HALOZYME THERAPEUTICS INC Form 10-K March 14, 2008

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

#### Form 10-K

b ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2007

OR

o TRANSITION REPORT UNDER 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 88-0488686

(State or other jurisdiction of incorporation or organization)

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

11388 Sorrento Valley Road, San Diego, California

**92121** (*Zip Code*)

(Address of principal executive offices)

(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 o No b

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No b

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 b No o

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. b

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 o

Accelerated filer b

Non-accelerated filer o

(Do not check if a smaller reporting company)

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 o No b

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 29, 2007 was approximately \$563,072,000 based on the closing price on the NASDAQ Stock Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2008, there were 78,432,949 shares of the registrant s \$.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 2008 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, 2007.

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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, similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this Annual Report. Additionally, statements concerning future matters such as the development or regulatory approval of new products, enhancements of existing products or technologies, third party performance under key collaboration agreements, revenue and expense levels and other statements regarding matters that are not historical are forward-looking statements.

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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 developing and commercializing products targeting the extracellular matrix (Matrix) for the drug delivery, oncology, and dermatology markets. Our portfolio of products is based on intellectual property covering the family of human enzymes known as hyaluronidases. Our key partnerships are with Roche to apply Enhanzettm Technology to Roche s biological therapeutic compounds for up to 13 targets and with Baxter to apply Enhanze Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUID 10%.

Our operations to date have been focused on organizing and staffing Halozyme Therapeutics, Inc. (Halozyme or the Company), acquiring, developing and securing its technology and undertaking product development for our existing products and for our product candidates. We have received FDA approval for two products: Cumulase®, for use in in-vitro fertilization, and HYLENEX, for use as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids.

In November 2007, we reincorporated from the State of Nevada to the State of Delaware. 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 (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 recombinant human PH20 (rHuPH20), a human synthetic version of hyaluronidase that degrades hyaluronic acid, a 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 hyaluronic acid to temporarily break down the gel, thereby facilitating the penetration and dispersion of other drugs and fluids that are injected under the skin or in the muscle. It also degrades the cumulus matrix surrounding oocytes (eggs) facilitating in vitro fertilization (IVF).

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Our proprietary technology, as evidenced by our exclusive license with the University of Connecticut of the patent covering the DNA sequence that encodes human hyaluronidase, may both expand existing markets and create new ones. Gaps in existing hyaluronidase offerings may create demand for our solution, and provide new market opportunities. Our objective is to apply our products and products under development to key markets in multiple therapeutic areas.

#### **Strategy**

We are a biopharmaceutical company developing and commercializing products targeting the Matrix for the drug delivery, oncology, and dermatology 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 hyaluronan, 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 Enhanze 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.

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 oncology, dermatology and metabolism. For instance, we are developing a pegylated version of rHuPH20 that lasts longer in the bloodstream, and may therefore better target solid tumors by clearing away the surrounding hyaluronan 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;

Continue to expand the commercialization of Hylenex through our partner, Baxter Healthcare;

Continue product development under our Roche Enhanze Technology collaboration;

Continue product development under our Baxter Bioscience Enhanze Technology collaboration;

Continue clinical development of our lead oncology product candidate, Chemophase<sup>®</sup>;

Continue to seek partnerships for our Enhanze Technology drug delivery platform; and

Continue to commercialize Cumulase through our distributors.

# **Current Products and Product Candidates**

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

Product Indication (Brief Description) Development Status

Cumulase	In vitro fertilization	Marketed
Hylenex	Agent for drug and fluid infusion	Marketed
Chemophase	Chemoadjuvant for superficial bladder cancer	Phase I/IIa
Enhanze Technology	Agent for enhanced drug delivery	Phase I
Proprietary PH20	Oncology, metabolism	Pre-Clinical
Proprietary Non-PH20	Oncology, dermatology	Pre-Clinical

## 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

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injection (ICSI), in which the enzyme is an essential component. The enzyme strips away the hyaluronic acid that surrounds the oocyte. This allows the clinician to then perform the ICSI procedure, injecting the sperm into the oocyte. The FDA considers hyaluronidase IVF products to be medical devices subject to 510(k) approval and we filed our 510(k) application during September 2004. We received a CE (European Conformity) Mark for Cumulase in December 2004, which allows us to market Cumulase in the European Union. We received FDA clearance in April 2005. We launched Cumulase in the European Union and in the United States in June 2005. We believe the total ICSI market consisted of an estimated 500,000 intracytoplasmic sperm injection cycles worldwide in 2005 (Source: CDC, 2001; ESHRE, 2002).

# Hylenex

Hylenex is a human recombinant formulation of rHuPH20 to facilitate the absorption and dispersion of other injected drugs or fluids. When injected under the skin or in the muscle, hyaluronidase can digest the hyaluronic acid gel, allowing for temporarily enhanced penetration and dispersion of other injected drugs or fluids. We filed a New Drug Application (NDA) in March 2005 and we received approval of our Hylenex NDA in December 2005.

Enzymatically-Augmented Subcutaneous Infusion (EASI): Hylenex facilitates subcutaneous delivery of fluids up to one liter without the need for intravenous access, a procedure known as EASI. Children and the elderly, in particular, often have difficult venous access (referred to as DVA), making it challenging even for skilled nurses to start and maintain intravenous access. Importantly, EASI for fluid replacement in children and the elderly may be achieved with limited or no need for nursing assistance.

*INFUSE-LR Study:* During January 2006, we completed the Increased Flow Utilizing Subcutaneously-Enabled Lactated Ringer's clinical trial, or INFUSE-LR study, which was designed to determine the subcutaneous (Sub-Q) infusion flow rate of Lactated Ringer's solution with and without Hylenex, determine the Sub-Q infusion flow rate dose response to Hylenex over one order of magnitude of dose, and assess safety and tolerability. This prospective, double-blind, randomized, placebo-controlled, within-subject, dose-comparison study enrolled 54 volunteer subjects who received Sub-Q infusions simultaneously in both upper arms through 24 gauge catheters. Key results from the study included:

The use of Hylenex compared to placebo preceding Sub-Q infusion, under gravity flow, to accelerate the flow rate was assessed. Hylenex accelerated flow versus placebo in every subject studied, and by an overall mean ratio of approximately four-fold. The overall mean flow rate for Sub-Q infusion with Hylenex was 464 mL/hr versus 118 mL/hr with placebo (p < 0.0001).

The faster flow rates did not result in an increase in edema. A total of 94% of subjects had moderate or severe arm edema with placebo compared to 17% with Hylenex (p < 0.0001).

In the study, there were no serious or severe adverse events (AE). Based on the AE profile, Hylenex was at least as well tolerated as placebo.

INFUSE-Morphine Study: During October 2006, we completed the Increased Flow Utilizing Subcutaneously-Enabled Morphine clinical trial, or INFUSE-Morphine study, which was designed to determine the time to maximal blood levels of morphine after subcutaneous administration with and without Hylenex, to determine the time to maximal blood levels after intravenous administration of morphine, and to assess safety and tolerability. This prospective, double-blind, randomized, placebo-controlled, within-subject, dose-comparison study enrolled 12 evaluable patients who received Sub-Q infusions. Key results from the study included:

The primary endpoint hypothesis was achieved by demonstrating a statistically significant acceleration in the average time to maximal plasma concentration (Tmax) of morphine. Tmax was reduced from 13.8 minutes when injected subcutaneously with the saline placebo to a Tmax of 9.2 minutes when injected with Hylenex, a 33% reduction in the time to maximal plasma concentration (p<0.05).

Sub-Q administration of morphine plus Hylenex provided total drug exposure (4-hour AUC) of morphine and its active metabolite that was at least comparable to IV morphine administration, as calculated based on the sampling time points for measuring absorption.

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Morphine plus Hylenex appeared to be safe and well tolerated. The most commonly reported adverse events were mild injection site redness, rash, swelling, and itching. However, no Hylenex-related toxicity was apparent based on a comparison of adverse events for Sub-Q injections with rHuPH20 versus saline placebo.

# Chemophase

Chemophase, our lead oncology product candidate, is an investigative chemoadjuvant designed to enhance the transport of chemotherapeutic agents to tumor tissue, increasing diffusion in tissues without affecting vascular permeability. Many solid tumor types (e.g., colon, breast, prostate) accumulate hyaluronic acid, creating a barrier to the effective penetration of current or future chemotherapeutics. Previous clinical trials of bovine PH20 in patients showed some promise in enhancing chemotherapy regimens using adjunctive systemic hyaluronidase in previously chemo-refractory patients.

Furthermore, we have observed significant reduction of tumor interstitial fluid pressure following the administration of rHuPH20 in solid tumors grown in mice. Tumor interstitial pressure is widely believed to be an important factor limiting the access of cytostatic regimens to solid tumors. By digesting the hyaluronic acid gel, rHuPH20 may reduce interstitial pressure in the tumor and promote more effective delivery of chemotherapy throughout the tumor, as it does under the skin in the case of Hylenex. This could potentially lead to increased patient survival and extended product lifecycles of many commonly used chemotherapeutic agents.

As we continue development of an intravenous formulation of rHuPH20, we hope to realize time and cost savings by leveraging our current manufacturing process and toxicology package to support a clinical program for a local oncology application. As such, during June 2005 we submitted an investigational new drug application ( IND ) in order to begin clinical testing of our Chemophase product candidate in combination with Mitomycin in superficial bladder cancer. We received authorization to initiate clinical testing of Chemophase in August 2005, and we commenced patient enrollment in our initial clinical protocol under this IND in October 2005. In March 2006, we completed enrollment in our Chemophase Phase I clinical trial. In April 2006, we commenced patient enrollment in our Chemophase Phase I/IIa clinical trial. In September 2007, we completed enrollment in our Phase I/IIa clinical trial.

Each year there are approximately 63,000 new cases of urinary bladder cancer in the United States (Source: American Cancer Society, 2005). Approximately 70% of these new cases are superficial bladder cancer (Source: AUA Bladder Cancer Guidelines Panel, 1999). There are approximately 500,000 prevalent cases of urinary bladder cancer (Source: NCI SEER Cancer Statistics Review, 2002) in the United States. Approximately 30% of treated patients have a recurrence within 12 months (Source: Southwest Oncology Group Study, 1995).

# Enhanze Technology

Enhanze Technology, a proprietary drug delivery platform using Halozyme's first approved enzyme, rHuPH20, is our broader technology opportunity that can potentially lead to partnerships with other pharmaceutical companies. When co-formulated with other injectable drugs, Enhanze Technology may facilitate the 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 Enhanze Technology platform is the use of rHuPH20 to facilitate subcutaneous or intramuscular routes of administration for large molecule biological therapeutics. We are seeking partnerships with pharmaceutical companies that market drugs requiring or benefiting from injection via the subcutaneous or intramuscular routes that could benefit from this technology. In December 2006, we signed our first Enhanze Technology partnership with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche, Inc. (collectively, Roche). In September 2007, we signed our second Enhanze Technology

partnership with Baxter Healthcare Corporation (  $\,$  BHC  $\,$ ) and Baxter Healthcare S.A. (  $\,$  BHSA  $\,$  and along with BHC, collectively,  $\,$  Baxter  $\,$ ).

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#### Roche Agreement

In December 2006, we signed our first Enhanze Technology partnership with Roche. Under the terms of the agreement, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Also under the terms of the agreement, we are obligated to significantly scale up the production of rHuPH20 and to identify a second source manufacturer to assist us in meeting these production obligations. Roche paid us \$20 million as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory, and sales events, Roche may pay us further milestones which could potentially reach a value of up to \$111 million. In addition, Roche may pay us royalties on potential product sales for these first three targets. Over the next ten years, 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 us in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche may pay us further upfront and milestone payments of up to \$47 million per target as well as royalties on potential product sales for each of these additional ten targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets. In addition, in December 2006, an affiliate of Roche purchased 3,385,000 shares of common stock for an aggregate of approximately \$11.1 million.

# **Baxter Gammagard Agreement**

In September 2007, we signed our second Enhanze Technology partnership with Baxter. Under the terms of the agreement, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, Halozyme s proprietary recombinant human hyaluronidase, with a current Baxter product, Gammagard Liquid<sup>tm</sup>. Gammagard Liquid is indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. Under the terms of the agreement, Baxter made an initial upfront payment of \$10 million to us. Pending successful completion of a series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37 million to us. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The agreement is applicable to both kit and co-formulation combinations. Baxter will assume all development, manufacturing, clinical, regulatory, sales and marketing costs under the agreement, 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 agreement.

## **Sales and Marketing**

#### Cumulase

Our sales and marketing strategy in the IVF market consists of a multi-channel approach that targets patients, clinicians, suppliers, and regulators. We are currently seeking to raise public awareness of the current risk of using animal-derived products in IVF applications among industry professionals and the general public through advertising in trade journals, presentations and booths at conferences and trade shows, Web initiatives, and brand-building efforts such as press releases and other public relations efforts. Two of the highest impact target audiences are, the Society for Assisted Reproductive Technology (SART) in the United States and, the European Society of Human Reproduction and Embryology (ESHRE) in Europe. We have signed non-exclusive distribution agreements with distributors of IVF reagents and media who sell directly to IVF clinics in both the United States and European markets. During 2007, sales to MediCult for the EU were approximately \$337,000 and sales to MidAtlantic were approximately \$179,000, of which approximately \$70,000 was to the EU.

### Hylenex

The sales and marketing strategy for Hylenex primarily consists of building a strong clinical foundation with post-marketing trials as well as educating 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 situations, since limited or no data with Hylenex exist in most situations in which our partner, Baxter, will market it. Examples of the trials include the completed INFUSE-LR study and the completed INFUSE-Morphine study. In addition, Baxter is currently

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enrolling patients in the 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 market education and development prior to commercial launches in various market segments following publication of related clinical data.

# **Baxter Agreements**

In February 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement, collectively the Baxter Agreements, for kits and co-formulations with rHuPH20. Under the terms of the Baxter Agreements, Baxter paid us a nonrefundable upfront payment of \$10 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 million. In addition, Baxter will make payments to us based on the sales of products covered under the Baxter Agreements. In February 2007, Baxter prepaid \$1.0 million of such product-based payments in connection with the execution of the Baxter Agreements. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the Baxter Agreements. We will continue to supply Baxter with the active pharmaceutical ingredient ( 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 us. In addition, in February 2007, an affiliate of Baxter purchased 2,070,394 shares of our common stock for an aggregate of approximately \$20 million. Additionally, Baxter will make product-based payments on the sales, if any, of the products that result from the collaboration.

# Competition

#### 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 us to enter the market with a recombinant human enzyme alternative. The leading IVF suppliers are CooperSurgical, Irvine Scientific, and Cook Ob/Gyn (all three of these companies produce bovine products) in the US, and MediCult (ovine product) and Vitrolife (bovine product) outside the US. Cumulase is priced at a premium compared to the animal-derived products sold by these leading IVF suppliers, which may make market penetration difficult.

# Hylenex

Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an ovine (ram) hyaluronidase, VitraseAmphastar Pharmaceuticals, Inc., with a bovine hyaluronidase, Amphadase<sup>tm</sup>, and Primapharm, Inc. also with a bovine hyaluronidase, Hydase<sup>tm</sup>. The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. As each of these products is established as distinctly different new chemical entities, the marketing exclusivity granted does not prohibit the marketing of the products. In addition, some commercial pharmacies now compound hyaluronidase preparations for institutions and physicians. However, there are some concerns with using a compounded sterile product. 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.

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

We also file trademark applications to protect the names of our products. 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.

#### **Development and Manufacturing**

We have signed a commercial supply agreement with Avid Bioservices, Inc. ( Avid ), a contract manufacturing organization, to produce bulk recombinant enzyme product for clinical and commercial use. Avid will manufacture the API under commercial good manufacturing practices for commercial scale production and will provide support for chemistry, manufacturing and controls sections for any FDA regulatory filings. We have entered into discussions to establish arrangements with an additional manufacturer for these ingredients. Difficulties in our relationship with Avid or delays or interruptions in Avid s supply of its requirements could limit or stop its ability to provide sufficient quantities of our products, on a timely basis, for clinical trials and commercial sales, which would have a material adverse effect on our business and consolidated financial condition.

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, fill, finish and package the products 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. We currently utilize a third party to prepare, fill, finish and package Cumulase. We have entered into an agreement with another third party to prepare, fill, finish and package Cumulase. We are currently in the technology transfer stage with this third party and expect to initiate commercial manufacturing later this year. We also utilize Baxter Pharmaceutical Solutions (BPS), a subsidiary of Baxter, to prepare, fill, finish and package Hylenex. 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 could limit its ability to provide sufficient quantities of our Hylenex product, on a timely basis, for commercial sales, which would have a material adverse effect on our business and consolidated financial condition.

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#### **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. Historically, our research and development activities were primarily focused on the development of our Cumulase and Hylenex products, but we are also developing our Chemophase product candidate, and we completed enrollment in our Phase I/IIa clinical trial for Chemophase in September 2007. 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 2007, 2006 and 2005 totaled approximately \$20.6 million, \$9.2 million and \$10.2 million, respectively. 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 and 2005 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.

#### **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 non-clinical 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;

Non-clinical evaluation in vitro and in vivo including extensive toxicology studies.

The results of these non-clinical studies may be submitted to the FDA as part of an IND application. The sponsor of an IND application may commence human testing of the compound 30 days after submission of the IND, unless notified to the contrary by the FDA.

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

Phase 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 non-clinical studies and evidence of product quality, typically are submitted to the FDA in an NDA. Although the FDA is requirements for clinical trials are well established and we believe that we have planned and conducted our clinical trials in accordance with the FDA is 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 is safety and/or

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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 (CDER) must approve a new drug application for a drug before it may be marketed in the U.S. 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 U.S. will also be subject to rigorous regulation, including compliance with current Good Manufacturing Practices (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 mice, including the hu-PBL-SCID mice and rats, 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 commercial 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.

#### **Employees**

As of February 29, 2008, we had 92 full-time employees, including 64 engaged in research and clinical development activities. Included in our total headcount are 32 employees who hold Ph.D. or M.D. degrees. We currently anticipate hiring approximately 25 to 50 additional employees by the end of 2008. 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 to date and may never generate significant revenues from future product sales. Even if we do achieve significant revenues from product sales, licensing revenues and milestone payments, we expect to incur significant operating losses over the next several years. We have never been profitable, and we may never become profitable. Through December 31, 2007, we have incurred aggregate net losses of approximately \$65.0 million.

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If we do not receive and maintain regulatory approvals for our product candidates, we will not be able to commercialize our products, which would substantially impair our ability to generate revenues.

With the exception of the December 2004 receipt of a CE (European Conformity) Mark, the April 2005 FDA clearance for Cumulase and the December 2005 FDA approval for our spreading agent, Hylenex, none of our product candidates has received regulatory approval from the FDA or from any similar national regulatory agency or authority in any other country in which we intend to do business. 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.

Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc., with an ovine-derived hyaluronidase, Vitrase®, Amphastar Pharmaceuticals, Inc., with a bovine-derived hyaluronidase, Amphadasetm, and Primapharm, Inc., also with a bovine-derived hyaluronidase, Hydasetm. The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are each distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. For so long as each of these products is established as a distinctly different new chemical entity, the marketing exclusivity granted does not prohibit the marketing of any of these products, including Hylenex. If the FDA changes its earlier determination that Hylenex is a distinct new chemical entity, our ability to market Hylenex will be materially impaired.

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 we intend to file with respect to any of our product candidates, or that the timing of any such approval will be appropriate for our product launch schedule and other business priorities, which are subject to change. We have not currently begun the NDA approval process for any of our other potential products, and we may not be successful in obtaining such approvals for any of our potential products.

We may not receive regulatory approvals for our product candidates 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 pre-clinical studies or clinical trial results are promising, we may obtain different results that fail to show the desired levels of safety and efficacy, or we may not obtain FDA approval for a variety of other reasons. The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from obtaining regulatory approval and commercializing the product. FDA approval can be delayed, limited or not granted for many reasons, including, among others:

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

FDA officials may not find that the data from pre-clinical 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.

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If the FDA does not approve our product candidates in a timely fashion on commercially viable terms, or if we terminate development of any of our product candidates due to difficulties or delays encountered in the regulatory approval process, it will have a material adverse impact on our business and we will be dependent on the development of our other product candidates and/or our ability to successfully acquire other products and technologies. We may not receive regulatory approval of our Chemophase product candidate or any other product candidates, in a timely manner, or at all.

We intend to market certain of our products, and perhaps have certain of our products manufactured, in foreign countries. The process of obtaining regulatory approvals in foreign countries is subject to delay and failure for many of the same reasons set forth above as well as for reasons that vary from jurisdiction to jurisdiction. The approval process varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. We may not obtain foreign regulatory 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 fail to comply with regulatory requirements, regulatory agencies may take action against us, 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, current Good Manufacturing Processes, or 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 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 may be slow to adapt or may not be able to adapt to these changes or new requirements.

Later discovery of previously unknown problems with our 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.

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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 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 have entered into non-exclusive distribution agreements with MediCult AS, a Denmark-based distributor, and MidAtlantic Diagnostics, Inc., a New Jersey-based distributor, to market and sell our Cumulase product. We have entered into an exclusive sales and marketing agreement with Baxter to market and sell our Hylenex product in the United States and Puerto Rico. Baxter also has the right to market and sell Hylenex on an exclusive basis in all territories outside of the United States, if and when we seek and receive the applicable regulatory approvals in those territories.

We depend upon the efforts of these third parties, such as Baxter, 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. Our 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.

If our sole contract manufacturer is unable to manufacture significant amounts of the active pharmaceutical ingredient used in our products, our product development and commercialization efforts could be delayed or stopped.

We have signed a commercial supply agreement with Avid Bioservices, Inc. ( Avid ), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. Avid will produce the active pharmaceutical ingredient used in each of Cumulase, Hylenex, Chemophase, and Enhanze Technology under cGMP for clinical or commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. Avid has only limited experience manufacturing our active pharmaceutical ingredient batches, and we rely on its ability to successfully manufacture these batches

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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 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 Avid does not maintain its status as an FDA-approved manufacturing facility, is unable to successfully scale up our active pharmaceutical ingredient production, or is 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 entered into discussions to establish arrangements with an additional manufacturer for these ingredients. 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 sole contract manufacturer is unable to adequately perform its responsibilities. Any delays or interruptions in the supply of materials by Avid could cause the delay of clinical trials and could delay or prevent the commercialization of product candidates that may receive regulatory approval. Such delays or interruptions would have a material adverse effect on our business and financial condition.

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

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, fill, finish, and package the products 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. We currently utilize a third-party to prepare, fill, finish, and package Cumulase. This third party has only limited experience manufacturing Cumulase batches and, to date, has not demonstrated a consistent ability to manufacture Cumulase according to product specifications. We have entered into an agreement with another third party to prepare, fill, finish and package Cumulase. We are currently in the technology transfer stage with this third party and expect to initiate commercial manufacturing in 2008. If our third party manufacturers are unable to successfully manufacture Cumulase, we may be unable to supply enough Cumulase product to meet demand. In addition, 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.

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 complete or accelerate the steps required to continue development of our product candidates and to fund general operations. 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 may be required to raise additional capital in the future through the public offering of securities, collaborative agreements, private financings and various other equity or debt financings, including calling outstanding warrants to purchase our common stock.

Currently, warrants to purchase approximately 4.9 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. Approximately 1.6 million of our outstanding warrants contain a call feature that, potentially, may allow us to raise funds from the holders of these warrants. We have the ability, at our sole discretion, to call warrants exercisable for up

to approximately 1.6 million shares of common stock and, upon such a call, the holders of these warrants have thirty days to decide whether to exercise their warrants at a price of \$1.75 per share or receive \$0.01 from us for each share of common stock that is not exercised.

Considering our stage of development and the nature of our capital structure, 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

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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 our product candidates are approved by the FDA but do not gain market acceptance, our business will suffer because we may not be able to fund future operations.

Assuming that we obtain the necessary regulatory approvals, a number of factors may affect the market acceptance of any of our existing product candidates or any other products we develop or acquire in the future, including, among others:

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

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

our ability to fund our sales and marketing efforts;

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

the effectiveness of our sales and marketing efforts; and

the introduction of generic competitors.

If our 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 ability to market and promote our product candidates will be restricted to the labels approved by the FDA. If the approved labels are restrictive, our sales and marketing efforts 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 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.

Our inability to attract, hire and retain key management and scientific personnel, and to recruit qualified independent directors, could negatively affect our business.

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our small staff size and 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 in this field. 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, as a result, our business may be harmed. In addition, we rely on the expertise and guidance of independent directors to develop business strategies and to guide our execution of these strategies. Due to changes in the regulatory environment for public companies over the past few years, the demand for independent directors has increased and it may be difficult for us, due to competition from both like-size and larger companies, to recruit qualified independent directors.

Furthermore, if we were to lose key management personnel, particularly Jonathan Lim, M.D., our chief executive officer, or Gregory Frost, Ph.D., our chief scientific officer, then we would likely lose some portion of our

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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. We have not entered into any retention or other agreements specifically designed to motivate officers or other employees to remain with us, other than standard agreements relating to the vesting of stock options that every optionee of the Company must enter into as a condition of receiving an option grant.

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

#### 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 January 2004 private financing transaction, we issued warrants to private investors for the purchase of approximately 10.5 million shares of common stock at purchase prices ranging from \$0.77 to \$1.75 per share. Currently, approximately 2.8 million shares of common stock remain issuable upon the exercise of these warrants. 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 2.0 million shares of common stock remain issuable upon the exercise of these warrants. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise which could negatively affect our stock price.

We currently have the ability, from time to time, to offer and sell up to \$32.5 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 year ended December 31, 2007 were \$11.00 and \$6.00, 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 shareholder, including, but not limited to, direct or indirect sales by members of 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 products;

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;

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

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

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

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

problems with our sole API contract manufacturer or our sole fill and finish manufacturer for Hylenex;

the exercise of our right to redeem certain outstanding warrants to purchase our common stock;

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 recent trading volumes decrease, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

Our decision to redeem outstanding warrants may drive down the market price of our stock.

We may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 1.6 million shares of common stock. The redemption price for these warrants is \$0.01 per share, but the warrant holders have the opportunity to exercise their warrants prior to redemption at the price of \$1.75 per share. If we decide to redeem any portion of our outstanding warrants in the future, some selling security holders may choose to sell outstanding shares of common stock in order to finance the exercise of the warrants prior to their redemption. 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 (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, Halozyme and its contract suppliers and manufacturers are subject to periodic inspection of its 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 Halozyme and its 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

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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.

Our suppliers and sole manufacturer are subject to regulation by the FDA and other agencies, and if they do not meet their commitments, we would have to find substitute suppliers or manufacturers, which could delay the supply of our products to market.

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.

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 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

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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.

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

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

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

an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, 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 disrupt our relationship with existing customers 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 revenue to offset 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.

# 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 paying 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-extracted 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.

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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 our 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.

We face intense competition and rapid technological change that could result in the development of products by others that are superior to the products we are developing.

We have numerous competitors in the United States and abroad including, among others, major pharmaceutical and specialized biotechnology firms, universities and other research institutions that may be developing competing products. Such competitors include, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc., or ISTA, Amphastar Pharmaceuticals, Inc., or Amphastar, and Primapharm, Inc. or Primapharm, among others. These competitors may develop technologies and products that are more effective, safer, or less costly than our current or future 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 pre-clinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare. Other manufacturers have FDA approved products for use as spreading agents, including ISTA, with an ovine-derived hyaluronidase, Vitrase®, Amphastar, with a bovine-derived hyaluronidase, Amphadasetm, and Primapharm, also with a bovine-derived hyaluronidase, Hydasetm. The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. As each of these products is established as distinctly different new chemical entities, the marketing exclusivity granted does not prohibit the marketing of the products.

# Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

Our administrative offices and research facilities are currently located in San Diego, California. We sublease an aggregate of approximately 48,800 square feet of office and research space for an initial monthly rent expense of approximately \$108,000, net of costs and property taxes associated with the operation and maintenance of the subleased facilities. We had two separate leases for approximately 18,400 combined square feet of facilities, which

expired in December 2007. 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

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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

A special meeting of stockholders was held on November 14, 2007. One proposal was considered. The proposal was to approve an Agreement and Plan of Merger pursuant to which we would reincorporate from the State of Nevada to the State of Delaware. This proposal received the following votes:

	Shares
For approval	40,216,282
Against approval	1,638,578
Abstained	71,428

The foregoing proposal was approved.

#### **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, 2006 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:

Fiscal Year 2007	High Low					
First Quarter	\$ 9.70	\$ 6.75				
Second Quarter	\$ 11.00	\$ 8.00				
Third Quarter	\$ 10.50	\$ 7.49				
Fourth Quarter	\$ 9.46	\$ 6.00				
Fiscal Year 2006	High	Low				
First Quarter	<b>High</b> \$ 3.71	<b>Low</b> \$ 1.79				
	<u> </u>					
First Quarter	\$ 3.71	\$ 1.79				

On February 29, 2008, the closing sales price of our common stock on the NASDAQ Stock Market was \$5.50 per share. As of February 29, 2008, 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.

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The graph below compares Halozyme Therapeutics, Inc. s cumulative 45-month total shareholder return on common stock with the cumulative total returns of the AMEX Composite index, the NASDAQ Composite index, the AMEX Biotechnology 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 3/12/2004 to 12/31/2007. The historical stock price performance included in this graph is not necessarily indicative of future stock price performance.

# **COMPARISON OF 45 MONTH CUMULATIVE TOTAL RETURN\***

Halozyme Therapeutics Inc.

\* \$100 invested on 3/12/04 in stock or on 2/29/04 in index-including reinvestment of dividends. Fiscal year ending December 31.

ļ	3/04	6/04	9/04	12/04	3/05	6/05	9/05	12/05	3/06	6/06	9/06	12/06	3/
)	105	77	54	53	40	44	51	44	83	65	64	194	1
)	101	98	100	115	118	125	141	141	157	154	155	168	1
)	98	101	94	108	99	102	108	110	118	110	114	123	1
)	96	100	98	104	95	112	130	137	134	127	132	131	1
)	98	98	94	103	90	96	113	116	121	109	113	115	1

# **Recent Sales of Unregistered Securities**

During the three months ended December 31, 2007, holders of various outstanding warrants exercised their rights to purchase 520,161 common shares for gross proceeds of approximately \$635,000. 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.

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#### Item 6. Selected Financial Data

The selected consolidated financial data set forth below as of December 31, 2007 and 2006, and for the fiscal years ended December 31, 2007, 2006 and 2005, 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, 2005, 2004 and 2003, and for the years ended December 31, 2004 and 2003, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC, not included herein.

# **Summary Financial Information**

	Years Ended December 31,									
Statement of operations data:		2007		2006	2005 _		2004		2003	
Total revenues	\$	3,799,521	\$	981,746	\$	127,209	\$		\$	
Net loss	\$	(23,896,183)	\$	(14,751,986)	\$	(13,275,373)	\$	(9,091,376)	\$	(2,115,025)
Net loss per share, basic and	·	( - , , ,	·	( , - , ,	Ċ	( - ,  - , - , - ,	·	(- , , , ,	·	( ) - ) )
diluted	\$	(0.32)	\$	(0.24)	\$	(0.26)	\$	(0.26)	\$	(0.31)
Shares used in computing net		, ,				, ,		, ,		, ,
loss per share, basic and diluted		74,317,930		62,610,265		50,317,021		35,411,127		6,826,109
				As	of l	December 31,				
Balance sheet data:		2007		2006		2005		2004		2003
Cash and cash equivalents	\$	97,679,085	\$	44,189,403	\$	19,132,194	\$	16,007,714	\$	503,580
Working capital	\$	92,312,937	\$	41,343,010	\$	17,802,804	\$	14,566,209	\$	230,140
Total assets	\$	103,460,374	\$	46,091,320	\$	20,510,255	\$	16,403,671	\$	647,247
Deferred revenues	\$	39,269,491	\$	19,981,537	\$	254,138	\$		\$	
Total liabilities	\$	45,692,450	\$	23,010,085	\$	2,303,368	\$	1,579,413	\$	273,440
Stockholders equity	\$	57,767,924	\$	23,081,235	\$	18,206,887	\$	14,824,258	\$	373,807

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 section entitled Risks Related to Our Business 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 drug delivery, oncology and dermatology 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 hyaluronic acid which is a naturally occurring substance in the human body. Our technology is based on our proprietary recombinant human PH20 enzyme, or rHuPH20, a human synthetic version of hyaluronidase that degrades hyaluronic acid, a 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 hyaluronic acid 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. It also degrades the cumulus matrix surrounding oocytes (eggs) facilitating in vitro fertilization, or IVF.

Our operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing our technology and undertaking product development for our existing products and a limited number of product candidates. We have two marketed products: Cumulase<sup>®</sup>, a product used for IVF, and Hylenex, a product

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used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids. Currently, we have only limited revenue from the sales of Cumulase and Hylenex, in addition to revenues from collaborative agreements with Baxter Healthcare Corporation, or Baxter, and F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., (collectively Roche). Revenues from product sales depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our product candidates. All of our product candidates are in the research, pre-clinical, or clinical stage. It may be years, if ever, before we are able to obtain the regulatory approvals necessary to generate meaningful revenue from the sale of these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$65.0 million as of December 31, 2007.

We currently have an effective universal shelf registration statement which will permit us, from time to time, to offer and sell up to \$32.5 million of additional equity or debt securities. Sales of a substantial number of shares of our common stock pursuant to this registration statement or in connection with other transactions, or even the potential for such sales through the exercise of currently outstanding warrants, 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 to fund the continued development of our product candidates and for other general corporate purposes.

#### **Current Products and Product Candidates**

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

Product	Indication (Brief Description)	<b>Development Status</b>
Cumulase	In vitro fertilization	Marketed
Hylenex	Agent for drug and fluid infusion	Marketed
	Chemoadjuvant for superficial bladder	
Chemophase	cancer	Phase I/IIa
Enhanze Technology	Agent for enhanced drug delivery	Phase I
Proprietary PH20	Oncology, metabolism	Pre-Clinical
Proprietary Non-PH20	Oncology, dermatology	Pre-Clinical

Cumulase is an *ex vivo* (used outside the body) formulation of rHuPH20 to replace the bovine enzyme currently used for the preparation of oocytes prior to IVF during the process of intracytoplasmic sperm injection, in which the enzyme is an essential component. We launched Cumulase in the European Union and the United States in June 2005.

Hylenex is a human recombinant formulation for rHuPH20 to facilitate the absorption and dispersion of other injected drugs or fluids. When injected under the skin or in the muscle, hyaluronidase can digest the hyaluronic acid gel, allowing for temporarily enhanced penetration and dispersion of other injected drugs or fluids. We received approval from the Food and Drug Administration, or FDA, for Hylenex in December 2005. In February 2007, we entered into an expanded collaboration agreement with Baxter under which Baxter fills and finishes Hylenex and holds it for subsequent distribution.

Chemophase, our lead oncology product candidate, is an investigative chemoadjuvant designed to enhance the transport of chemotherapeutic agents to tumor tissue, potentially increasing diffusion in tissues without affecting vascular permeability. Chemophase is being developed for potential use in the treatment of patients with superficial bladder cancer. In April 2006, we commenced patient enrollment in our Chemophase Phase I/IIa clinical trial. In

September 2007, we completed enrollment in our Phase I/IIa clinical trial.

Enhanze<sup>tm</sup> Technology, a proprietary drug enhancement system using rHuPH20, is our broader technology opportunity that can potentially lead to proprietary partnerships with other pharmaceutical companies. We are currently seeking partnerships with pharmaceutical companies that market or develop drugs requiring or benefiting from injection via the subcutaneous or intramuscular routes that could benefit from this technology. In December 2006, we signed our first Enhanze Technology partnership with Roche. In September 2007, we signed our second Enhanze Technology partnership with Baxter.

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# **Collaborative Agreements**

#### Roche Agreement

In December 2006, we entered into a License and Collaboration Agreement (the Roche Agreement ) with Roche for Enhanze Technology. Under the terms of the Roche Agreement, 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. Roche paid us \$20 million as an initial upfront license fee for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory, and sales events, Roche will pay us further milestones which could potentially reach a value of up to \$111 million. In addition, Roche will pay us royalties on product sales for these first three targets. Over the next ten years, 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 us in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche may pay us further upfront and milestone payments of up to \$47 million per target, as well as royalties on product sales for each of these additional ten targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets. In addition, in December 2006, an affiliate of Roche purchased 3,385,000 shares of common stock for an aggregate of approximately \$11.1 million.

# **Baxter Agreements**

In September 2007, we entered into an Enhanze Technology License and Collaboration Agreement (the Gammagard License) with Baxter. Under the terms of the Gammagard License, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with a current Baxter product, Gammagard Liquid<sup>tm</sup>. Under the terms of the agreement, Baxter made an initial upfront payment of \$10 million to us. Pending successful completion of a series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37 million to us. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard License is applicable to both kit and co-formulation combinations. Baxter will assume all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard License, 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 February 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement, collectively the Baxter Agreements, for kits and co-formulations with rHuPH20. Under the terms of the Baxter Agreements, Baxter paid us a nonrefundable upfront payment of \$10 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 million. In addition, Baxter will make payments to us based on the sales of products covered under the Baxter Agreements. In February 2007, Baxter prepaid \$1.0 million of such product-based payments in connection with the execution of the Baxter Agreements. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the Baxter Agreements. We will continue to supply Baxter with the API for Hylenex, and Baxter will prepare, fill, finish and package 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, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, the rights to which have been retained by us. In addition, in February 2007, an affiliate of Baxter purchased 2,070,394 shares of our common stock for an aggregate of approximately \$20 million. Additionally, Baxter will make product-based payments on the sales, if any, of the products that result from the collaboration.

# Revenues

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

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Revenues from license and collaboration agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before earned. Non-refundable upfront 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 Agreement, the Baxter Agreements and the Gammagard License, which consist of non-refundable upfront 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 the agreements, we recorded the non-refundable upfront license fees as deferred revenues. Such revenues are being recognized over the terms of the underlying agreements.

# 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 2007, we have incurred research and development expenses of \$48.9 million. From 2005 through 2007, approximately 27% of our research and development expenses were associated with the research and development of our recombinant human PH20 enzyme used in our Cumulase and Hylenex products, and approximately 17% of our research and development expenses were associated with the development of our Chemophase product candidate. 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 Chemophase product candidate for commercialization. However, we expect our research and development expenses to increase substantially if we are able to advance our Chemophase product candidate and our other product candidates into later stages of clinical development.

Clinical development timelines, likelihood of success, and total costs vary widely. Although we are currently focused primarily on advancing Chemophase, we anticipate that we will make 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.

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 Chemophase product candidate, or any of our other product candidates, will receive regulatory approval or whether any net cash inflow from our Chemophase product candidate, or any of our other product candidates, or development projects, will commence.

Selling, General and Administrative. Selling, general and administrative 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 selling, general and administrative expenses as our operations continue to expand.

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#### 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

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

Under the terms of the Baxter Agreements, 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. In addition, we receive product-based payments upon the sale of Hylenex by Baxter, in accordance with the terms of the Baxter Agreements. 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. In February 2007, Baxter prepaid \$1.0 million of such product-based payments which was deferred and is being recognized as earned. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009.

#### 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 earned. Nonrefundable upfront payments, 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. In February 2007, we entered into the Baxter Agreements which

consist of nonrefundable upfront license fees, reimbursements of research and development services, various clinical, regulatory or sales milestones and product-based payments. Due to our ongoing involvement obligations, the nonrefundable upfront license fee received in February 2007 under the Baxter Agreements was deferred and is being recognized over the term of the agreement. In September 2007, we entered

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into the Gammagard License with Baxter. Under the terms of that agreement, Baxter made an initial upfront payment of \$10 million, which is being deferred and recognized over the term of the agreement.

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 Compensation**

We account for share-based awards exchanged for employee services in accordance with Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or SFAS 123R, which we adopted effective January 1, 2006, including the provisions of the SEC s Staff Accounting Bulletin No. 107, or SAB 107. 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 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 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 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.

If factors change and we employ different assumptions in the application of SFAS 123R in future periods, the share-based compensation expense that we record under SFAS 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 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 123R and SAB 107 using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

#### Clinical Trial and Contract Research Expenses

Research and development expenses are charged to operations as incurred. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions, clinical research organizations, and other vendors 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 or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on

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contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

In addition, we have several contracts that extend across multiple reporting periods, including our largest contract representing a \$1.3 million research contract for the management of a toxicology study. We recognize expenses as the services are provided pursuant to management s assessment of the progress that has been made to date. Such contracts require an assessment of the work that has been completed during the period, including measurement of progress, analysis of data that justifies the progress and management s judgment. Based on our experience and management s intimate involvement with these outsourced contracts, it is reasonably likely that we may experience a 3% variance in our estimate of the work completed. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by approximately \$40,000 which would not represent a material change to historically reported results of operations.

# **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 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.

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, 2007 and 2006

**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%. Cumulase product sales were \$516,000 and \$342,000 for the years ended December 31, 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.

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.

*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. Our research and development expenses, which include costs incurred in connection with the collaborative agreements, consisted 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. 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 pre-clinical 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.

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

Selling, General and Administrative Selling, general and administrative expenses (SG&A) 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. We expect SG&A expenses to increase in future periods as we continue to increase headcount.

Share-Based Compensation Total compensation cost for our share-based payments for the years ended December 31, 2007 and 2006 was \$2.6 million and \$1.3 million, respectively. Research and development expense included share-based compensation of approximately \$663,000 and \$425,000, respectively, for the years ended December 31, 2007 and 2006. Selling, general and administrative expense included share-based compensation of approximately \$1.9 million and \$850,000, respectively, for the years ended December 31, 2007 and 2006. As of December 31, 2007, \$5.0 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 2.2 years.

*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.

#### Comparison of Years Ended December 31, 2006 and 2005

**Product Sales** Product sales were \$671,000 for the year ended December 31, 2006 compared to \$127,000 for the year ended December 31, 2005, an increase of \$544,000, or 428%. Cumulase product sales were \$342,000 and \$127,000 and sales of the API for Hylenex were \$329,000 and \$0 for the years ended December 31, 2006 and 2005, respectively.

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements increased by \$311,000 for the year ended December 31, 2006 from \$0 for the year ended December 31, 2005. Revenues under collaborative agreements primarily consist of the amortization of the upfront fee from Roche and reimbursements for research and development services from Baxter.

*Cost of Sales* Cost of sales were \$437,000 for the year ended December 31, 2006 compared to \$52,000 for the year ended December 31, 2005, an increase of \$385,000, or 740%. This increase was due to the increase in product sales for Cumulase and the API for Hylenex.

**Research and Development** Research and development expenses were \$9.2 million for the year ended December 31, 2006 compared to \$10.2 million for the year ended December 31, 2005. Our research and development expenses consisted 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. Research and development expenses decreased by \$1.0 million, primarily due to decreased contract manufacturing, analytical, and stability costs related to the development and production of our rHuPH20 enzyme of \$1.5 million and decreased contract research studies of \$1.6 million, primarily due to a Chemophase toxicology study of \$1.0 million performed in 2005, and decreased consulting fees of \$200,000, partially offset by higher clinical trial costs of \$1.0 million, increased compensation costs of \$650,000 and share-based compensation costs of \$425,000.

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Selling, General and Administrative SG&A expenses were \$6.9 million for the year ended December 31, 2006 compared to \$3.4 million for the year ended December 31, 2005. SG&A expenses increased by \$3.5 million primarily related to increased compensation costs of \$558,000, share-based compensation expenses of \$850,000, increased recruiting costs of \$251,000, increased professional fees of \$900,000 mainly associated with increased legal services related to collaborative agreements and increased audit and consulting fees related to internal controls documentation and testing under the Sarbanes-Oxley Act of 2002. In addition, marketing costs increased \$800,000 due primarily to our share of Hylenex pre-launch marketing expenses.

Share-Based Compensation Through 2005, we accounted for our stock plans using the intrinsic value method and recorded no stock based compensation for options granted to employees. Effective at the beginning of 2006, we adopted Statement of Financial Accounting Standards No. 123(R) (SFAS 123R), Share-Based Payment, and elected to adopt the modified prospective application method. SFAS 123R requires us to use a fair-valued based method to account for share-based compensation. Accordingly, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employees requisite service period. Total compensation cost for our share-based payments for the year ended December 31, 2006 was \$1.3 million. SG&A expense and research and development expense for the year ended December 31, 2006 included share-based compensation of \$850,000 and \$425,000, respectively. As of December 31, 2006, \$2.2 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 1.9 years.

*Interest Income* Interest income was \$831,000 for the year ended December 31, 2006 compared to \$286,000 for the year ended December 31, 2005. The increase in interest income was due to higher interest income as a result of maintaining higher average cash balances during 2006.

*Net Loss* Net loss for the year ended December 31, 2006 was \$14.8 million, or \$0.24 per common share, compared to \$13.3 million, or \$0.26 per common share for the year ended December 31, 2005. The increase in net loss was due to an increase in operating expenses.

#### **Liquidity and Capital Resources**

Our principal sources of liquidity are our existing cash and cash equivalents. As of December 31, 2007, cash and cash equivalents were \$97.7 million versus \$44.2 million as of December 31, 2006, an increase of \$53.5 million. This increase resulted primarily from the net proceeds from the sale of common stock to New River Management V, LP (New River) for approximately \$32.1 million in the second quarter of 2007, approximately \$20.0 million in net proceeds from the sale of common stock to an affiliate of Baxter in February 2007, and \$21.0 million of initial upfront payments from Baxter during 2007 of which \$20.3 million was recorded as deferred revenue as of December 31, 2007, offset by our net cash used in operations and for the purchase of property and equipment for the year ended December 31, 2007. A member of our Board of Directors, Randal J. Kirk, is an affiliate of New River. Additionally, we received cash of approximately \$4.0 million related to the exercise of stock options and warrants during the year ended December 31, 2007.

#### **Operating Activities**

Net cash used by 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 the year ended December 31, 2007 as compared to 2006.

Net cash provided by operations was \$7.1 million during the year ended December 31, 2006 compared to \$13.0 million of cash used in operations during the year ended December 31, 2005. This change was due to the

\$20.0 million initial up front payment received from Roche in 2006 of which \$19.9 million was recorded as deferred revenue as of December 31, 2006.

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#### **Investing Activities**

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 the increased purchase of property and equipment during 2007.

Net cash used in investing activities was \$365,000 during the year ended December 31, 2006 compared to \$351,000 during the year ended December 31, 2005. This was due to the increased purchase of property and equipment during 2006.

#### Financing Activities

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. In the second quarter of 2007, we sold 3.5 million shares of our common stock to New River for an aggregate price of approximately \$32.1 million. In February 2007, an affiliate of Baxter purchased approximately 2.1 million shares of our common stock for an aggregate price of approximately \$20 million. Additionally, we received approximately \$4.0 million and \$7.3 million in net proceeds from warrant and stock option exercises during the years ended December 31, 2007 and 2006, respectively.

Net cash provided by financing activities was \$18.3 million during the year ended December 31, 2006 versus \$16.5 million during the year ended December 31, 2005. In December 2006, we sold common stock for approximately \$11.0 million, net of issuance costs. Additionally, we received approximately \$7.3 million in net proceeds from warrant and stock option exercises during the year ended December 31, 2006.

We expect our cash requirements to increase significantly 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 significant 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 2008 cash expenses of approximately \$40 million to \$50 million, depending on the progress of various pre-clinical and clinical programs and the timing of our manufacturing scale up. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of the Roche and Baxter collaborations and the sale of our common stock to New River. We may finance future cash needs through the sale of other equity securities, the exercise of our callable warrants, strategic collaboration agreements, debt financing, or any combination of the foregoing.

In June 2005, we filed a shelf registration statement on Form S-3 (Registration No. 333-125731) which initially allowed us, from time to time, to offer and sell up to \$50 million of equity or debt securities. We have previously sold common stock under this registration statement for an aggregate of approximately \$17.5 million, so we currently have the ability to issue debt and equity securities for an aggregate of \$32.5 million. 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 may 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.

Off-Balance Sheet Arrangements As of December 31, 2007, 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-

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exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Contractual Obligations As of December 31, 2007, future minimum payments due under our contractual obligations are as follows:

Contractual Obligations	Payments Due by Period								
		Less than							Iore than
	Total		1 Year		1-3 Years	4	4-5 Years		5 Years
Operating leases	\$ 7,488,000	\$	943,000	\$	3,086,000	\$	3,392,000	\$	67,000
License payments	2,565,000		305,000		610,000		610,000		1,040,000
Purchase obligations(1)	6,644,000		6,644,000						
Total	\$ 16,697,000	\$	7,892,000	\$	3,696,000	\$	4,002,000	\$	1,107,000

(1) Purchase obligations include outstanding purchase orders for outsourced research and development services for our various pre-clinical 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, 2007, 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 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, 2007, 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 highly liquid investments.

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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**

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 (the Exchange Act). 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.

# **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, 2007, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

# Management s Report on Internal Control Over Financial Reporting

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

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. 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, 2007, 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, 2007. 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, 2007, 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, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, cash flows and stockholders equity for each of the two years in the period ended December 31, 2007 and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California March 12, 2008

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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 2008 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. (36), President, Chief Executive Officer and Director. Dr. Lim joined Halozyme in 2003. 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 start-ups to Fortune 500 companies in the biopharmaceutical, medical products, and payor/provider segments. From 1999 to 2001, Dr. Lim was a recipient of a National Institutes of Health Postdoctoral Fellowship, during which time he conducted clinical outcomes research at Harvard Medical School. He has published articles in peer-reviewed medical journals such as the Annals of Surgery and the Journal of Refractive Surgery. Dr. Lim s prior experience also includes two years of 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; and basic science and clinical research at the Salk Institute for Biological Studies and Massachusetts Eye and Ear Infirmary. Dr. Lim is currently a California licensed physician and volunteer surgeon in his spare time. He was a member of the strategic planning committee of the American Medical Association from 2002 to 2005. Dr. Lim earned his BS, with honors, and MS degrees in molecular biology from Stanford University, his MD degree from McGill University, and his MPH degree in health care management from Harvard University.

Gregory I. Frost, Ph.D. (36), Vice President & Chief Scientific Officer and Director. Dr. Frost co-founded Halozyme in 1999 and has spent more than twelve years researching 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 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 (SE), Biophausia AB (SE), and Active Biotech (SE). Dr. Frost is registered to practice before the US Patent Trademark Office, and earned his BA 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 ARCS-Scholar.

David A. Ramsay, MBA (43), Vice President & Chief Financial Officer. Mr. Ramsay joined Halozyme in 2003 and 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 the Vice President, Treasurer of ICN Pharmaceuticals, now called Valeant Pharmaceuticals International, a multinational, specialty pharmaceutical company. Mr. Ramsay joined ICN in 1998 from ARCO, where he spent four years in various financial roles, most recently serving as

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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 on the Board of Directors for Axxora Life Sciences, Inc., a privately held, worldwide research reagent company which was recently sold to Enzo Biochem (NYSE:ENZ) of New York. He was also Chairman of the Audit Committee of Axxora. Mr. Ramsay graduated from the University of California, Berkeley, with a BS degree in Business Administration and earned his MBA degree with a dual major in Finance and Strategic Management from The Wharton School at the University of Pennsylvania.

Richard C. Yocum, M.D. (52), Vice President of Clinical Development and Medical Affairs. Dr. Yocum joined Halozyme in 2005 and has over 23 years of professional experience in clinical drug development, project team management, clinical research trial design and implementation, and the practice of general internal medicine. His experience spans all phases of clinical development, including IND submissions; Phase I, II, III, and IV trials; multinational clinical trials; NDA, NDS and MAA preparation and submissions, including proven successes with multiple NDA and MAA approvals and new product launches; FDA advisory panel meetings and CHMP Oral Hearing; and lifecycle management. Dr. Yocum s broad-based training and experience in internal medicine has enabled him to successfully lead drug development efforts in multiple therapeutic areas, including oncology, dermatology, cardiovascular, immunology, endocrinology, and gastroenterology. Prior to Halozyme, from May 2002 to March 2005, Dr. Yocum was Vice President of Clinical Development and Medical Affairs at Chugai Pharma USA, LLC (CPUSA), a member of the Chugai-Roche group. From 1995 to 2002, Dr. Yocum was responsible for the clinical development of several retinoid-based drugs for the treatment of various cancers and benign dermatological diseases at Ligand Pharmaceuticals, where he was involved in the approval of seven new drug registration dossiers, and served most recently as Executive Medical Director of Clinical Development. From 1993 to 1995, Dr. Yocum was employed in the Clinical Research department at Gensia. Dr. Yocum is board-certified in general internal medicine, and maintained a clinical practice for nine years before transitioning to the pharmaceutical industry. He received his AB in Chemistry from Dartmouth College, his M.D. from Johns Hopkins University, and completed his medical residency at the University of California, San Diego.

Don A. Kennard (61), Vice President of Regulatory Affairs & Quality Assurance. Mr. Kennard joined Halozyme in 2004 and brings to Halozyme nearly 30 years of professional senior management experience in the fields of regulatory affairs (RA), clinical programs, and quality assurance (QA). He has worked directly with the U.S. Food and Drug Administration (FDA), as well as regulatory authorities of various foreign ministries of health, to secure registration, authorize commercialization, and successfully implement quality programs, for a broad range and extensive number of product approvals across pharmaceuticals, biologics, medical devices, and diagnostics. Prior to Halozyme, Mr. Kennard was Vice President of Worldwide RA/QA at Quidel, Inc., a manufacturer of diagnostic products, where he led the RA/QA and Clinical functions, while also establishing a Quality System CE marking program that enabled Quidel to expand and sustain sales in the European Union. From 1991 to 2001, he was Vice President of RA/QA/R&D for Nobel Biocare, Inc. and Steri-Oss (acquired by Nobel Biocare), where he directed all regulatory affairs, quality assurance, clinical trials, and R&D activities. From 1981 to 1991, Mr. Kennard was Director of RA/QA at Allergan, Inc., where he directed regulatory affairs, quality assurance and quality control in the development and manufacture of prescription and OTC ophthalmic and dermatological drugs, injectable drugs, biotechnology products, and ophthalmic products. Prior to Allergan, he was Director of Quality Control at B. Braun. Mr. Kennard holds a BS degree in Microbiology.

Robert L. Little (58), Vice President & Chief Commercial Officer. Mr. Little joined Halozyme in 2006 and brings to Halozyme over 30 years of general management, commercial operations, and finance experience in the pharmaceutical industry. 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 Company s 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 initially co-detail Zoloft with Pfizer, and to later launch 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

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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 A.G. in the U.K., Italy, and the United States. Mr. Little earned his degree in economics and finance from the West London Business School, Ealing Technical College.

William J. Fallon (51), Vice President, Manufacturing & Operations. Mr. Fallon joined Halozyme in 2006. He was previously President and Chief Executive Officer and a member of the board of directors of Cytovance Biologics, a contract manufacturing organization that provides manufacturing and development services to the biotechnology industry. At Cytovance, Mr. Fallon oversaw the design, construction, and validation of a state-of-the-art, greenfield cGMP manufacturing facility. 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 \$138 million acquisition by Genzyme in 2001. He joined Novazyme and Genzyme from Transkaryotic Therapies, where he was Vice President of Manufacturing from 1998 to 2001. From 1993 through 1998, he was employed in several management positions for the Ares-Serono Group, culminating in the position of Vice President, US Manufacturing Operations. In this role, he served as general manager, overseeing the production and distribution of all of Serono s approved biotechnology products. 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. degree in Marine Science and a B.A. degree in Biology from Long Island University and an M.S. degree in Biology from Northeastern University.

Matthew R. Hooper (50), Vice President & General Counsel. Mr. Hooper joined Halozyme in 2007 and brings to Halozyme nearly 25 years of legal experience. Most recently, he was Assistant General Counsel at Johnson & Johnson (J&J), where he served in a dual role as member of J&J s Law Department, and Vice President of Law for Scios, Inc., a wholly-owned J&J subsidiary focused on cardiovascular therapeutics, from 2005 to 2006. He also assumed responsibility for commercial legal affairs for Nitinol Devices & Components (J&J subsidiary specializing in cardiovascular medical device components). From 2003 to 2005, Mr. Hooper served as Senior Counsel at J&J, where he handled all commercial legal affairs related to Scios integration into J&J following completion of the \$2.5 billion merger in April 2003. From 2001 to 2003, he served as Vice President, General Counsel of Scios, where he oversaw all legal aspects of the Company s operations. Mr. Hooper joined Scios in 2000 as Senior Patent Counsel, with responsibility for all intellectual property matters for the Company. From 1999 to 2000, Mr. Hooper was senior counsel in the litigation group of Jones Day Reavis and Pogue in Chicago. From 1994 to 1999, he held the position of Patent Counsel at Abbott Laboratories in its patent and trademark department, where he was responsible for U.S. and foreign patent preparation and prosecution, litigation support, legal opinions and contract preparation supporting Abbott s diagnostics businesses. In this role, he also delivered comprehensive analysis and legal opinions on competitor patent portfolios to evaluate business risk and guide Abbott s product and business development strategies. Before joining Abbott, Mr. Hooper served as a patent attorney at Amoco Corporation from 1985 to 1994, and was an associate attorney in private practice in Chicago from 1982 to 1985. He received his JD degree from Northwestern University Law School and his BS degree in Chemistry from LaSalle University.

#### Item 11. Executive Compensation

The information required by this item is incorporated by reference to the information under the caption Executive Compensation 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 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 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.

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## **PART IV**

## Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report:

## (a) Financial Statements and Schedules:

10.13\*

March 24, 2005(9)

Report of Inc	dependent Registered Public Accounting Firm Ernst & Young LLP	F-1
Report of Inc	dependent Registered Public Accounting Firm Cacciamatta Accountancy Corporation	F-2
Consolidated	l Financial Statements:	
Consolidated	1 Balance Sheets at December 31, 2007 and 2006	F-3
Consolidated	Statements of Operations for the Years Ended December 31, 2007, 2006 and 2005	F-4
Consolidated	1 Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005	F-5
Consolidated	Statements of Stockholders Equity for the Years Ended December 31, 2007, 2006 and 2005	F-6
Notes to Cor	asolidated Financial Statements	F-7
(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)	ne
3.1	Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of Stat October 7, 2007(2)	e on
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, November 12, 2007	dated
10.1	License Agreement between University of Connecticut and Registrant, dated November 15, 200	2(3)
10.2*	Agreement for Services between Avid Bioservices, Inc. and Registrant, dated November 19, 200	03(3)
10.3*	Distribution Agreement between MidAtlantic Diagnostics, Inc. and Registrant, dated January 30 2004(3)	),
10.4*	Distribution Agreement between MediCult AS and Registrant, dated February 9, 2004(3)	
10.5	2004 Stock Plan and Form of Option Agreement thereunder(4)	
10.6	Form of Indemnity Agreement for Directors and Executive Officers(22)	
10.7*	Exclusive Distribution Agreement between Baxter Healthcare and Registrant, dated August 13,	2004(5)
10.8	Form of Callable Stock Purchase Warrant(4)	
10.9	Form of Common Stock Purchase Warrant(6)	
10.10	DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Op Agreements for options assumed thereunder(7)	ption
10.11	Nonstatutory Stock Option Agreement With Andrew Kim(7)	
10.12*	Commercial Supply Agreement with Avid Bioservices Inc. and Registrant, dated February 16	2005(8)

Development and Supply Agreement with Baxter Healthcare Corporation and Registrant, dated

**Page** 

- 10.14\* First Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation and Registrant, dated March 24, 2005(9)
   10.15 Halozyme Therapeutics, Inc. 2005 Outside Directors Stock Plan(10)
   10.16\* Second Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation
- and Registrant, dated December 8, 2005(11)

  10.17 First Amendment to the License Agreement between University of Connecticut and Registrant, dated January 9, 2006(12)
- 10.18 Halozyme Therapeutics, Inc. 2006 Stock Plan(14)

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10.19	Form of Stock Option Agreement (2005 Outside Directors Stock Plan)(15)
10.20	Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan)(15)
10.21	Form of Stock Option Agreement (2006 Stock Plan)(15)
10.22	Form of Restricted Stock Agreement (2006 Stock Plan)(15)
10.23*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006(16)
10.24	Stock Purchase Agreement between Roche Finance Ltd and Registrant, dated December 5, 2006(16)
10.25*	First Amendment to the Commercial Supply Agreement between Avid Bioservices, Inc. and Registrant, dated December 15, 2006(17)
10.26*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation,
	Baxter Healthcare S.A. and Registrant, dated February 14, 2007(18)
10.27*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation,
	Baxter Healthcare S.A. and Registrant, dated February 14, 2007(18)
10.28*	License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007(18)
10.29	Stock Purchase Agreement between Baxter International, Inc. and Registrant, dated February 14, 2007(18)
10.30	Stock Purchase Agreement between New River Management V, LP and Registrant, dated April 23, 2007(19)
10.31	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007(20)
10.32	Sublease Agreement (11388 Sorrento Valley Road), effective as of July 2, 2007(20)
10.33	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007(20)
10.34*	Enhanze Technology License and Collaboration Agreement, by Baxter Healthcare Corporation, Baxter

- 21.1 Subsidiaries of Registrant(13)
- 23.1 Consent of Independent Registered Public Accounting Firm Ernst & Young LLP
- 23.2 Consent of Independent Registered Public Accounting Firm Cacciamatta Accountancy Corporation
- 31.1 Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Healthcare S.A. and Registrant, dated September 7, 2007(21)

- 31.2 Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of CEO pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of CFO 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 Quarterly Report on Form 10-QSB, filed November 12, 2004.
- (6) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed October 15, 2004.

- (7) Incorporated by reference to the Registrant s Registration Statement on Form S-8 filed with the Commission on October 26, 2004.
- (8) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 22, 2005.
- (9) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed March 30, 2005.
- (10) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed July 6, 2005.
- (11) Incorporated by reference to the Registrant s Annual Report on Form 10-KSB, filed March 24, 2006.

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- (12) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2006.
- (13) Incorporated by reference to the Registrant s Annual Report on Form 10-KSB/A, filed March 29, 2005.
- (14) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.
- (15) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2006.
- (16) Incorporated by reference to the Registrant s Current Report on Form 8-K/A, filed December 15, 2006.
- (17) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed December 21, 2006.
- (18) Incorporated by reference to the Registrants Current Report on Form 8-K/A, filed February 20, 2007.
- (19) Incorporated by reference to the Registrants Current Report on Form 8-K, filed April 24, 2007.
- (20) Incorporated by reference to the Registrants Current Report on Form 8-K, filed July 31, 2007.
- (21) Incorporated by reference to the Registrants Current Report on Form 8-K, filed September 12, 2007.
- (22) Incorporated by reference to the Registrants Current Report on Form 8-K, filed December 20, 2007.
  - \* 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.

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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, 2008.

Halozyme Therapeutics, Inc., a Delaware corporation

By: /s/ Jonathan E. Lim

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

Date: March 13, 2008

## 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.

Signature	Title	Date
/s/ Jonathan E. Lim, M.D.	President and Chief Executive Officer (Principal Executive Officer), Director	March 13, 2008
Jonathan E. Lim, M.D.	( 1	
/s/ David A. Ramsay	Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2008
David A. Ramsay	(- 1.1.1.2.put - 1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1	
/s/ Gregory I. Frost, Ph.D.	Vice President and Chief Scientific Officer, Director	March 13, 2008
Gregory I. Frost, Ph.D.		
/s/ Kenneth J. Kelley	Chairman of the Board of Directors	March 13, 2008

# Kenneth J. Kelley

/s/ Robert L. Engler, M.D.	Director	March 13, 2008
Robert L. Engler, M.D.		
/s/ Kathryn E. Falberg	Director	March 13, 2008
Kathryn E. Falberg		
/s/ Randal J. Kirk	Director	March 13, 2008
Randal J. Kirk		

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Signature	Title	Date
/s/ Connie Matsui	Director	March 13, 2008
Connie Matsui		
/s/ John S. Patton, Ph.D.	Director	March 13, 2008
John S. Patton, Ph.D.		
/s/ Steven T. Thornton	Director	March 13, 2008
Steven T. Thornton		
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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, 2007 and 2006, and the related consolidated statements of operations, cash flows and stockholders equity for each of the two years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006 the Company changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment.

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, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California March 12, 2008

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## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders Halozyme Therapeutics, Inc.

We have audited the accompanying consolidated balance sheet of Halozyme Therapeutics, Inc. and subsidiary (the Company ) as of December 31, 2005, and the related consolidated statements of operations, stockholders equity and cash flows for each of the years in the two year period ended December 31, 2005. 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. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes, examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2005, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

/s/ Cacciamatta Accountancy Corporation

Irvine, California March 12, 2006

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# HALOZYME THERAPEUTICS, INC.

# CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2007 AND 2006

		2007	2006
ASSETS			
Cash and cash equivalents Accounts receivable	\$	97,679,085 779,825	\$ 44,189,403 363,565
Inventory Prepaid expenses and other assets		703,468 2,014,680	442,492 598,090
Total current assets Property and equipment, net		101,177,058 2,283,316	45,593,550 497,770
Total Assets	\$	103,460,374	\$ 46,091,320
LIABILITIES AND STOCKHOLDERS	<b>EQU</b>	ITY	
Accounts payable	\$	3,055,637	\$ 2,017,395
Accrued expenses		2,502,259	1,011,153
Deferred revenue		3,306,225	1,221,992
Total current liabilities		8,864,121	4,250,540
Deferred revenue, net of current portion		35,963,266	18,759,545
Deferred rent, net of current portion		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; 77,903,94 and 68,736,993 shares issued and outstanding as of December 31, 2007 and	14		
2006, respectively		77,904	68,737
Additional paid-in capital		122,685,443	64,111,738
Accumulated deficit		(64,995,423)	(41,099,240)
Treatmanded deficit		(01,550,120)	(11,000,210)
Total stockholders equity		57,767,924	23,081,235
Total Liabilities and Stockholders Equity	\$	103,460,374	\$ 46,091,320

See accompanying notes to consolidated financial statements.

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# HALOZYME THERAPEUTICS, INC.

# CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

	2007	2006	2005
REVENUES:			
Product sales	\$ 639,590	\$ 670,625	\$ 127,209
Revenue under collaborative agreements	3,159,931	311,121	
Total revenues	3,799,521	981,746	127,209
OPERATING EXPENSES:			
Cost of sales	240,429	436,990	51,968
Research and development	20,554,105	9,214,759	10,220,079
Selling, general and administrative	11,155,194	6,912,853	3,416,579
Total operating expenses	31,949,728	16,564,602	13,688,626
OPERATING LOSS	(28,150,207)	(15,582,856)	(13,561,417)
Interest income	4,254,024	830,870	286,044
NET LOSS	\$ (23,896,183)	\$ (14,751,986)	\$ (13,275,373)
Basic and diluted net loss per share	\$ (0.32)	\$ (0.24)	\$ (0.26)
Shares used in computing basic and diluted net loss per share	74,317,930	62,610,265	50,317,021
OTIMI V	, 1,511,550	02,010,203	20,217,021

See accompanying notes to consolidated financial statements.

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# HALOZYME THERAPEUTICS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

		2007		2006		2005
OPERATING ACTIVITIES:						
Net loss	\$	(23,896,183)	\$	(14,751,986)	\$	(13,275,373)
Adjustments to reconcile net loss to net cash (used in)	Ψ	(20,000,100)	4	(11,701,700)	4	(10,270,070)
provided by operating activities:						
Share-based compensation		2,580,204		1,274,567		
Depreciation and amortization		576,491		243,999		206,348
Loss (gain) on disposal of equipment		3,289		4,278		(1,200)
Issuance of stock options for services		,		9,322		186,402
Changes in operating assets and liabilities:				,		,
Accounts receivable		(416,260)		13,802		(377,367)
Inventory		(260,976)		(163,534)		(227,136)
Prepaid expenses and other assets		(1,416,590)		(257,602)		(231,857)
Accounts payable and accrued expenses		2,529,348		979,318		469,816
Deferred rent		865,063				
Deferred revenue		19,287,954		19,727,399		254,138
Net cash (used in) provided by operating activities		(147,660)		7,079,563		(12,996,229)
INVESTING ACTIVITIES:						
Purchases of property and equipment		(2,365,326)		(364,799)		(350,891)
Net cash used in investing activities		(2,365,326)		(364,799)		(350,891)
FINANCING ACTIVITIES:						
Proceeds from issuance of common stock, net		51,989,488		11,043,862		16,020,809
Proceeds from exercise of stock options, net		1,707,337		156,114		218,422
Proceeds from exercise of warrants, net		2,305,843		7,142,469		232,369
Net cash provided by financing activities		56,002,668		18,342,445		16,471,600
NET INCREASE IN CASH AND CASH EQUIVALENTS		53,489,682		25,057,209		3,124,480
CASH AND CASH EQUIVALENTS at beginning of year		44,189,403		19,132,194		16,007,714
CASH AND CASH EQUIVALENTS at end of year	\$	97,679,085	\$	44,189,403	\$	19,132,194

See accompanying notes to consolidated financial statements.

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# HALOZYME THERAPEUTICS, INC.

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

	Common Shares	Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders Equity
BALANCE AT DECEMBER 31, 2004 Issuance of common stock	49,202,083	\$ 49,202	\$ 27,846,937	\$ (13,071,881)	\$ 14,824,258
pursuant to exercise of stock options Issuance of common stock	620,146	620	217,802		218,422
pursuant to exercise of warrants, net Issuance of stock options to	424,768	425	231,944		232,369
consultants for services Issuance of common stock			186,402		186,402
for cash, net Net loss	10,000,000	10,000	16,010,809	(13,275,373)	16,020,809 (13,275,373)
BALANCE AT DECEMBER 31, 2005	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 restricted stock awards Issuance of common stock pursuant to exercise of	90,000	90	(90)		
warrants, net Issuance of common stock pursuant to exercise of stock	4,818,846	4,819	7,137,650		7,142,469
options Issuance of stock options to	196,150	196	155,918		156,114
consultants for services Issuance of common stock			9,322		9,322
for cash, net Net loss	3,385,000	3,385	11,040,477	(14,751,986)	11,043,862 (14,751,986)
BALANCE AT DECEMBER 31, 2006 Share-based compensation	68,736,993	68,737	64,111,738	(41,099,240)	23,081,235
expense Issuance of restricted stock			2,580,204		2,580,204
awards	105,000 1,783,852	105 1,784	(105) 2,304,059		2,305,843

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Issuance of common stock pursuant to exercise of warrants, net Issuance of common stock pursuant to exercise of stock options 1,707,705 1,708 1,705,629 1,707,337 Issuance of common stock for cash, net 5,570,394 5,570 51,983,918 51,989,488 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

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 developing and commercializing products targeting the extracellular matrix for the drug delivery, oncology and dermatology markets.

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 has two products: Cumulase®, a product used for in vitro fertilization, and Hylenex, a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids. The Company has only limited revenues from the sales of these products.

## 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 maturities of three months or less from the original purchase date.

#### **Concentrations**

Financial instruments that potentially subject us to a significant concentration of credit risk consist of cash and cash equivalents and accounts receivable. Halozyme 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 91% and 95% of the accounts receivable balance as of December 31, 2007 and 2006, respectively, represents amounts due from two customers. 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, 2007 and 2006. For the years ended December 31, 2007, 2006 and 2005, 36%, 55% and 0% of total revenues were from Baxter Healthcare Corporation

( Baxter ) and 50%, 10% and 0% were from F. Hoffmann-La Roche Ltd ( LTD ) and Hoffmann-La Roche Inc. ( INC ) (LTD and INC, collectively, Roche ), respectively.

The Company relies on a single third-party manufacturer for the supply of the active pharmaceutical ingredient in each of its current products. Payments due to this supplier represent 20% and 16% of the accounts payable balance at December 31, 2007 and 2006, respectively.

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## Halozyme Therapeutics, Inc.

## Notes to Consolidated Financial Statements (Continued)

#### 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 and furniture 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, 2007, there has been no impairment of the value of such assets.

## Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses, are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

## 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, 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.

The Company recognizes revenues in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (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 sale 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

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## Halozyme Therapeutics, Inc.

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

meet product specifications. Historically, the Company has not had any product returns; therefore, no allowance for product returns has been established.

In accordance with the Amended and Restated Development and Supply Agreement (the Development and Supply Agreement ) 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 Development and Supply Agreement 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 agreement with Baxter. Product sales revenues are recognized as the Company earns such revenues based on Baxter s shipments of Hylenex to its distributors when such amounts can be reasonably estimated. In February 2007, Baxter prepaid \$1.0 million of such product-based payments which was deferred and is being recognized as earned. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009.

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 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 are recognized as earned.

## Cost of Sales

Cost of sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight associated with the sales of Cumulase, and the API for Hylenex.

## Research and Development Expenses

Research and development expenses consist primarily of costs associated with the development and manufacturing of the Company s 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. The Company charges all research and development expenses to operations as they are incurred, in accordance with SFAS No. 2, *Accounting for Research and Development Costs*. The Company s research and development activities

are primarily focused on the development of its Chemophase and Enhanze<sup>tm</sup> Technology product candidates, both of which are based on the Company s proprietary recombinant human PH20 enzyme (rHuPH20).

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## Halozyme Therapeutics, Inc.

## Notes to Consolidated Financial Statements (Continued)

#### Clinical Trial and Contract Research Expenses

The Company s expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions, clinical research organizations, and other vendors that conduct and manage clinical trials on its behalf.

## **Share-Based Compensation**

On January 1, 2006, the Company adopted the provisions of revised SFAS No. 123 ( SFAS 123R ), *Share-Based Payment*, including the provisions of Staff Accounting Bulletin No. 107 ( SAB 107 ), using the modified prospective transition method to account for its employee share-based awards. Under SFAS 123R, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period. Halozyme has no awards with market or performance conditions. The valuation provisions of SFAS 123R apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). The Company s consolidated financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123R. In accordance with the modified prospective transition method, the consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of SFAS 123R.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* (FAS 123R-3). Management elected to adopt the alternative transition method provided in FAS 123R-3. The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123R.

Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Share-based compensation expense recognized in the Company s consolidated statements of operations for the years ended December 31, 2007 and 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123R. Share awards are amortized under the straight-line method. As share-based compensation expense recognized in the consolidated statement of operations for the years ended December 31, 2007 and 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 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, 2007 and 2006 based on the Company s historical experience and those of its peer group. In the pro forma information required under SFAS 123 for the year ended December 31, 2005, the Company accounted for forfeitures as they occurred.

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## Halozyme Therapeutics, Inc.

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

Total share-based compensation expense related to share-based awards, recognized under SFAS 123R, for the years ended December 31, 2007 and 2006 was comprised of the following:

	Years Ended December 2007 200				
Research and development Selling, general and administrative	\$	662,690 1,917,514	\$	424,305 850,262	
Share-based compensation expense before taxes Related income tax benefits		2,580,204		1,274,567	
Share-based compensation expense	\$	2,580,204	\$	1,274,567	
Net share-based compensation expense per basic and diluted share	\$	0.03	\$	0.02	
Share-based compensation expense from: Stock options Restricted stock awards	\$	1,857,249 722,955	\$	1,136,530 138,037	
Total	\$	2,580,204	\$	1,274,567	

Prior to January 1, 2006, the Company accounted for share-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations and provided the required pro forma disclosures of SFAS 123. Under the intrinsic value method, no share-based compensation expense had been recognized in the consolidated statement of operations for share-based awards to employees, because the exercise price of the stock options granted to employees equaled the fair market value of the underlying stock at the date of grant.

The following table summarizes the pro forma effect on the Company s net loss and per share data as if it had applied the fair value recognition provisions of SFAS 123 in determining share-based compensation for the year ended December 31, 2005:

	2005
Net loss, as reported	\$ (13,275,373)
Add: Share-based employee compensation expense	
Deduct: Total share-based employee compensation expense determined under fair value based	
method for all awards	(1,224,943)
Pro forma net loss	\$ (14,500,316)

1	Net loss per share, basic and diluted, as reported	\$ (0.26)

(0.00)

Pro forma net loss per share, basic and diluted \$ (0.29)

The Company accounts for stock options granted to non-employees in accordance with Emerging Issues Task Force 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*, (EITF 96-18). Under EITF 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.

#### **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

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## Halozyme Therapeutics, Inc.

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

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 No. 48, *Accounting for Uncertainty in Income Taxes* An Interpretation of FASB Statement No. 109 (FIN 48). FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions (tax contingencies) accounted for in accordance with SFAS No. 109. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 had no impact on the Company s consolidated financial position or results of operations. At the date of adoption and at December 31, 2007, the Company s unrecognized income tax benefits and uncertain tax provisions were not material.

#### Net Loss Per 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. Under SFAS No. 128, diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period. Such common equivalent shares have not been included in the computation of net loss per share as their effect would have been anti-dilutive.

	Years Ended December 31,				
		2007		2006	2005
Numerator Net loss	\$	(23,896,183)	\$	(14,751,986)	\$ (13,275,373)
Denominator Weighted average shares outstanding		74,317,930		62,610,265	50,317,021
Net loss per share	\$	(0.32)	\$	(0.24)	\$ (0.26)
Incremental common shares (not included because of their anti-dilutive nature)					
Stock options and awards		7,914,979		8,727,322	8,535,751
Stock warrants		4,859,030		6,714,403	11,561,578
Potential common equivalents		12,774,009		15,441,725	20,097,329

## Comprehensive Income

Comprehensive income (loss) is defined as all changes in a company s net assets, except changes resulting from transactions with shareholders. At December 31, 2007, 2006, and 2005, the Company had no reportable differences between net loss and comprehensive loss.

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## Halozyme Therapeutics, Inc.

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

## **Segment Information**

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

## Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosure about fair value measurements. The Company will be required to adopt SFAS 157 in the first quarter of 2008. The Company does not expect the adoption of SFAS 157 to significantly affect its consolidated financial position or results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), which allows certain financial assets and liabilities to be recognized, at the Company s election, at fair value. The provisions of SFAS 159 will be effective for the Company beginning January 1, 2008. The Company is in the process of determining the effect, if any, the adoption of SFAS 159 will have on its consolidated financial position or results of operations.

In June 2007, the FASB ratified EITF Issue No. 07-03, *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which requires that non-refundable advance payments for goods or services that will be used or performed in future research and development activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. The Company will adopt EITF Issue No. 07-03 in the first quarter of 2008, and it is not expected to have a material impact on its consolidated financial position or results of operations.

In December 2007, the FASB ratified EITF Issue No. 07-01, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property*, 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. The Company will be required to adopt EITF Issue No. 07-01 in the first quarter of 2009 and it is not expected 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, 2007 and 2006:

	2007	2006
Raw materials	\$ 578,397	
Work in process	46,394	76,257

Finished goods 78,677 28,891

\$ 703,468 \$ 442,492

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

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## Halozyme Therapeutics, Inc.

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

## 4. Property and Equipment

Property and equipment consists of the following as of December 31, 2007 and 2006:

	2007	2006
Research equipment	\$ 1,892,658	\$ 805,077
Computer and office equipment	789,851	217,418
Leasehold improvements	633,996	179,822
	3,316,505	1,202,317
Less accumulated depreciation	(1,033,189)	(704,547)
	\$ 2,283,316	\$ 497,770

Depreciation and amortization expense totaled \$576,491, \$243,999 and \$206,348, for the years ended December 31, 2007, 2006 and 2005, respectively.

## 5. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2007 and 2006:

	2007	2006
Accrued expenses	\$ 1,083,946	\$ 602,140
Accrued compensation and payroll taxes	1,418,313	409,013
	\$ 2,502,259	\$ 1,011,153

#### 6. Deferred Revenue

Deferred revenue consists of the following as of December 31, 2007 and 2006:

	2007	2006
Collaborative agreements Product sales	\$ 39,079,524 189,967	\$ 19,918,965 62,572
	\$ 39,269,491	\$ 19,981,537

Current portion	\$ 3,306,225	\$ 1,221,992
Long-term portion	35,963,266	18,759,545
Total Deferred Revenue	\$ 39.269.491	\$ 19.981.537

Roche Agreement In December 2006, the Company entered into a license and collaborative agreement with Roche. Under the terms of the Roche Agreement, Roche will obtain 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 million to Halozyme in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets.

Due to Halozyme s continuing involvement obligations, revenue from the \$20 million upfront payment was deferred and is being recognized over the term of the agreement. The Company recognized \$1.2 million and \$81,000 in revenue from the Roche upfront payment in the years ended December 31, 2007 and 2006, respectively.

Baxter Agreements In September 2007, the Company and Baxter entered into an Enhanze Technology License and Collaboration Agreement (the Gammagard License). Under the terms of the Gammagard License,

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### Halozyme Therapeutics, Inc.

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

Baxter paid the Company a nonrefundable upfront payment of \$10 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 License. The Company recognized revenues of \$192,000 under the Gammagard License for the year ended December 31, 2007.

In February 2007, the Company amended certain agreements with Baxter for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20 (the Baxter Agreements ). Under the terms of the Baxter Agreements, Baxter paid the Company a nonrefundable upfront payment of \$10 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 agreements. The Company recognized \$516,000 in revenues under the Baxter Agreements for the year ended December 31, 2007.

In addition, Baxter will make payments to the Company based on sales of the products covered under the Baxter Agreements. Baxter prepaid \$1.0 million of such product-based payments in connection with the execution of the Baxter Agreements. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. The prepaid product-based payments are deferred and are being recognized as product sales revenues as the Company earns such revenues from the sales of Hylenex by Baxter.

### 7. Stockholders Equity

Issuance of Common Stock In 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, 2007, 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.

In December 2005, the Company issued 10,000,000 shares of common stock in a registered direct offering at a price per share of \$1.75, generating approximately \$16.0 million in net proceeds.

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### Halozyme Therapeutics, Inc.

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

During 2005, the Company issued an aggregate of 1,044,914 shares of common stock in connection with the exercises of stock purchase warrants (424,768 shares at a weighted average price of \$0.55 per share) and stock options (620,146 shares at a weighted average price of \$0.35 per share) for cash in the aggregate amount of approximately \$451,000.

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 \$9,322. In 2005, options to purchase 50,000 shares of the Company s common stock were issued to members of our Scientific Advisory Board for services valued at \$77,000 and options to purchase 74,000 shares of the Company s common stock were issued to consultants for services valued at \$109,000. 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, 2007 and 2006, 2,030,572 and 2,623,828, 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, 2007 and 2006, 1,634,143 and 2,340,412, respectively, of the Callable Warrants were outstanding.

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 are exercisable until October 15, 2008. As of December 31, 2007 and 2006, 1,194,315 and 1,398,749, respectively, of these warrants were outstanding.

In connection with the promissory notes issued in 2003 and 2002, the Company granted warrants to purchase 867,419 shares of common stock at an exercise price of \$0.4496 per share. These warrants expired in October 2007. As of December 31, 2007 and 2006, zero and 351,414, respectively, of these warrants were outstanding.

### 8. Equity Incentive Plans

The Company currently has four equity incentive plans (the Plans ): the 2001 Stock Plan, the 2004 Stock Plan, the 2005 Outside Directors Stock Plan, and the 2006 Stock Plan. All of the Plans were approved by the stockholders. 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). At the present time, management intends to issue new common shares upon the exercise of stock options.

During the year ended December 31, 2007, the Company granted share-based awards under the 2006 Stock Plan and the 2005 Outside Directors Stock Plan. The Company had an aggregate of 12,625,000 shares of common stock reserved for issuance as of December 31, 2007. Of those shares, 7,809,979 shares were subject to outstanding options and 1,308,338 shares were available for future grants of share-based awards.

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### 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, 2007 and 2006 is as follows:

	Shares	Weighted Average Exercise Price per		Weighted Average	Aggregate	
	Underlying			Remaining Contractual		Intrinsic
	<b>Stock Options</b>		Share	Term (yrs)		Value
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	6.5	\$	40.7 million
Vested and expected to vest in the						
future at December 31, 2007	7,590,826	\$	1.91	6.4	\$	40.4 million
Exercisable at December 31, 2007	5,867,469	\$	0.95	5.8	\$	36.2 million

The weighted average grant-date fair values of options granted during the years ended December 31, 2007, 2006 and 2005 were \$4.94 per share, \$1.57 per share and \$1.16 per share, respectively. As of December 31, 2007, \$4.6 million of total unrecognized compensation costs related to non-vested stock option awards is expected to be recognized over a weighted average period of 2.3 years. The intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was \$13.5 million, \$342,355 and \$935,188, respectively. No tax benefit was realized for the tax deductions from option exercise of the share-based payment arrangements in the year ended December 31, 2007.

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:

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		Years Ended December 31,				
		2007	2006	2005		
Expected volatility Average expected term (in years) Risk-free interest rate		70.0% 5.0 3.5-4.7%	75.0% 4.0 4.6-5.1%	76.0% 4.0 3.9%		
Expected dividend yield		0%	0%	0%		
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### Halozyme Therapeutics, Inc.

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

The following table summarizes information for outstanding and exercisable options as of December 31, 2007:

	Ор	otions Outstanding Weighted	<b>Options Exercisable</b>				
Exercise Price	Number Outstanding	Average Remaining Contractual Life in Years	Weighted Average Exercise Price		Number Vested and Exercisable	Weighted Average Exercise Price	
\$0.06 - \$ 0.43	4,192,932	5.4	\$	0.40	4,182,635	\$	0.40
\$0.44 - \$ 2.05	1,772,754	6.9	\$	1.95	1,192,202	\$	1.92
\$2.06 - \$ 4.10	827,546	7.8	\$	3.02	492,445	\$	3.29
\$4.11 - \$10.37	1,016,747	9.5	\$	8.09	187	\$	6.78
	7,809,979	6.5	\$	2.03	5,867,469	\$	0.95

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 Plan 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.

During the year ended December 31, 2007, the Company issued 105,000 restricted stock awards under the 2005 Outside Directors Stock Plan. As of December 31, 2007, these 105,000 outstanding restricted stock awards were nonvested. The grant-date fair value of restricted stock awards granted during the year ended December 31, 2007 was \$1.1 million, or \$10.37 per share.

During the year ended December 31, 2006, the Company issued 90,000 restricted stock awards under the 2005 Outside Directors Stock Plan. As of December 31, 2007, these 90,000 restricted stock awards were fully vested. The grant-date fair value of restricted stock awards granted during the year ended December 31, 2006 was \$244,950, or \$2.72 per share. No restricted stock awards were granted in the year ended December 31, 2005. As of December 31, 2007, total unrecognized compensation cost related to unvested shares was \$364,140, which is expected to be recognized over a weighted-average period of 4.5 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 48,800 square feet of office and research space.

In July 2007, the Company entered into two sublease agreements with Avanir Pharmaceuticals, Inc. ( Avanir ) for Avanir s excess leased facilities in San Diego, California (the Subleases ). The Company subleases approximately 48,800 square feet of office and research space for an initial monthly rent expense of approximately \$108,000, net of costs and property taxes associated with the operation and maintenance of the subleased facilities. The annual base rent is subject to approximately 4% annual increases each year throughout the terms of the subleases. In addition, the Company received free rent totaling approximately \$1.0 million, of which \$674,000 was included in deferred rent as of December 31, 2007. 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 will pay a pro rata share of operating costs, insurance costs, costs of utilities and real property taxes incurred by Avanir for the subleased facilities.

One of the Subleases runs through 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 will not commence until September 2008 after the obligations in the short-term Sublease have concluded. The annual base rent is subject to approximately 4% annual increases each year

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### Halozyme Therapeutics, Inc.

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

throughout the term of the Lease. Under the Lease, the Company received an allowance for the cost of tenant improvements totaling \$276,000 and will receive free rent totaling approximately \$219,000 beginning in September 2008. 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.

Additionally, the Company leases certain office equipment under operating leases. Total rent expense was approximately \$1,050,000, \$297,000 and \$238,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Approximate annual future minimum operating lease payments as of December 31, 2007 are as follows:

Year	Operating Leases			
2008	\$ 943,000			
2009	1,480,000			
2010	1,606,000			
2011	1,663,000			
2012	1,729,000			
Thereafter	67,000			
Total minimum lease payments	\$ 7,488,000			

Material Agreements In September 2007, Halozyme entered into the Gammagard License with Baxter. Under the terms of the Gammagard License, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, with a current Baxter product, Gammagard Liquid<sup>tm</sup>. Under the terms of the Gammagard License, Baxter paid the Company a nonrefundable upfront payment of \$10 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 License.

Pending successful completion of a series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37 million to us. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard License is applicable to both kit and co-formulation combinations. Baxter will assume all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard License, while Halozyme 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 February 2007, the Company amended certain agreements with Baxter for Hylenex and entered into a new agreement, collectively the Baxter Agreements, for kits and co-formulations with rHuPH20. Under the terms of the Baxter Agreements, Baxter paid a nonrefundable upfront payment of \$10 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 million. In addition, Baxter will make payments to Halozyme based on the sales of products covered under the Baxter Agreements. In February 2007, Baxter prepaid \$1.0 million of such product-based payments in connection with the execution of the Baxter Agreements. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the Baxter Agreements. 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 us. Additionally, Baxter will make product-based payments on the

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### Halozyme Therapeutics, Inc.

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

sales, if any, of the products that result from the collaboration. Due to the Company s continuing involvement obligations, the \$10 million upfront payment was deferred and is being recognized over the term of the agreements.

In December 2006, Halozyme entered into the Roche Agreement with Roche for Enhanze Technology. Under the terms of the Roche Agreement, 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. Roche paid \$20 million as an initial upfront license fee for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory, and sales events, Roche will pay the Company further milestones which could potentially reach a value of up to \$111 million. In addition, Roche will pay the Company royalties on product sales for these first three targets. Over the next ten years, 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 Halozyme in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche may pay Halozyme further upfront and milestone payments of up to \$47 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.

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 Cumulase and Hylenex products.

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 cash flows, financial condition or results of operations.

#### 10. Income Taxes

Significant components of the Company s net deferred tax assets at December 31, 2007 and 2006 are shown below. A valuation allowance of \$28.6 million and \$17.8 million has been established to offset the net deferred tax assets as of December 31, 2007 and 2006, respectively, as realization of such assets is uncertain.

	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 15,303,000	\$ 15,134,000
Deferred revenue	7,639,000	
Research and development credits	4,321,000	2,081,000
Share-based compensation	696,000	386,000
Depreciation	95,000	92,000
Other, net	505,000	71,000

 Total deferred tax assets
 28,559,000
 17,764,000

 Valuation allowance for deferred tax assets
 (28,559,000)
 (17,764,000)

Net deferred tax assets \$

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### 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, 2007, 2006 and 2005, due to the following:

	2007	2006	2005
Federal income tax rate of 34%	\$ (8,125,000)	\$ (5,016,000)	\$ (4,514,000)
State income tax, net of federal benefit	(1,394,000)	(861,000)	(775,000)
Research and development credits	(2,133,000)	(615,000)	(573,000)
Tax effect on non-deductible expenses and other	857,000	286,000	(196,000)
Increase in valuation allowance	10,795,000	6,206,000	6,058,000
	\$	\$	\$

At December 31, 2007, the Company had federal and California tax net operating loss carryforwards of approximately \$47.7 million and \$48.8 million, which will begin to expire in 2018 and 2010, respectively, unless previously utilized. At December 31, 2007, the Company also had federal and California research and development tax credit carryforwards of approximately \$3.0 million and \$1.9 million, respectively, which will begin to expire in 2024 unless previously utilized. The tax benefit of approximately \$9.5 million of net operating losses, attributable to stock option deductions, will be credited to equity if realized.

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 recently 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, 2007, the Company s unrecognized income tax benefits and uncertain tax provisions were not material and would not, if recognized, affect the effective tax rate. The Company does not anticipate that there will be a significant change in the unrecognized tax benefits within the next 12 months.

Interest and/or penalties related to uncertain income tax positions are recognized by the Company as a component of income tax expense. For the year ended December 31, 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 two sublease agreements with Avanir for Avanir s excess leased facilities in San Diego, California (the Subleases). One of the Subleases runs through August 2008. As a result, in July 2007, the Company entered into a lease agreement (the Lease) with BC Sorrento for these facilities through January 2013. Connie Matsui, a director of the Company, and her husband have a controlling ownership interest in an entity that holds a minority ownership position in BC Sorrento. In addition, this entity currently serves as the managing member of BC Sorrento. The transaction with BC Sorrento was reviewed and approved by the Company s Board of Directors in accordance with the Company s related party transaction policy.

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### Halozyme Therapeutics, Inc.

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

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 \$75,000 in January 2007 under the terms of this agreement and 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:

				Quarte	rs Ei	nded		
<b>2007</b> (Unaudited):	March 31,		June 30,		September 30,		December 31,	
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 Shares used in computing net loss per	\$	(0.05)	\$	(0.07)	\$	(0.09)	\$	(0.11)
share, basic and diluted		69,984,931		73,217,967		76,502,867		77,459,803
				Quarte	rs Ei	nded		
<b>2006</b> (Unaudited):	]	March 31, June 30,		<b>June 30</b> ,	Se	ptember 30,	De	ecember 31,
Total revenues	\$	73,281	\$	119,662	\$	362,476	\$	426,327
Total operating expenses	\$	3,746,321	\$	3,534,635	\$	4,188,514	\$	5,095,132
Net loss	\$	(3,490,194)	\$	(3,232,791)	\$	(3,651,038)	\$	(4,377,963)
Net loss per share, basic and diluted Shares used in computing net loss per	\$	(0.06)	\$	(0.05)	\$	(0.06)	\$	(0.07)
share, basic and diluted		60,456,462		61,841,867		62,731,254		65,402,770

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