 2009, 2008 and 2007 was approximately \$1.0 million, \$844,000 and \$1.7 million, respectively.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ( Black-Scholes model ) that uses the assumptions noted in the following table. Expected volatility is based on historical volatility of 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>2009</b>	<b>2008</b>	<b>2007</b>
Expected volatility	65.0%	65.0%	70.0%
Average expected term (in years)	5.5	5.5	5.0
Risk-free interest rate	1.65-2.73%	1.26-3.14%	3.5-4.7%
Expected dividend yield	0%	0%	0%

F-16

---

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

The following table summarizes information for outstanding and exercisable options as of December 31, 2009:

Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Vested and Exercisable	Weighted Average Exercise Price
\$0.39	2,209,720	3.9	\$ 0.39	2,209,720	\$ 0.39
\$0.40 - \$2.83	1,671,072	5.4	\$ 2.17	1,595,395	\$ 2.15
\$2.84 - \$5.81	1,380,079	7.5	\$ 4.85	746,853	\$ 4.55
\$5.82 - \$10.37	2,543,395	8.6	\$ 7.05	650,976	\$ 8.01
	7,804,266	6.4	\$ 3.73	5,202,944	\$ 2.48

*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. 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, 2009, 2008 and 2007, the Company issued 120,000, 192,500 and 105,000 restricted stock awards, respectively, 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, 2009, 2008 and 2007:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2007	90,000	\$ 2.72

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

Granted	105,000	\$ 10.37
Vested	(90,000)	\$ 2.72
Forfeited		\$
Unvested at December 31, 2007	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

F-17

---

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

The total grant-date fair value of restricted stock awards vested during the years ended December 31, 2009 and 2008 was approximately \$951,000 and \$1.1 million, respectively. As of December 31, 2009, total unrecognized compensation cost related to unvested shares was approximately \$247,000, which is expected to be recognized over a weighted-average period of approximately 4 months.

**9. 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 (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 (BC Sorrento) for these facilities through January 2013. 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 \$758,000 and \$870,000 was included in deferred rent as of December 31, 2009 and 2008, 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 \$355,000 and \$418,000 was included in deferred rent as of December 31, 2009 and 2008, 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 \$62,000 was included in deferred rent at December 31, 2009.

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

Additionally, the Company leases certain office equipment under operating leases. Total rent expense was approximately \$1.4 million, \$1.4 million and \$1.1 million for the years ended December 31, 2009, 2008 and 2007, respectively.

F-18

---



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

Approximate annual future minimum operating lease payments as of December 31, 2009 are as follows:

<b>Year:</b>	<b>Operating Leases</b>
2010	\$ 1,858,000
2011	1,920,000
2012	1,992,000
2013	77,000
Total minimum lease payments	\$ 5,847,000

*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 series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37.0 million to us. 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, a new agreement 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 will make milestone payments to us which could potentially reach a value of up to \$25.0 million. In addition, Baxter will make payments to the Company based on the sales of products covered under the HYLENEX Partnership. Baxter has prepaid a total of \$10.0 million of such product-based payments. Baxter also assumes all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. The Company continues to supply Baxter with the API for HYLENEX, and Baxter fills and finishes HYLENEX and holds 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 is being recognized over the term of the HYLENEX Partnership.

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, 2009, Roche has elected two additional exclusive targets. Through December 2016, Roche will also have the option to exclusively develop and commercialize rHuPH20 with an additional eight targets to be identified by Roche, provided that Roche will be obligated to pay continuing exclusivity maintenance fees to the Company in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche

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

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 ten 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. This manufacturer 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 of rHuPH20 were produced to support planned future clinical studies.

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

In December 2006, the Company amended its Commercial Supply Agreement (the *Amendment*) with Avid Bioservices, Inc. ( *Avid* ) which was originally entered into in February 2005. Under the terms of the Amendment, the Company is committed to certain minimum annual purchases of API equal to two 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, 2009, the Company has a minimum purchase obligation of approximately \$1.0 million.

*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.

**10. Income Taxes**

Significant components of the Company's net deferred tax assets at December 31, 2009 and 2008 are shown below. A valuation allowance of \$75.1 million and \$49.6 million has been established to offset the net deferred tax assets as of December 31, 2009 and 2008, respectively, as realization of such assets is uncertain.

	<b>2009</b>	<b>2008</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 42,253,000	\$ 25,466,000
Deferred revenue	18,370,000	14,566,000
Research and development credits	12,175,000	7,775,000
Share-based compensation	1,171,000	929,000
Depreciation	327,000	80,000
Other, net	789,000	743,000
Total deferred tax assets	75,085,000	49,559,000

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-K

Valuation allowance for deferred tax assets	(75,085,000)	(49,559,000)
Net deferred tax assets	\$	\$

F-20

---

**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, 2009, 2008 and 2007, due to the following:

	<b>2009</b>	<b>2008</b>	<b>2007</b>
Federal income tax rate of 34%	\$ (19,843,000)	\$ (16,544,000)	\$ (8,125,000)
State income tax, net of federal benefit	(3,405,000)	(2,839,000)	(1,394,000)
Research and development credits	(4,464,000)	(3,099,000)	(2,133,000)
Tax effect on non-deductible expenses and other	2,186,000	2,445,000	857,000
Increase in valuation allowance	25,526,000	20,037,000	10,795,000
Benefit due to refundable R&D credit		(63,000)	
	\$	\$ (63,000)	\$

At December 31, 2009, the Company had federal and California tax net operating loss carryforwards of approximately \$121.2 million and \$125.1 million, respectively. Included in these amounts are federal and California net operating losses of approximately \$15.7 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, 2009, the Company also had federal and California research and development tax credit carryforwards of approximately \$8.9 million and \$5.0 million, respectively. The federal research and development tax credits will begin to expire in 2024 unless previously utilized. The California research and development tax credits will carryforward indefinitely until utilized.

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, 2009. 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.

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, 2009 and 2008, 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.

**11. 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 \$374,000, \$0 and \$0 in the years ended December 31, 2009, 2008 and 2007, respectively.

**12. Related Party Transactions**

In July 2007, the Company entered into the 11388 Sublease with Avanir for Avanir's excess leased facilities in San Diego, California. The 11388 Sublease expired in August 2008. As a result, in July 2007, the Company entered

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

into the Lease with BC Sorrento for these facilities through January 2013. Connie L. Matsui, a director of the Company, and her husband have a controlling ownership interest in an entity that holds a minority ownership position in BC Sorrento. In addition, this entity currently serves as the managing member of BC Sorrento. 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. The Lease commenced in September 2008. The Company paid BC Sorrento approximately \$1.2 million, \$281,000 and \$0 for the years ended December 31, 2009, 2008 and 2007, 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 no longer an employee or director of Nektar. The Company paid Nektar approximately \$73,000 and \$75,000 for the years ended December 31, 2008 and 2007, respectively.

The Company entered into the Purchase Agreement with New River on April 23, 2007, under which it sold 3,500,000 shares of its common stock to New River. The transaction under the Purchase Agreement closed on May 31, 2007. Randal J. Kirk, an affiliate of New River, was appointed to the Company's Board of Directors on May 15, 2007. There were no other material transactions between Mr. Kirk and the Company for the years ended December 31, 2009, 2008 and 2007.

**13. 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>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

<b>2008 (Unaudited):</b>	<b>Quarters Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Total revenues	\$ 1,805,518	\$ 1,434,219	\$ 2,462,226	\$ 3,062,176
Total operating expenses	\$ 12,638,984	\$ 12,808,789	\$ 13,661,945	\$ 20,089,123
Net loss	\$ (9,953,997)	\$ (11,002,390)	\$ (10,872,158)	\$ (16,825,654)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.14)	\$ (0.14)	\$ (0.21)

Shares used in computing net loss per share, basic and diluted	78,300,319	79,454,496	80,293,800	81,213,985
--	------------	------------	------------	------------

F-22