

HALOZYME THERAPEUTICS INC

Form 10-K

March 13, 2009

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**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, 2008**
- 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)*

**88-0488686**

*(I.R.S. Employer  
Identification No.)*

**11388 Sorrento Valley Road,  
San Diego, California**

*(Address of principal executive offices)*

**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

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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, 2008 was approximately \$323.2 million based on the closing price on the NASDAQ Stock Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 27, 2009, there were 82,946,449 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 2009 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, 2008.

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**PART I**

**Item 1. Business**

*This Annual Report on Form 10-K contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as expects, anticipates, intends, plans, believes, seeks, estimates, thinks, may, could, will, would, should, continue, 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 been limited to organizing and staffing our operating subsidiary, Halozyme, Inc., acquiring, developing and securing our technology and undertaking product development for our existing products and product candidates. Over the last year, we increased our focus on our proprietary product pipeline and expanded investments in our proprietary product candidates. Our key partnerships are with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, to apply Enhance<sup>™</sup> Technology to Roche's biological therapeutic compounds for up to thirteen targets and with Baxter Healthcare Corporation, or Baxter, to apply Enhance Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID<sup>™</sup>. We have two marketed products: HYLENEX, a registered trademark of Baxter International, Inc., a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids, and Cumulase<sup>®</sup>, a product used for *in vitro* fertilization, or IVF. Currently, we have only limited revenue from the sales of HYLENEX and Cumulase, in addition to 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 products 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 \$113.6 million as of December 31, 2008.

We currently have an effective universal shelf registration statement which allows us to offer and sell up to \$50.0 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.

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We reincorporated from the State of Nevada to the State of Delaware in November 2007. Our principal offices and research facilities are located at 11388 Sorrento Valley Road, San Diego, California 92121. Our telephone number is (858) 794-8889 and our e-mail address is info@halozyme.com. Additional information about the Company can be found on our website at www.halozyme.com, and in our periodic and current reports filed with the 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 and our website at www.halozyme.com.

## **Technology**

Our 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 tissues throughout the body, such as skin and bone. The PH20 enzyme is a naturally occurring enzyme that digests HA to temporarily break down the gel, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. Our proprietary technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones. Our technology may be utilized for the development of our own proprietary products. For example, we are developing a PEGylated version of our rHuPH20 enzyme, or PEGPH20, that is being tested as a single agent oncology therapy. The PH20 enzyme may also be applied to existing and developmental products of third parties through key partnerships.

## **Strategy**

We are a biopharmaceutical company dedicated to the development and commercialization of products targeting the Matrix for the endocrinology, oncology, dermatology and drug delivery markets. The Matrix is a key structural component found in both normal tissues such as skin and bone, and abnormal tissues such as tumors. By expanding upon our scientific expertise in the Matrix, we hope to develop therapeutic and aesthetic drugs. Our lead enzyme, rHuPH20 hyaluronidase, is an example of a Matrix-modifying enzyme. By degrading HA, a key Matrix component in the skin, rHuPH20 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 or co-formulate rHuPH20 with previously approved small molecule drugs to develop new proprietary products, with potentially new patent protection. Other benefits include patient convenience.

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 PEGPH20 enzyme 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.



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**Products and Product Candidates**

There are two marketed products that utilize our technology and there are multiple product candidates targeting several indications in various stages of development. The following table summarizes the proprietary and partnered products and product candidates that utilize our technology:

***Insulin-PH20***

One of our proprietary programs focuses on the formulation of our lead enzyme rHuPH20 and insulin for the treatment of diabetes mellitus. Diabetes mellitus is an increasingly prevalent, costly condition associated with substantial morbidity and mortality. Attaining and maintaining normal blood sugar levels to minimize the long-term clinical risks is a key treatment goal for diabetic patients. Combining rHuPH20 with insulin may facilitate faster insulin spreading from the subcutaneous space into the vascular compartment leading to faster insulin response and improved glycemic control potentially resulting in fewer hypoglycemic episodes. By making mealtime insulin faster, i.e., shifting insulin exposure and glucose lowering activity to earlier times and away from late postprandial times, combination with rHuPH20 may yield a profile of insulin kinetics and activity more like that of natural, endogenous prandial insulin release.

In November 2008, we started a Phase II clinical trial of rHuPH20 formulations with Humulin<sup>®</sup> R (regular insulin) and Humalog<sup>®</sup> (insulin lispro) in Type 1 diabetic patients. This exploratory, crossover design, single blind, open label, liquid meal Phase II study is designed to collect data on at least 20 patients who complete the study. The study allows for insulin dose titration and each patient will receive a minimum of four and up to three additional study drug injections that include Humulin R and Humalog with and without rHuPH20.

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The primary endpoint of this study, a pharmacokinetic measure, is the area under the curve for plasma insulin concentration from zero to 60 minutes after injection. Secondary endpoints include additional pharmacokinetic data, as well as blood glucose concentration at various time points. Safety data such as adverse reactions, hypoglycemia, blood chemistry and injection site tolerability will be collected, measured and evaluated. Patients may be on study for up to an estimated 14 weeks from screening to completion and the results should be available for presentation at a medical or scientific forum in mid-2009.

In June 2008, we announced data from our Phase I clinical trial showing that combining rHuPH20 with Humulin R or Humalog yielded pharmacokinetics and glucodynamics that better mimicked physiologic prandial (mealtime) insulin release and activity than either Humulin R or Humalog alone. The Phase I crossover, euglycemic clamp study was conducted in 26 healthy male volunteers. The study had two stages: the first stage compared the pharmacokinetics and glucodynamics of Humalog injected subcutaneously with and without rHuPH20, and the second stage compared the pharmacokinetics and glucodynamics of Humulin R injected subcutaneously with and without rHuPH20.

Key pharmacokinetic and glucodynamic improvements observed in the study included:

- Significantly faster systemic absorption of each insulin, starting with the first observation time point of three minutes after injection

- Significantly faster and greater glucose lowering activity early after injection

- Significantly greater peak insulin levels for the same dose administered

- Significantly lower variability of key pharmacokinetic and glucodynamic variables across subjects

- rHuPH20 in combination with Humulin demonstrated statistically significant improvement across all parameters when compared to Humalog alone

## ***Bisphosphonate-PH20***

Bisphosphonates are a class of molecules that bind to mineralized bone matrix and inhibit bone resorption. Currently, there are both oral and intravenous bisphosphonates available commercially. Oral bisphosphonates often cause gastrointestinal side effects and require a cumbersome dosing regimen. The gastrointestinal side effects of oral bisphosphonates may lead to patient non-compliance to prescribed therapy. Certain bisphosphonates are indicated for the treatment of osteoporosis and skeletal metastases, but can only be administered today by intravenous infusion. As such, patients often have to travel to an infusion center or see a specialist to receive their intravenous bisphosphonate infusion. Subcutaneous injections of bisphosphonates are not considered feasible due to injection site reactions in the skin and/or impractical injection volumes.

The goal of our bisphosphonate program is to provide an alternative dosage formulation that may offer greater convenience, compliance and tolerability to patients for the treatment of osteoporosis. If rHuPH20 hyaluronidase can rapidly disperse, dilute and facilitate the systemic absorption of subcutaneous bisphosphonates, it may prevent local irritation and provide a more convenient route of administration. We completed studies in animal models to investigate whether increasing the dispersion and absorption of bisphosphonates in the skin and subcutaneous tissues with rHuPH20 could modify injection site reaction profiles from two intravenous bisphosphonate formulations, zoledronic acid and ibandronate. The pharmacokinetics of bisphosphonates in blood were also examined and compared to intravenous infusion. Key findings from the studies were as follows:

In rodent intradermal models, injection of bisphosphonates without rHuPH20 created injection site reactions characterized by erythema, induration and ulceration in a concentration dependent manner.

In rodent intradermal models, the maximal concentration of bisphosphonates that could be administered without producing injection site reactions was increased 3- to 5-fold when co-administered in combination with rHuPH20.

In porcine pharmacokinetic models, absolute bioavailability by subcutaneous injection with rHuPH20 was comparable to IV infusion.

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In the fourth quarter of 2008, we initiated a Phase I clinical trial for a bisphosphonate administered with rHuPH20 as a subcutaneous injection. This study will explore the safety, tolerability and pharmacokinetics of subcutaneous administration of a bisphosphonate plus rHuPH20.

### ***PEGPH20***

We are investigating our PEGPH20 enzyme as a candidate for the systemic treatment of tumors with high levels of HA. PEGylation refers to the attachment of polyethyleneglycol to our rHuPH20 enzyme, which extends its half life in the blood from less than 30 seconds to more than 24 hours. HA is a component of the Matrix that frequently accumulates in human cancers. The quantity of HA produced by the tumor cells correlates with increased tumor growth and metastasis and has been linked with tumor progression and poor prognosis in some studies. In animal studies, the removal of HA from tumors with hyaluronidase has demonstrated reduction of tumor growth, and in some experiments, enhanced efficacy of certain anti-cancer drugs. Increased sensitivity to chemotherapeutic agents may be achieved once the HA has been removed.

Numerous solid tumors, including prostate, breast, pancreas and colon, accumulate HA that forms a halo-like coating over the surface of the tumor cell. 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.

We performed certain preclinical studies to determine whether HA-dependent pericellular matrices produced *in vitro* and *in vivo* by a hormone-refractory prostate cancer cell line could be enzymatically depleted in prostate carcinoma xenografts following intravenous administration of the PEGPH20 enzyme. The dose-dependent effects of systemic enzyme treatment were evaluated by a combination of direct micropressure measurements, magnetic resonance imaging, or MRI, ultrasound, immunohistochemistry and determination of tumor water content. The studies explored the physiologic responses to enzymatic removal of HA-based matrices surrounding tumor cells in the tumor microenvironment of prostate tumors following systemic administration of PEGPH20. Prostate tumors were grown around the bone as a model of elevated interstitial fluid pressure, or IFP. Treatment commenced when tumors had reached approximately 500 mm<sup>3</sup> in size and pressure within the tumor had reached 30-40 mm Hg.

A summary of findings is as follows:

Prostate carcinoma cells assembled large pericellular coats *in vitro* that collapsed in the presence of rHuPH20. Similar pericellular matrices containing HA were also assembled *in vivo* following inoculation of tumors around the bone in mice.

PEGPH20 significantly reduced tumor IFP in a dose dependent fashion, achieving more than 85% reduction in IFP following IV administration. Peritumoral HA remained depleted over three days after a single dose of enzyme.

Consistent with the histologic collapse of pericellular HA surrounding the tumor cells, tumor water content significantly decreased over three days, consistent with changes detected in the tumor by MRI and IFP monitoring.

Furthermore, a 3.5-fold selective increase in tumor vascular volume was achieved within eight hours post-dosing as a result of vascular decompression of blood vessels within the tumor, which was confirmed by histology and ultrasound.

We recently initiated a first Phase I clinical trial for our PEGPH20 program. This first trial with the agent is a dose-escalation, multicenter, pharmacokinetic and pharmacodynamic, safety study. Patients with advanced solid tumors will receive intravenous administration of PEGPH20 as a single agent.

***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 PH20 enzyme with mitomycin C, a cytotoxic

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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.

In June 2008, we announced the results of a Phase I/IIa clinical trial in which Chemophase was well tolerated and appears safe. The study reported no dose-limiting toxicities and no observed side effects attributable to the enzyme, and established the dose for subsequent clinical trials, therefore achieving the pre-defined primary objective of the study. In addition, there were no neutralizing antibodies to rHuPH20 detected and the plasma concentration of mitomycin C was either non-measurable or negligible and well below the threshold that may be predictive for myelosuppression (such as a decrease in bone marrow activity, resulting in fewer red blood cells, white blood cells and platelets). During the first quarter of 2009, we decided to reallocate certain resources previously budgeted for Chemophase to other higher priority programs, such as our Insulin-PH20 and PEGPH20 programs. We are currently exploring strategic alternatives that will allow the Chemophase program to continue its clinical development.

### ***Enhance Technology***

Enhance Technology, a proprietary drug enhancement approach using rHuPH20, is a broad technology that we have licensed to other pharmaceutical companies. When formulated with other injectable drugs, Enhance Technology may facilitate the subcutaneous penetration and dispersion 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. Potential benefits of subcutaneous administration of biologics include life cycle management, patient convenience and benefits to payors.

We currently have Enhance Technology partnerships with Roche and Baxter and we are currently seeking 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 Roche Partnership. 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 collaboration. Under the terms of the Roche Partnership, we were obligated to scale up the production of rHuPH20 and to identify a second source manufacturer that would help meet anticipated production obligations arising from the partnership. To that end, during 2008, we entered into a Technology Transfer Agreement and a Clinical Supply Agreement with a second rHuPH20 manufacturer. This manufacturer has the capacity to produce the clinical quantities we are required to deliver under the terms of the Roche Partnership and, we believe, the commercial quantities as well. The technology transfer was completed in 2008 with scale-up and clinical supply manufacturing planned for 2009.

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. 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. In December 2008, we announced that Roche elected to add a fourth exclusive target to the three original exclusive targets, and we previously announced the commencement of Phase I clinical trials for products directed at two of these four exclusive targets.

Roche retains the option to exclusively develop and commercialize rHuPH20 with an additional nine targets through the payment of annual license maintenance fees.

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

GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, 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 III clinical trial for GAMMAGARD LIQUID with rHuPH20.

### ***HYLENEX Partnership***

HYLENEX is a human recombinant formulation of rHuPH20 that, when injected under the skin, facilitates the absorption and dispersion 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 the active pharmaceutical ingredient for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. 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, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, 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 six issued patents 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

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disclosed to third parties except in specific circumstances. In the case of employees and some other parties, the agreements provide that all inventions conceived by the individual will be our exclusive property. Despite the use of these agreements and our efforts to protect our intellectual property, there will always be a risk of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

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

## **Research and Development Activities**

Our research and development expenses consist primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization and depreciation. We charge all research and development expenses to operations as they are incurred. Over the past two years, our research and development activities were primarily focused on the development of our proprietary product candidates. Our industry is subject to rapid technological advancements, developing industry standards and new product introductions and enhancements. As a result, our success depends, in large part, on our ability to develop and commercialize products.

Our research and development expenditures in fiscal 2008, 2007 and 2006 totaled approximately \$44.2 million, \$20.6 million and \$9.2 million, respectively. Research and development expenditures in fiscal 2008 were primarily related to continued development of our various proprietary product candidates and the manufacturing and production of our rHuPH20 enzyme. Research and development expenditures in fiscal 2007 were primarily related to the manufacturing and production of our rHuPH20 enzyme, and the development of Enhanze Technology, our HYLENEX product and our Chemophase product candidate. Research and development expenditures in fiscal 2006 were primarily related to the development of our Cumulase and HYLENEX products and our Chemophase product candidate. We anticipate that we will incur significant research and development expenses in the future in connection with the development of product candidates.

## **Manufacturing**

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. These manufacturers will produce the active pharmaceutical ingredient used in our products and product candidates under commercial good manufacturing practices for both clinical and commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. These manufacturers, Cook in particular, have limited experience manufacturing our active pharmaceutical ingredient batches, and we rely on their ability to successfully manufacture these batches according to product specifications. In addition, as a result of our contractual obligations to Roche, we will be required to significantly scale up our active pharmaceutical ingredient production at Cook during the next few years. We do not currently have a significant inventory of the active pharmaceutical ingredient used in our products and product candidates, so the ability of these manufacturers to maintain their status as FDA-approved manufacturing facilities and to successfully scale up our active pharmaceutical ingredient production is essential to our corporate strategy.

## **Sales and Marketing**

### ***HYLENEX***

Baxter is responsible for the development and execution of the HYLENEX 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 ongoing to explore the potential of HYLENEX in a variety of medical settings, since limited or no data with HYLENEX exist in conditions for

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which Baxter will market the product. Examples of the trials include the completed INFUSE-Pediatric Rehydration study, completed INFUSE-LR study and completed INFUSE-Morphine study. In addition, Baxter is currently enrolling patients in a second INFUSE-Pediatric Rehydration Study, which is designed to determine the rehydration success rate (efficacy) and safety in children treated with HYLENEX-augmented subcutaneous fluid infusion. Baxter currently has a team of medical science liaisons as well as nurse educators that are engaging in education prior to commercial launch in the pediatric hydration market following publication of related clinical data. We expect the launch of HYLENEX by Baxter in the fourth quarter of 2009.

### ***Cumulase***

Our sales and marketing strategy in the IVF market consists of a multi-channel approach that targets patients, clinicians and suppliers. We have an existing non-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 2008, sales of Cumulase in the European Union and the United States were approximately \$325,000 and \$93,000, respectively.

### **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>, Amphastar Pharmaceuticals, Inc., with a bovine hyaluronidase, Amphadase<sup>™</sup>, and Primapharm, Inc. also with a bovine hyaluronidase, Hydase<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 these 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.

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

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

Phase II 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 III studies involve large, well-controlled investigations in diseased subjects and are aimed at verifying the safety and effectiveness of the drug.

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

The FDA's Center for Drug Evaluation and Research, or CDER, must approve an NDA for a drug before it may be marketed in the United States. If we begin to market our proposed products for commercial sale in the U.S., any manufacturing operations that may be established in or outside the United States will also be subject to rigorous regulation, including compliance with 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 \$5,000,000 per incident and \$5,000,000 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.

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### **Employees**

As of February 28, 2009, we had 129 full-time employees, including 91 engaged in research and clinical development activities. Included in our total headcount are 43 employees who hold Ph.D. or M.D. degrees. We currently anticipate hiring approximately 10 additional employees by the end of 2009. 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.***

We have generated only minimal revenue from product sales, licensing fees and milestone payments to date and may never generate significant revenues from future product sales, licensing fees and milestone payments. Even if we do achieve significant revenues from product sales, licensing fees and/or milestone payments, we expect to incur significant operating losses over the next few years. We have never been profitable, and we may never become profitable. Through December 31, 2008, we have incurred aggregate net losses of approximately \$113.6 million.

***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.

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

We have existing supply agreements with contract manufacturing organizations Avid and Cook to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. These manufacturers will produce the active pharmaceutical ingredient used in our products and product candidates under cGMP for both clinical and commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. These manufacturers have limited experience manufacturing our active pharmaceutical ingredient batches, and we rely on their ability to successfully manufacture these batches according to product specifications. In addition, as a result of our contractual obligations to Roche, we will be required to significantly scale up our active pharmaceutical ingredient production at Cook during the next few years. We do not currently have a significant inventory of the active pharmaceutical ingredient used in our products and product candidates, so if these manufacturers do not maintain their status as FDA-approved manufacturing facilities, are unable to successfully scale up our active pharmaceutical ingredient production, or are unable to manufacture the active pharmaceutical ingredient used in our



products and product candidates according to product specifications for any other reason, the commercialization of our products and the development of our product candidates will be delayed and our business will be adversely affected. We have not yet established, and may not be able to establish, favorable arrangements with additional manufacturers for these ingredients or products should the existing supplies become unavailable or in the event that our existing contract manufacturers are unable to adequately perform their responsibilities. Any delays or interruptions in the supply of materials by Avid and/or Cook could cause the delay of

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clinical trials and could delay or prevent the commercialization of product candidates that may receive regulatory approval. Such delays would likely damage our relationship with our partners under our key collaboration agreements. Lastly, such delays or interruptions would have a material adverse effect on our business and financial condition.

***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. We are currently in the process of developing our sales, marketing and distribution capabilities. However, our current capabilities in these areas 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.

For example, the resources dedicated by Baxter to the sales and marketing of HYLENEX have not met our expectations to date and we believe that Baxter's resource allocation has resulted in disappointing sales for HYLENEX. There can be no assurances, despite representations made to us by Baxter, that the resources will be increased to a level we believe to be appropriate.

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

We rely on third parties to 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 economically 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. For example, we previously entered into an agreement with another third party to prepare, fill, finish and package Cumulase, but that third party did not meet the manufacturing, technical and cost targets that were originally established and, as a result, we terminated our agreement with that third party. We currently utilize a subsidiary of Baxter to prepare, fill, finish and package HYLENEX under a development and supply agreement. Baxter has only limited experience manufacturing HYLENEX batches, and 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.



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***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 approval is extensive, time-consuming and costly, and there is no guarantee that the FDA will approve any 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 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 FDA 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. 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;

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 contract manufacturers or 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 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

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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 FDA 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 no internal manufacturing capabilities and are, and expect to be in the future, entirely dependent on contract manufacturers and suppliers for the manufacture of our products and for their active and other ingredients. The disqualification of these manufacturers and suppliers through their failure to comply with regulatory requirements could negatively impact our business because the delays and costs in obtaining and qualifying alternate suppliers (if such alternative suppliers are available, which we cannot assure) could delay clinical trials or otherwise inhibit our ability to bring approved products to market, which would have a material adverse effect on our business and financial condition.

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

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

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

product seizure; or

injunctions or the imposition of civil or criminal penalties.

***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

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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.

***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.

Currently, warrants to purchase approximately 1.9 million shares of our common stock are outstanding and this amount of outstanding warrants may make us a less desirable candidate for investment for some potential investors. 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 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 proprietary or partnered product candidates are approved by 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;

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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 product label approved by the FDA;

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

the introduction of generic competitors.

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 the FDA and these restrictions may limit the marketing and promotion of the ultimate products. If the approved labels are restrictive, the sales and marketing efforts for these products may be negatively affected.

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

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

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

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our relatively small staff size relative to the number of programs currently under development, we depend substantially on our ability to hire, train, retain and motivate 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.

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

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

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

***Future sales of shares of our common stock upon the exercise of currently outstanding securities or pursuant to our universal shelf registration statement may negatively affect our stock price.***

As a result of our October 2004 financing transaction, we issued warrants for the purchase of approximately 2.7 million shares of common stock at a purchase price of \$2.25 per share. Currently, approximately 1.9 million shares of common stock remain issuable upon the exercise of these warrants. The exercise of these warrants could result in dilution to stockholders at the time of exercise which could negatively affect our stock price.

We currently have the ability to offer and sell up to \$50.0 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.

***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, 2008 were \$8.26 and \$2.60, 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:

our failure, or the failure of one of our third party partners, to comply with the terms of our collaboration agreements;

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

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

general negative conditions in the healthcare industry;

general negative conditions in the financial markets;

the failure, for any reason, to obtain FDA 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;

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our failure, or the failure of our third party partners, to successfully commercialize products approved by 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; and

the departure of key personnel.

***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.

***The exercise of outstanding warrants may drive down the market price of our stock.***

Outstanding warrants that may be exercised for approximately 1.9 million shares of common stock will expire per their terms in October 2009. Some warrant holders may choose to sell outstanding shares of common stock in order to finance the exercise of their warrants and this pattern of selling may result in a reduction of our common stock's market price.

## **Risks Related To Our Industry**

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

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

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

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

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***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 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. 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, 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 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

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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 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.

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

Our proprietary and partnered products have numerous competitors in the United States and abroad including, among others, major pharmaceutical and specialized biotechnology firms, universities and other research institutions that have developed competing products. For example, for HYLENEX, such competitors include, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc., Amphastar Pharmaceuticals, Inc. and Primapharm, Inc. among others. For our Insulin-PH20 product candidate, such competitors include Bidel 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 51,500 square feet of office and research space for a monthly rent expense of approximately \$114,000, 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 litigation relating to claims arising out of operations in the normal course of our business. Any of these claims could subject us to costly litigation 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 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 results of operations or financial position.

**Item 4. *Submission of Matters to a Vote of Security Holders***

Not applicable.

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

Since May 10, 2007, our common stock has traded on the NASDAQ Stock Market under the symbol HALO. During the period from January 1, 2007 to May 9, 2007, our common stock traded under the symbol HTI on The American Stock Exchange (the AMEX). 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:

	2008		2007	
	High	Low	High	Low
First Quarter	\$ 7.25	\$ 4.19	\$ 9.70	\$ 6.75
Second Quarter	\$ 6.62	\$ 4.75	\$ 11.00	\$ 8.00
Third Quarter	\$ 8.26	\$ 5.35	\$ 10.50	\$ 7.49
Fourth Quarter	\$ 7.29	\$ 2.60	\$ 9.46	\$ 6.00

On February 27, 2009, the closing sales price of our common stock on the NASDAQ Stock Market was \$4.43 per share. As of February 27, 2009, 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.

**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 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 57-month 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 March 12, 2004 to December 31, 2008. The historical stock price performance included in this graph is not necessarily indicative of future stock price performance.

**COMPARISON OF 57 MONTH CUMULATIVE TOTAL RETURN\***  
Among Halozyme Therapeutics, Inc., The NASDAQ Composite Index  
And The NASDAQ Biotechnology Index

\* \$100 invested on March 12, 2004 in stock or on February 29, 2004 in index-including reinvestment of dividends. Fiscal year ending December 31.

	3/04	12/04	12/05	12/06	12/07	12/08
<b>Halozyme Therapeutics, Inc.</b>	<b>\$ 100.00</b>	<b>\$ 53.01</b>	<b>\$ 43.86</b>	<b>\$ 193.98</b>	<b>\$ 171.33</b>	<b>\$ 134.94</b>
<b>NASDAQ Composite</b>	<b>\$ 100.00</b>	<b>\$ 107.97</b>	<b>\$ 110.72</b>	<b>\$ 124.09</b>	<b>\$ 135.48</b>	<b>\$ 78.93</b>
<b>NASDAQ Biotechnology</b>	<b>\$ 100.00</b>	<b>\$ 103.56</b>	<b>\$ 120.50</b>	<b>\$ 120.06</b>	<b>\$ 122.08</b>	<b>\$ 112.72</b>

**Recent Sales of Unregistered Securities**

During the quarter ended December 31, 2008, holders of various outstanding warrants exercised their rights to purchase 391,308 common shares for gross proceeds of approximately \$429,000. 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, 2008 and 2007, and for the fiscal years ended December 31, 2008, 2007 and 2006, 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, 2006, 2005 and 2004, and for the fiscal years ended December 31, 2005 and 2004, 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,				
	2008	2007	2006	2005	2004
Total revenues	\$ 8,764,139	\$ 3,799,521	\$ 981,746	\$ 127,209	\$
Net loss	(48,654,199)	(23,896,183)	(14,751,986)	(13,275,373)	(9,091,376)
Net loss per share, basic and diluted	\$ (0.61)	\$ (0.32)	\$ (0.24)	\$ (0.26)	\$ (0.26)
Shares used in computing net loss per share, basic and diluted	79,843,707	74,317,930	62,610,265	50,317,021	35,411,127

Balance Sheet Data:	As of December 31,				
	2008	2007	2006	2005	2004
Cash and cash equivalents	\$ 63,715,906	\$ 97,679,085	\$ 44,189,403	\$ 19,132,194	\$ 16,007,714
Working capital	59,794,370	92,312,937	41,343,010	17,802,804	14,566,209
Total assets	76,562,713	103,460,374	46,091,320	20,510,255	16,403,671
Deferred revenues	49,448,456	39,269,491	19,981,537	254,138	
Total liabilities	61,182,717	45,692,450	23,010,085	2,303,368	1,579,413
Stockholders' equity	15,379,996	57,767,924	23,081,235	18,206,887	14,824,258

**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 tissues throughout the body, such as skin and bone. Our 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 digests HA to temporarily break down the gel, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. Our proprietary technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones. Our technology may be utilized for the development of our own proprietary products and it may also be applied to existing and developmental products of third parties through key partnerships.



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Our operations to date have been limited to 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. Over the last year, we increased our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have five programs in various stages of research and development, including three programs in clinical development. We also have three partnered programs. Our key partnerships are 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 and with Baxter Healthcare Corporation, or Baxter, to apply Enhanze Technology to Baxter's biological therapeutic compound, GAMMAGARD LIQUID™. We have two marketed products: HYLENEX, a registered trademark of Baxter International, Inc., a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, we have only limited revenue from the sales of HYLENEX and Cumulase, in addition to 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 \$113.6 million as of December 31, 2008.

We currently have an effective universal shelf registration statement which allows us to offer and sell up to \$50.0 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 Roche Partnership. 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 collaboration. Under the terms of the Roche Partnership, we were obligated to scale up the production of rHuPH20 and to identify a second source manufacturer that would help meet anticipated production obligations arising from the partnership. To that end, during 2008, we 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 we are required to deliver under the terms of the Roche Partnership. The technology transfer was completed in 2008 with scale-up and clinical supply manufacturing planned for 2009.

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. 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. In December 2008, we announced that Roche elected to add a fourth exclusive target to the three original exclusive targets, and we previously announced the commencement of Phase I clinical trials for products directed at two of these four exclusive targets. Roche retains the option to exclusively develop and commercialize rHuPH20 with an additional nine targets through the payment of annual license maintenance fees.

#### ***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

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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 III clinical trial for GAMMAGARD LIQUID with rHuPH20.

### ***HYLENEX Partnership***

HYLENEX is a human recombinant formulation of rHuPH20 that, when injected under the skin, facilitates the absorption and dispersion 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 the active pharmaceutical ingredient for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. 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, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, 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 payment 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.

During 2006 and 2007, we entered into the Roche Partnership, the HYLENEX Partnership and the Gammagard Partnership. Elements of these partnerships include nonrefundable license fees, reimbursements of research and development services, various clinical, regulatory or sales milestones and future product-based or royalty payments, as applicable. Due to our ongoing involvement obligations under these partnerships, we recorded the nonrefundable license fees 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, and the API for HYLENEX.

*Research and Development.* 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 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 2008, we have incurred research and development expenses of \$93.1 million. From 2006 through 2008, approximately 11% of our research and development expenses were associated with the research and development of our recombinant human PH20 enzyme used in our HYLENEX

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product, and approximately 11% and 8% of our research and development expenses were associated with the development of our PEGPH20 and Insulin-PH20 product candidates, respectively. Due to the uncertainty in obtaining FDA approval, 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 substantially if we are able to advance our product candidates 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 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. We anticipate continued increases in SG&A expenses as our operations continue to expand.

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

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

### ***Revenue Recognition***

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

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. 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 sale of Cumulase are recognized when the transfer of ownership occurs, which is upon shipment to the distributors. We are obligated to accept returns for product that does not meet product

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specifications. Historically, we have not had any product returns; therefore, no allowance for product returns has been established.

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. Through February 2009, Baxter has prepaid \$10.0 million of product-based payments which has been deferred and is being recognized as earned.

### *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 account for share-based awards exchanged for employee services in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, which we adopted effective January 1, 2006, including the provisions of the SAB No. 107 and 110. We use the fair value method to account for share-based payments with a modified prospective application which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of SFAS No. 123R apply to new awards and awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods were not revised for comparative purposes.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model, or Black-Scholes model, that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on the historical volatility of our common stock 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%. SFAS No. 123R requires forfeitures to be 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 and those of our peer group.



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If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods, the share-based compensation expense that we record under SFAS No. 123R 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 under SFAS No. 123R. 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 SFAS No. 123R and SAB No. 107 and 110 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. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the U.S. Food and Drug Administration or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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

### ***Inventory***

Inventory consists of our Cumulase product and our API for HYLENEX. Inventory primarily represents raw materials used in production, work in process and finished goods inventory on hand, valued at actual cost. Inventory is reviewed periodically for slow-moving or obsolete items. If a launch of a new product is delayed, inventory may

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not be fully utilized and could be subject to impairment, at which point we would record a reserve to adjust inventory to its net realizable value.

### ***Fair Value Measurements***

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, and FASB Staff Position, or FSP, No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. FSP No. FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The adoption of SFAS No. 157 and FSP No. FAS 157-3 did not have a material impact on our consolidated financial position or results of operations.

SFAS 157 prioritizes the inputs used in measuring fair value into the following hierarchy:

- 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 and cash equivalents of approximately \$63.7 million at December 31, 2008 are carried at fair value based on quoted market prices for identical securities (Level 1 inputs).

Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting SFAS No. 159, we did not elect the fair value option for any of our financial assets or financial liabilities.

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, 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. 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. Such reimbursements are for research and development services rendered by us at the request of Baxter

and Roche 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 \$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

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of HYLENEX and the API for HYLENEX. Based upon representations made to us by Baxter regarding the 2009 launch of HYLENEX, we expect product sales to increase in future periods due to increased HYLENEX sales.

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

**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. We expect SG&A expenses to increase in future periods as we continue to expand our operations.

**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.

**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.

***Comparison of Years Ended December 31, 2007 and 2006***

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements were approximately \$3.2 million for the year ended December 31, 2007 compared to \$311,000 for the year ended December 31, 2006.

Revenues under collaborative agreements primarily consisted of the amortization of upfront fees received from Baxter and Roche of approximately \$1.9 million and \$81,000 in 2007 and 2006, respectively. Revenues under collaborative agreements also included reimbursements for research and development services from Baxter and Roche of \$1.3 million and \$230,000 in 2007 and 2006, respectively.

**Product Sales** Product sales were \$640,000 for the year ended December 31, 2007 compared to \$671,000 for the year ended December 31, 2006, a decrease of \$31,000, or 5%. Cumulative product sales were \$516,000 and

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\$342,000 in 2007 and 2006, respectively. Sales of the API for HYLENEX decreased by \$205,000 resulting from the disposition by Baxter of short-dated HYLENEX vials in 2006.

**Cost of Sales** Cost of sales were \$240,000 for the year ended December 31, 2007 compared to \$437,000 for the year ended December 31, 2006, a decrease of \$197,000, or 45%. The decrease was primarily due to the decrease in sales of the API for HYLENEX resulting from the disposition by Baxter of short-dated HYLENEX vials in 2006.

**Research and Development** Research and development expenses were \$20.6 million for the year ended December 31, 2007 compared to \$9.2 million for the year ended December 31, 2006. The increase of approximately \$11.4 million was primarily due to the increase in outsourced research and development expenses of \$6.2 million due to our various preclinical programs and the manufacturing scale-up of our rHuPH20 enzyme. In addition, compensation costs increased by \$2.8 million, of which \$238,000 related to share-based compensation. At December 31, 2007, our headcount for research and development functions totaled 56 employees, compared with 25 employees at December 31, 2006. Additionally, our facilities expenses increased by \$1.3 million, research supplies and services expenses increased by \$740,000 and depreciation expense increased by \$281,000.

**Selling, General and Administrative** SG&A expenses were \$11.2 million for the year ended December 31, 2007 compared to \$6.9 million for the year ended December 31, 2006. The increase of approximately \$4.3 million was primarily due to the increase in compensation costs of \$2.5 million, of which \$1.1 million related to share-based compensation. At December 31, 2007, our headcount for SG&A functions totaled 27 employees, compared with 11 employees at December 31, 2006. In addition, other increases included an increase in legal expenses, primarily related to intellectual property matters and collaborative agreements, of \$554,000 and an increase in facilities expenses of \$367,000.

**Share-Based Compensation** Total compensation cost for our share-based payments was \$2.6 million for the year ended December 31, 2007 compared to \$1.3 million for the year ended December 31, 2006. Research and development expense included share-based compensation of approximately \$663,000 and \$424,000, respectively, for the years ended December 31, 2007 and 2006. SG&A expenses included share-based compensation of approximately \$1.9 million and \$850,000, respectively, for the years ended December 31, 2007 and 2006.

**Interest Income** Interest income was \$4.3 million for the year ended December 31, 2007 compared to \$831,000 for the year ended December 31, 2006. The increase in interest income was due to higher average cash and cash equivalents balances during 2007.

**Net Loss** Net loss for the year ended December 31, 2007 was \$23.9 million, or \$0.32 per common share, compared to \$14.8 million, or \$0.24 per common share for the year ended December 31, 2006. The increase in net loss was primarily due to an increase in operating expenses, partially offset by increases in revenues and interest income.

## **Liquidity and Capital Resources**

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2008, we had cash and cash equivalents of approximately \$63.7 million. We expect our cash requirements to increase as we continue to increase our research and development for, seek regulatory approvals of, and develop and manufacture our current product candidates. As we expand our research and development efforts and pursue additional product opportunities, we anticipate additional cash requirements for hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure. The amount and timing of cash requirements will depend on the research, development, manufacture, regulatory and market acceptance of our product candidates, if any, and the resources we devote to researching, developing, manufacturing, commercializing and supporting our product candidates.

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 net cash burn of approximately \$30.0 to \$35.0 million for the year ending December 31, 2009, 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



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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 November 2008, we filed a shelf registration statement on Form S-3 (Registration No. 333-155787) which initially allowed us, from time to time, to offer and sell up to \$50.0 million of equity or debt securities. We cannot be certain that our existing cash and cash equivalents will be adequate for our anticipated needs or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds will require us to delay, scale back or eliminate some or all of our research and development programs or delay the launch of our product candidates. 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 and specific financial ratios that may restrict our ability to operate our business.

### ***Operating Activities***

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.

Net cash used in operations was \$148,000 during the year ended December 31, 2007 compared to \$7.1 million of cash provided by operations during the year ended December 31, 2006. This change was primarily due to the \$9.1 million increase in the total net loss for 2007 as compared to 2006.

### ***Investing Activities***

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.

Net cash used in investing activities was \$2.4 million during the year ended December 31, 2007 compared to \$365,000 during the year ended December 31, 2006. This was due to an increase in purchases of property and equipment during 2007.

### ***Financing Activities***

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.

Net cash provided by financing activities was \$56.0 million during the year ended December 31, 2007 versus \$18.3 million during the year ended December 31, 2006. Net cash provided by financing activities during 2006 primarily consisted of approximately \$11.0 million in proceeds, net of issuance costs, from sales of our common stock and approximately \$7.3 million in proceeds from warrant and stock option exercises.

*Off-Balance Sheet Arrangements* As of December 31, 2008, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we did not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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*Contractual Obligations* As of December 31, 2008, future minimum payments due under our contractual obligations are as follows:

<b>Contractual Obligations:</b>	<b>Total</b>	<b>Payments Due by Period</b>			<b>More than 5 Years</b>
		<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	
Operating leases	\$ 9,945,275	\$ 2,350,130	\$ 4,936,207	\$ 2,658,938	\$
License payments	2,435,000	480,000	610,000	610,000	735,000
Purchase obligations(1)	15,352,737	15,352,737			
<b>Total</b>	<b>\$ 27,733,012</b>	<b>\$ 18,182,867</b>	<b>\$ 5,546,207</b>	<b>\$ 3,268,938</b>	<b>\$ 735,000</b>

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

As of December 31, 2008, we had no long-term debt or capital lease obligations.

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

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

the number and scope of our research activities;

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

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

the effect of competing technological and market developments;

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

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

**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 intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds 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, 2008, 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.

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

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

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

None.

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

**Evaluation of Disclosure Controls and Procedures**

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

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

**Changes in Internal Control Over Financial Reporting**

There have been no significant changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2008, 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.

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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, 2008. 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, 2008, 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, 2008. The report appears below.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Halozyme Therapeutics, Inc.

We have audited Halozyme Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2008, 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, 2008, 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, 2008 and 2007, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2008 and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 11, 2009





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

None.

**PART III**

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

The information required by this item regarding directors is incorporated by reference to our Definitive Proxy Statement (the Proxy Statement) to be filed with the Securities and Exchange Commission in connection with our 2009 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. (37)*, 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 \$180 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 130 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. (37)*, Vice President, Chief Scientific Officer and Director. Dr. Frost co-founded Halozyme in 1999 and has spent more than fourteen years conducting research on the hyaluronidase family of enzymes. From 1998 to 1999, he was a Senior Research Scientist at the Sidney Kimmel Cancer Center (SKCC), where he focused much of his work on developing the hyaluronidase technology. Prior to SKCC, 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 hyaluronidase field and is an inventor on several key patents. Dr. Frost's prior experience includes serving as a scientific consultant to a number of biopharmaceutical companies, including Q-Med AB, BioPhausia AB and Active Biotech AB. 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, where he was an Achievement Rewards for College Scientists Scholar.

*David A. Ramsay, MBA (44)*, Vice President, Chief Financial Officer. Mr. Ramsay joined Halozyme in 2003. 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

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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.

*Robert L. Little (59)*, 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 Zoloft® 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 U.K., Italy, and the U.S. Mr. Little earned his degree in economics and finance from the West London Business School, Ealing Technical College.

*William J. Fallon (52)*, Vice President, Manufacturing & Operations. Mr. Fallon joined Halozyme in 2006 as Vice President, Manufacturing & Operations. His responsibilities include oversight of all aspects of internal and external manufacturing and facilities operations, as well as bioprocess development. Prior to Halozyme, he served as President and Chief Executive Officer of Cytovance Biologics, a contract manufacturing organization that provides manufacturing and development services to the biotechnology industry. From 2001 to 2003, he was Vice President of Technical Operations at Genzyme Corporation, having held the same position at Novazyme Pharmaceuticals, Inc. prior to its acquisition by Genzyme in 2001. Mr. Fallon joined Novazyme from Transkaryotic Therapies, where he was Vice President of Manufacturing from 1998 to 2001. From 1993 to 1998, he was employed in several management positions for the Ares-Serono Group, including Vice President, U.S. Manufacturing Operations. In this role, he served as general manager, overseeing the production and distribution of all of Serono's approved biotechnology products in the U.S. 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.

**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.

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

The 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.

**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 Ernst &amp; Young LLP</u>	F-1
<u>Consolidated Balance Sheets at December 31, 2008 and 2007</u>	F-2
<u>Consolidated Statements of Operations for Each of the Years Ended December 31, 2008, 2007 and 2006</u>	F-3
<u>Consolidated Statements of Cash Flows for Each of the Years Ended December 31, 2008, 2007 and 2006</u>	F-4
<u>Consolidated Statements of Stockholders Equity for Each of the Years Ended December 31, 2008, 2007 and 2006</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(20)
- 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(9)
- 10.3\* Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005(7)
- 10.4\* First Amendment to the Commercial Supply Agreement between Avid Bioservices, Inc. and Registrant, dated December 15, 2006(14)
- 10.5\* Clinical Supply Agreement between Cook Pharmica, LLC and Registrant, dated August 15, 2008(24)
- 10.6 Form of Common Stock Purchase Warrant(5)
- 10.7# DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder(6)
- 10.8 Nonstatutory Stock Option Agreement With Andrew Kim(6)
- 10.9# 2004 Stock Plan and Form of Option Agreement thereunder(4)
- 10.10# Halozyyme Therapeutics, Inc. 2005 Outside Directors Stock Plan(8)

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- 10.11# Form of Stock Option Agreement (2005 Outside Directors Stock Plan)(12)
- 10.12# Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan)(12)
- 10.13# Halozyme Therapeutics, Inc. 2006 Stock Plan(11)
- 10.14# Form of Stock Option Agreement (2006 Stock Plan)(12)
- 10.15# Form of Restricted Stock Agreement (2006 Stock Plan)(12)
- 10.16# Halozyme Therapeutics, Inc. 2008 Stock Plan(21)

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10.17#	Halozyyme Therapeutics, Inc. 2008 Outside Directors Stock Plan(21)
10.18#	Form of Indemnity Agreement for Directors and Executive Officers(19)
10.19#	Outside Director Compensation Plan(23)
10.20#	2007 Senior Executive Incentive Plan(23)
10.21#	2008 Senior Executive Incentive Structure(22)
10.22#	2009 Senior Executive Incentive Plan(25)
10.23#	Change in Control Policy(22)
10.24#	Severance Policy(23)
10.25*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(15)
10.26*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(15)
10.27*	License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(15)
10.28*	Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007(18)
10.29*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(13)
10.30	Stock Purchase Agreement between New River Management V, LP and Registrant, dated April 23, 2007(16)
10.31	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(17)
10.32	Sublease Agreement (11388 Sorrento Valley Road), effective as of July 2, 2007(17)
10.33	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(17)
21.1	Subsidiaries of Registrant(10)
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) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed October 15, 2004.
- (6) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the Commission on October 26, 2004.



- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 22, 2005.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed July 6, 2005.
- (9) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2006.
- (10) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.
- (11) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.

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

\* 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.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on March 13, 2009.

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 13, 2009

**POWER OF ATTORNEY**

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Jonathan E. Lim and David A. Ramsay, 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 13, 2009
/s/ David A. Ramsay David A. Ramsay	Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2009
/s/ Gregory I. Frost, Ph.D. Gregory I. Frost, Ph.D.	Vice President and Chief Scientific Officer, Director	March 13, 2009
/s/ Kenneth J. Kelley	Chairman of the Board of Directors	March 13, 2009

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Kenneth J. Kelley

/s/ Kathryn E. Falberg

Director

March 13, 2009

Kathryn E. Falberg

/s/ Randal J. Kirk

Director

March 13, 2009

Randal J. Kirk

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<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Connie L. Matsui Connie L. Matsui	Director	March 13, 2009
/s/ John S. Patton, Ph.D. John S. Patton, Ph.D.	Director	March 13, 2009
/s/ Steven T. Thornton Steven T. Thornton	Director	March 13, 2009

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Halozyme Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Halozyme Therapeutics, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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, 2008, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
March 11, 2009

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 63,715,906	\$ 97,679,085
Accounts receivable	7,264,410	779,825
Inventory	441,323	703,468
Prepaid expenses and other assets	2,591,149	2,014,680
 Total current assets	 74,012,788	 101,177,058
Property and equipment, net	2,549,925	2,283,316
 Total Assets	 \$ 76,562,713	 \$ 103,460,374
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,668,791	\$ 3,055,637
Accrued expenses	3,995,897	2,502,259
Deferred revenue	3,553,730	3,306,225
 Total current liabilities	 14,218,418	 8,864,121
Deferred revenue, net of current portion	45,894,726	35,963,266
Deferred rent, net of current portion	1,069,573	865,063
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; 81,553,654 and 77,903,944 shares issued and outstanding at December 31, 2008 and 2007, respectively	81,554	77,904
Additional paid-in capital	128,948,064	122,685,443
Accumulated deficit	(113,649,622)	(64,995,423)
 Total stockholders' equity	 15,379,996	 57,767,924
 Total Liabilities and Stockholders' Equity	 \$ 76,562,713	 \$ 103,460,374

See accompanying notes to consolidated financial statements.

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

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>REVENUES:</b>			
Revenues under collaboration agreements	\$ 8,052,202	\$ 3,159,931	\$ 311,121
Product sales	711,937	639,590	670,625
Total revenues	8,764,139	3,799,521	981,746
<b>OPERATING EXPENSES:</b>			
Cost of product sales	332,324	240,429	436,990
Research and development	44,232,936	20,554,105	9,214,759
Selling, general and administrative	14,633,581	11,155,194	6,912,853
Total operating expenses	59,198,841	31,949,728	16,564,602
<b>OPERATING LOSS</b>	<b>(50,434,702)</b>	<b>(28,150,207)</b>	<b>(15,582,856)</b>
Interest income	1,717,503	4,254,024	830,870
<b>NET LOSS BEFORE INCOME TAXES</b>	<b>(48,717,199)</b>	<b>(23,896,183)</b>	<b>(14,751,986)</b>
Income tax benefit	(63,000)		
<b>NET LOSS</b>	<b>\$ (48,654,199)</b>	<b>\$ (23,896,183)</b>	<b>\$ (14,751,986)</b>
Basic and diluted net loss per share	\$ (0.61)	\$ (0.32)	\$ (0.24)
Shares used in computing basic and diluted net loss per share	79,843,707	74,317,930	62,610,265

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>2008</b>	<b>2007</b>	<b>2006</b>
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (48,654,199)	\$ (23,896,183)	\$ (14,751,986)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Share-based compensation	3,695,842	2,580,204	1,274,567
Depreciation and amortization	1,047,878	576,491	243,999
Loss on disposal of equipment	4,729	3,289	4,278
Issuance of stock options for services			9,322
Changes in operating assets and liabilities:			
Accounts receivable	(6,484,585)	(416,260)	13,802
Inventory	262,145	(260,976)	(163,534)
Prepaid expenses and other assets	(576,469)	(1,416,590)	(257,602)
Accounts payable and accrued expenses	4,788,346	2,529,348	979,318
Deferred rent	363,484	865,063	
Deferred revenue	10,178,965	19,287,954	19,727,399
Net cash (used in) provided by operating activities	(35,373,864)	(147,660)	7,079,563
<b>INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(1,159,744)	(2,365,326)	(364,799)
Net cash used in investing activities	(1,159,744)	(2,365,326)	(364,799)
<b>FINANCING ACTIVITIES:</b>			
Proceeds from exercise of warrants, net	1,726,713	2,305,843	7,142,469
Proceeds from exercise of stock options, net	843,716	1,707,337	156,114
Proceeds from issuance of common stock, net		51,989,488	11,043,862
Net cash provided by financing activities	2,570,429	56,002,668	18,342,445
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(33,963,179)</b>	<b>53,489,682</b>	<b>25,057,209</b>
<b>CASH AND CASH EQUIVALENTS at beginning of period</b>	<b>97,679,085</b>	<b>44,189,403</b>	<b>19,132,194</b>
<b>CASH AND CASH EQUIVALENTS at end of period</b>	<b>\$ 63,715,906</b>	<b>\$ 97,679,085</b>	<b>\$ 44,189,403</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Accounts payable for purchases of property and equipment	\$ 159,472	\$	\$

See accompanying notes to consolidated financial statements.

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**Table of Contents****HALOZYME THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**Years Ended December 31, 2008, 2007 and 2006**

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Stockholders</b>
			<b>Capital</b>		<b>Equity</b>
BALANCE AT JANUARY 1, 2006	60,246,997	\$ 60,247	\$ 44,493,894	\$ (26,347,254)	\$ 18,206,887
Share-based compensation expense			1,274,567		1,274,567
Issuance of common stock for cash, net	3,385,000	3,385	11,040,477		11,043,862
Issuance of common stock pursuant to exercise of warrants, net	4,818,846	4,819	7,137,650		7,142,469
Issuance of common stock pursuant to exercise of stock options	196,150	196	155,918		156,114
Issuance of restricted stock awards	90,000	90	(90)		
Issuance of stock options to consultants for services			9,322		9,322
Net loss				(14,751,986)	(14,751,986)
BALANCE AT DECEMBER 31, 2006	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)
BALANCE AT DECEMBER 31, 2007	77,903,944	77,904	122,685,443	(64,995,423)	57,767,924
Share-based compensation expense			3,695,842		3,695,842
	1,628,374	1,628	1,725,085		1,726,713

Issuance of common stock pursuant to exercise of warrants, net					
Issuance of common stock pursuant to exercise of stock options	1,828,836	1,829	841,887		843,716
Issuance of restricted stock awards	192,500	193	(193)		
Net loss				(48,654,199)	(48,654,199)
 BALANCE AT DECEMBER 31, 2008	 81,553,654	 \$ 81,554	 \$ 128,948,064	 \$ (113,649,622)	 \$ 15,379,996

See accompanying notes to consolidated financial statements.

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**Halozyme Therapeutics, Inc.**

**Notes to Consolidated Financial Statements**

**1. Organization and Business**

Halozyme Therapeutics, Inc. ( Halozyme or the Company ) is a biopharmaceutical company dedicated to 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 been limited to 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 s key partnerships are 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 and with Baxter Healthcare Corporation ( Baxter ), to apply Enhance Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUID™. The Company has two marketed products: HYLENEX, a registered trademark of Baxter International, Inc., a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, the Company has only limited revenue from the sales of HYLENEX and Cumulase, in addition to 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.

The Company has restricted certificates of deposits totaling \$675,000 and \$400,000 as of December 31, 2008 and 2007, respectively. These restricted deposits represent amounts pledged to the Company s bank as collateral for letters of credit issued in connection with certain of the Company s real estate lease agreements and are included in cash and cash equivalents. The lease agreements expire in January 2013.

***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 99% and 91% of the accounts receivable balance as of December 31, 2008 and 2007, respectively, represents amounts due from two customers.

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**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, 2008 and 2007. For the years ended December 31, 2008, 2007 and 2006, 51%, 36% and 55% of total revenues were from Baxter and 44%, 50% and 10% were from Roche, 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 39% and 20% of the accounts payable balance at December 31, 2008 and 2007, 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 are 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 the impairment and disposition of long-lived assets in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. In accordance with SFAS No. 144, long-lived assets are reviewed for events of changes in circumstances, which indicate that their carrying value may not be recoverable. At December 31, 2008, there has been no impairment of the value of such assets.

***Fair Value of Financial Instruments***

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

***Fair Value Measurements***

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, and FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. FSP No. FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a

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**Halozyme Therapeutics, Inc.**

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

financial asset when the market for that financial asset is not active. The adoption of SFAS No. 157 and FSP No. FAS 157-3 did not have a material impact on the Company's consolidated financial position or results of operations.

SFAS No. 157 prioritizes the inputs used in measuring fair value into the following hierarchy:

- 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 and cash equivalents of approximately \$63.7 million at December 31, 2008 are carried at fair value based on quoted market prices for identical securities (Level 1 inputs).

Effective January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting SFAS No. 159, the Company did not elect the fair value option for any of its financial assets or financial liabilities.

***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 SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. 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 are recognized when the transfer of ownership occurs, which is upon shipment to the distributors. 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 the active pharmaceutical ingredient (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

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**Halozyme Therapeutics, Inc.**

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

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 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, and the API for HYLENEX.

***Research and Development Expenses***

Effective January 1, 2008, the Company adopted Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. EITF Issue No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed or such time when the entity does not expect the goods to be delivered or services to be performed. The adoption of EITF Issue No. 07-3 did not have a material impact on the Company's consolidated financial position or results of operations.

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. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

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

FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)*****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 accounts for share-based awards exchanged for employee services in accordance with SFAS No. 123(R), *Share-Based Payment*. Under SFAS No. 123R, share-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense, net of estimated forfeitures, over the employee's requisite service period and/or performance period.

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 awards are amortized under the straight-line method. 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. SFAS No. 123R 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, 2008, 2007 and 2006 based on the Company's historical experience and those of its peer group.

Total share-based compensation expense related to share-based awards, recognized under SFAS No. 123R, for the years ended December 31, 2008, 2007 and 2006 was comprised of the following:

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Research and development	\$ 1,541,003	\$ 662,690	\$ 424,305
Selling, general and administrative	2,154,839	1,917,514	850,262
Share-based compensation expense before taxes	3,695,842	2,580,204	1,274,567
Related income tax benefits			
Share-based compensation expense	\$ 3,695,842	\$ 2,580,204	\$ 1,274,567

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Net share-based compensation expense, per basic and diluted share	\$ 0.05	\$ 0.03	\$ 0.02
Share-based compensation expense from:			
Stock options	\$ 2,691,571	\$ 1,857,249	\$ 1,136,530
Restricted stock awards	1,004,271	722,955	138,037
	\$ 3,695,842	\$ 2,580,204	\$ 1,274,567

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**Halozyme Therapeutics, Inc.**

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

SFAS No. 123R requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be 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 Company accounts for stock options granted to non-employees in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Under EITF Issue No. 96-18, the Company determines the fair value of the stock options granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The Company recognized approximately \$0, \$0 and \$9,000 in stock-based compensation expense related to stock options granted to non-employees for the years ended December 31, 2008, 2007 and 2006, respectively.

***Income Taxes***

Income taxes are recorded in accordance with SFAS No. 109, *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, SFAS No. 109 requires an evaluation of the probability of being able to realize the future benefits indicated by such assets. 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.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*. Under FIN No. 48, 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, FIN No. 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN No. 48 had no impact on the Company's consolidated financial position or results of operations. At the date of adoption and at December 31, 2008 and 2007, the Company's unrecognized income tax benefits and uncertain tax provisions were not material.

***Net Loss Per Share***

The Company calculates basic and diluted net loss per common share in accordance with SFAS No. 128, *Earnings Per Share*, and SEC Staff Accounting Bulletin (SAB) No. 98. 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,

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unvested stock awards and warrants from the calculation of diluted net loss per common share as of December 31, 2008, 2007 and 2006 because their effect is anti-dilutive:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Stock options and awards	7,447,285	7,914,979	8,727,322
Warrants	3,230,656	4,859,030	6,714,403
	10,677,941	12,774,009	15,441,725

**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.

**Pending Adoption of Recent Accounting Pronouncements**

In December 2007, the FASB ratified EITF Issue No. 07-01, *Accounting for Collaboration Arrangements*, which is focused 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. EITF No. 07-01 is effective for the Company in the first quarter of 2009. The Company does not expect the adoption of EITF No. 07-01 to have a material impact on its consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in connection with business combinations. SFAS 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141(R) is effective for fiscal years beginning on or after December 15, 2008. The Company does not expect the adoption of SFAS 141(R) to have a material effect on its consolidated financial condition and results of operations.

In May 2008, the FASB issued SFAS No. 162, *Hierarchy of Generally Accepted Accounting Principles*. This statement is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement will be effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendment to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS No. 162 to have a material impact on its consolidated financial position or results of operations.

In June 2008, the FASB issued FSP No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities*. FSP No. EITF 03-6-1 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. FSP No. EITF 03-6-1 is effective for the Company in the first quarter of 2009. The Company does not expect the adoption of FSP EITF 03-6-1 to have a material impact on its consolidated financial position or results of operations.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF Issue No. 07-5 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

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

impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF Issue No. 07-5 is effective for the Company in the first quarter of 2009. The Company does not expect the adoption of EITF Issue No. 07-5 to have a material impact on its consolidated financial position or results of operations.

**3. Inventory**

Inventory consists of the following as of December 31, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Raw materials	\$ 435,386	\$ 578,397
Finished goods	5,937	78,677
Work in process		46,394
	\$ 441,323	\$ 703,468

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, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Research equipment	\$ 2,699,706	\$ 1,892,658
Computer and office equipment	1,079,034	789,851
Leasehold improvements	814,067	633,996
	4,592,807	3,316,505
Accumulated depreciation and amortization	(2,042,882)	(1,033,189)
	\$ 2,549,925	\$ 2,283,316

Depreciation and amortization expense was approximately \$1.0 million, \$576,000 and \$244,000, for the years ended December 31, 2008, 2007 and 2006, respectively.

**5. Accrued Expenses**

Accrued expenses consist of the following as of December 31, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Accrued compensation and payroll taxes	\$ 2,060,866	\$ 1,418,313
Accrued outsourced research and clinical trial expenses	1,329,954	424,385
Accrued expenses	605,077	659,561
	<b>\$ 3,995,897</b>	<b>\$ 2,502,259</b>

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**Table of Contents****Halozyme Therapeutics, Inc.****Notes to Consolidated Financial Statements (Continued)****6. Deferred Revenue**

Deferred revenue consists of the following as of December 31, 2008 and 2007:

	<b>2008</b>	<b>2007</b>
Collaborative agreements	\$ 49,273,306	\$ 39,079,524
Product sales	175,150	189,967
Total deferred revenue	49,448,456	39,269,491
Less current portion	3,553,730	3,306,225
Deferred revenue, net of current portion	\$ 45,894,726	\$ 35,963,266

*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. In December 2008, the Company was entitled to receive an aggregate of approximately \$9.3 million from Roche in connection with Roche's selection of a fourth exclusive target and annual designation maintenance fees for the remaining nine Roche targets.

Due to the Company's continuing involvement obligations, revenues from the upfront payment, exclusive designation fees and annual designation 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 maintenance designation fees under the Roche Partnership in the amounts of approximately \$1.2 million, \$1.2 million and \$81,000 for the years ended December 31, 2008, 2007 and 2006, 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, 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 and \$192,000 for the years ended December 31, 2008 and 2007, respectively.

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, 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 and \$516,000 for the years ended

December 31, 2008 and 2007, respectively.

In addition, Baxter will make payments to the Company based on sales of the products covered under the HYLENEX Partnership. Through December 31, 2008, Baxter prepaid a total of \$4.5 million of such product-based payments in connection with the execution of the HYLENEX Partnership. In January 2009, Baxter prepaid another \$5.5 million of such product-based payments. 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* 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

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**Halozyme Therapeutics, Inc.**

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

\$1.06 per share), stock options (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.

In December 2006, the Company issued and sold to an accredited investor, an affiliate of Roche (the *Purchaser*), 3,385,000 shares (the *Shares*) of the Company's common stock at a price of \$3.27 per share, for gross proceeds of approximately \$11.1 million. The *Shares* were sold pursuant to exemptions from registration under Regulation D of the Securities Act. In December 2006, the Company also entered into a registration rights agreement (the *Rights Agreement*) with the *Purchaser*, under which the Company may be required to register the *Shares* upon the occurrence of certain events set forth in the *Rights Agreement*. Such triggering events include, but are not limited to, the registration of shares pursuant to a registration statement not currently in effect. The *Rights Agreement* will terminate at such time as the *Purchaser* may sell the *Shares* in any three-month period pursuant to the provisions of Rule 144 under the Securities Act of 1933, as amended. As of December 31, 2008, the Company had not filed a registration statement with the SEC covering the resale of the *Shares*.

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.

During 2006, the Company issued an aggregate of 5,104,996 shares of common stock in connection with the exercises of stock purchase warrants (4,818,846 shares at a weighted average price of \$1.48 per share), stock options (196,150 shares at a weighted average price of \$0.80 per share) and restricted stock awards (90,000 shares at a price of \$0) for cash in the aggregate amount of approximately \$7.3 million.

*Issuance of Common Stock Options for Services* In 2006, an option to purchase 13,332 shares of the Company's common stock was issued to a consultant for services received and the stock option was valued at approximately \$9,000. These options were fully exercisable and fully vested on the date of grant and shall expire in ten years based on the terms of the options. The fair value of these options was recorded as a noncash stock expense.

*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 are exercisable until October 12, 2009. As of December 31, 2008 and 2007, 1,927,715 and 2,030,572, respectively, of these warrants were outstanding.

In connection with the January 2004 private placement, the Company issued warrants (the Callable Warrants ) to purchase 8,094,829 shares of common stock at an exercise price of \$1.75 per share, as amended. These warrants are exercisable until January 28, 2009 and are callable by the Company under certain conditions. In December 2004, the Company called the first tranche of the Callable Warrants and holders of the Callable Warrants exercised warrants to purchase 1,571,682 shares of common stock at \$1.75 per share, or approximately \$2.7 million in net proceeds. In August 2006, the Company called the second tranche of the Callable Warrants and holders of the Callable Warrants exercised warrants to purchase 2,204,188 shares of common stock at \$1.75 per share, or approximately \$3.9 million in net proceeds. As of December 31, 2008 and 2007, 1,302,941 and 1,634,143, respectively, of the Callable Warrants were outstanding. In January 2009, holders of the Callable Warrants exercised



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**Halozyme Therapeutics, Inc.**

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

warrants to purchase 1,264,866 shares of the common stock for an aggregate of \$2.2 million in proceeds. The remaining Callable Warrants to purchase 38,075 shares of common stock expired on January 28, 2009.

In October 2003, in conjunction with the issuance of the Company's Series C Convertible Preferred Stock (the Series C), the Company granted warrants to purchase 2,367,114 shares of common stock to purchasers of the Series C at an exercise price of \$0.7667 per share. These warrants expired on October 15, 2008. As of December 31, 2008 and 2007, 0 and 1,194,315, 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. In May 2008, the Company's stockholders approved the Company's 2008 Stock Plan, which provides for the grant of up to a total of 5,000,000 shares of common stock (subject to certain limitations as described in the 2008 Stock Plan) to selected employees, consultants and non-employee members of the Company's Board of Directors (Outside Directors) as stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and performance awards. Also in May 2008, the Company's stockholders approved the Company's 2008 Outside Directors Stock Plan, which provides for grants of restricted stock awards up to a total of 600,000 shares of common stock to the Company's Outside Directors.

During the year ended December 31, 2008, the Company granted share-based awards under the 2008 Stock Plan, the 2006 Stock Plan and the 2005 Outside Directors Stock Plan. The Company had an aggregate of 18,225,000 shares of common stock reserved for issuance as of December 31, 2008. Of those shares, 7,254,785 shares were subject to outstanding options and 5,413,554 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, 2008, 2007 and 2006 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, 2006	8,535,751	\$ 1.01		
Granted	577,682	\$ 2.64		
Exercised	(196,150)	\$ 0.80		
Cancelled/forfeited	(279,961)	\$ 1.20		
Outstanding at December 31, 2006	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	6.5	\$ 21.5 million
Vested and expected to vest at December 31, 2008	6,969,104	\$ 2.90	6.4	\$ 21.4 million
Exercisable at December 31, 2008	5,043,244	\$ 1.80	5.5	\$ 20.2 million

The weighted average grant-date fair values of options granted during the years ended December 31, 2008, 2007 and 2006 were \$3.39 per share, \$4.94 per share and \$1.57 per share, respectively. As of December 31, 2008, approximately \$6.1 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 2.8 years. The intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was approximately \$9.9 million, \$13.5 million and \$342,000, respectively. Cash received from stock option exercises for the years ended December 31, 2008, 2007 and 2006 was approximately \$844,000, \$1.7 million and \$156,000, respectively.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ( Black-Scholes model ) that uses the assumptions noted in the following table. Expected volatility is based on historical volatility of the Company's common stock 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>2008</b>	<b>2007</b>	<b>2006</b>
Expected volatility	65.0%	70.0%	75.0%
Average expected term (in years)	5.5	5.0	4.0
Risk-free interest rate	1.26-3.14%	3.5-4.7%	4.6-5.1%
Expected dividend yield	0%	0%	0%

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**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, 2008:

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	
\$0.06 - \$ 0.39	2,499,027	4.8	\$ 0.39	2,499,027	\$ 0.39	
\$0.40 - \$ 2.05	1,608,080	5.4	\$ 1.95	1,540,695	\$ 1.94	
\$2.06 - \$ 5.60	1,872,082	8.0	\$ 4.22	630,582	\$ 3.16	
\$5.61 - \$10.37	1,275,596	8.8	\$ 7.78	372,940	\$ 8.40	
	7,254,785	6.5	\$ 3.02	5,043,244	\$ 1.80	

*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. The Performance Awards will become fully vested only if certain development performance milestone criteria are successfully achieved before October 1, 2009 ( Performance Goal ). If the Performance Goal is not met, the Performance Awards will be terminated and the Company will automatically reacquire the unvested shares for the original purchase price. The Company recognized \$201,000 of share-based compensation expense related to the Performance Awards during the year ended December 31, 2008 as management believes achievement of the Performance Goal is probable at December 31, 2008.

During the years ended December 31, 2008, 2007 and 2006, the Company issued 192,500, 105,000 and 90,000 restricted stock awards, respectively, under the 2008 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, 2008, 2007 and 2006:

Number of Shares	Weighted Average Grant Date Fair Value
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Unvested at January 1, 2006		\$	
Granted	90,000	\$	2.72
Vested		\$	
Forfeited		\$	
Unvested at December 31, 2006	90,000	\$	2.72
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

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**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, 2008 and 2007 was \$1.1 million and \$245,000, respectively. As of December 31, 2008, total unrecognized compensation cost related to unvested shares was \$420,000, which is expected to be recognized over a weighted-average period of 6.5 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 51,500 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 will increase 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 received an allowance for the cost of tenant improvements totaling approximately \$276,000 and received free rent totaling approximately \$794,000, of which approximately \$870,000 and \$625,000 was included in deferred rent as of December 31, 2008 and 2007, respectively. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year has been recorded as an adjustment to deferred rent.

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 \$418,000 and \$299,000 was included in deferred rent as of December 31, 2008 and 2007, respectively. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year has been recorded as an adjustment to deferred rent. 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.

Subsequent to December 31, 2008, 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 2,700 square feet of office and research space for a monthly rent payment of approximately \$6,000. Payment obligations under the Sub-Sublease will commence after certain tenant improvements to these facilities are completed, which is expected to occur in April 2009.

Additionally, the Company leases certain office equipment under operating leases. Total rent expense was approximately \$1.4 million, \$1.1 million and \$297,000 for the years ended December 31, 2008, 2007 and 2006, respectively.



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

Approximate annual future minimum operating lease payments as of December 31, 2008 are as follows:

<b>Year:</b>	<b>Operating Leases</b>
2009	\$ 1,490,000
2010	1,615,000
2011	1,665,000
2012	1,729,000
2013	67,000
Thereafter	
Total minimum lease payments	\$ 6,566,000

*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 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 will assume all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while the Company 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 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. Through December 31, 2008, Baxter prepaid a total of \$4.5 million of such product-based payments. In January 2009, Baxter prepaid another \$5.5 million of such product-based payments. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. The Company will continue to supply Baxter with the API for HYLENEX, and Baxter will fill and finish HYLENEX and hold it for subsequent distribution. In addition, Baxter will obtain 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 (iii) cytotoxic chemotherapeutic agents, the rights to which have been retained



by the Company. Additionally, Baxter will make product-based payments on the sales, if any, of the products that result from the collaboration. 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

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

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 2016, Roche will also have the option to exclusively develop and commercialize rHuPH20 with an additional ten 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 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 with scale-up and clinical supply manufacturing planned for 2009.

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, 2008, 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, 2008 and 2007 are shown below. A valuation allowance of \$49.6 million and \$28.6 million has been established to offset the net deferred tax assets as of December 31, 2008 and 2007, respectively, as realization of such assets is uncertain.

	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	\$ 25,466,000	\$ 15,303,000
Deferred revenue	14,566,000	7,639,000
Research and development credits	7,775,000	4,321,000

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Share-based compensation	929,000	696,000
Depreciation	80,000	95,000
Other, net	743,000	505,000
Total deferred tax assets	49,559,000	28,559,000
Valuation allowance for deferred tax assets	(49,559,000)	(28,559,000)
Net deferred tax assets	\$	\$

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

The provision for income taxes on earnings subject to income taxes differs from the statutory federal income tax rate at December 31, 2008, 2007 and 2006, due to the following:

	2008	2007	2006
Federal income tax rate of 34%	\$ (16,544,000)	\$ (8,125,000)	\$ (5,016,000)
State income tax, net of federal benefit	(2,839,000)	(1,394,000)	(861,000)
Research and development credits	(3,099,000)	(2,133,000)	(615,000)
Tax effect on non-deductible expenses and other	2,445,000	857,000	286,000
Increase in valuation allowance	20,037,000	10,795,000	6,206,000
Benefit due to refundable R&D credit	(63,000)		
	\$ (63,000)	\$	\$

At December 31, 2008, the Company had federal and California tax net operating loss carryforwards of approximately \$77.5 million and \$79.8 million, respectively. Included in these amounts are federal and California net operating losses of approximately \$13.9 million attributable to stock option deductions of which the tax benefit will be credited to equity when realized. The federal and California tax loss carryforwards will begin to expire in 2018 and 2012, respectively, unless previously utilized.

At December 31, 2008, the Company also had federal and California research and development tax credit carryforwards of approximately \$5.6 million and \$3.3 million, respectively. The federal research and development tax credits will begin to expire in 2024 unless previously utilized. The California research and development tax credits will carryforward indefinitely until utilized.

Pursuant to Internal Revenue Code Section 382, the annual use of the net operating loss carryforwards and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As a result of any such ownership change, portions of the Company's net operating loss carryforwards and research and development tax credits are subject to annual limitations. The Company completed a Section 382 analysis regarding the limitation of the net operating losses and research and development credits. 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.

The Company adopted the provisions of FIN 48 on January 1, 2007. The adoption of FIN 48 did not impact the Company's consolidated financial position or results of operations. At the date of adoption and at December 31, 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.

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, 2008 and 2007, 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. 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 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

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

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 \$281,000 and \$0 for the years ended December 31, 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. Nektar's co-founder, Chief Scientific Officer and Director, Dr. John Patton, is currently a member of the Company's Board of Directors. Dr. Patton recused himself from the segments of the various Board of Directors meetings at which this transaction was discussed, evaluated or approved. The Company paid Nektar approximately \$73,000 and \$75,000 for the years ended December 31, 2008 and 2007. Under the terms of this agreement, the Company is obligated to make certain payments in the future upon achieving certain specified milestones and royalties on product sales.

**12. 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>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

<b>2007 (Unaudited):</b>	<b>Quarters Ended</b>			
	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
Total revenues	\$ 810,215	\$ 708,516	\$ 942,881	\$ 1,337,909
Total operating expenses	\$ 4,890,626	\$ 6,542,830	\$ 9,252,533	\$ 11,263,739
Net loss	\$ (3,357,304)	\$ (4,801,707)	\$ (7,028,781)	\$ (8,708,391)
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.07)	\$ (0.09)	\$ (0.11)
Shares used in computing net loss per share, basic and diluted	69,984,931	73,217,967	76,502,867	77,459,803