HALOZYME THERAPEUTICS INC
Form 10-K
March 09, 2007

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

Form 10-K

þ **ANNUAL REPORT UNDER SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

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: 000-49616

Halozyme Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**88-0488686**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
11588 Sorrento Valley Road, Suite 17, San Diego, California	**92121**
(Address of principal executive offices)	*(Zip Code)*

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

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

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

Common Stock, Par Value $.001
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

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 þ

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 þ 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. þ

Indicated by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act:

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2006 was approximately $155,000,000, based on the closing price on the American Stock Exchange reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 28, 2007, there were 71,042,402 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 Commission pursuant to Regulation 14A in connection with the registrant s 2007 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, 2006.

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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, estim 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, revenue and expense levels and other statements regarding matters that are not historical are forward-looking statements.

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

Overview

We are a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the drug delivery, palliative care, oncology, and infertility markets. Our operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for our existing products and for a limited number of product candidates. In June 2005, we launched our first product, Cumulase®, a product used for in vitro fertilization, and transitioned from a development-stage organization to a commercial entity.

Our predecessor company, DeliaTroph Pharmaceuticals, Inc. was incorporated in California in 1998. Our principal offices and research facilities are located at 11588 Sorrento Valley Road, Suite 17, San Diego, California 92121. Our telephone number is (858) 794-8889 and our e-mail address is *info@halozyme.com.* Additional information about Halozyme 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 cartilage. 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 (IVF).

Bovine and ovine-derived hyaluronidases have been used in multiple therapeutic areas, including in vitro fertilization and ophthalmology, where an FDA-approved bovine version was used as a drug delivery agent to

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enhance dispersion of local anesthesia for over 50 years. Despite the multiple potential therapeutic applications for hyaluronidase, there are problems with existing and potential animal-derived product offerings, including:

Impurity: Most such commercial enzyme preparations are crude extracts from cattle testes and are typically 1-10% pure.

Prion disease: Because most commercial enzyme preparations are only 1-10% pure, they may contain whole blood cellular components (leukocytes) that are not adequately flushed from the testes organ in the manufacturing process. White blood cells (leukocytes) have been implicated in the development of neurodegenerative disorders associated with infectious prion disease.

Immunogenicity: Hyaluronidases can also be found in bacteria, leeches, certain venoms, and marine organisms. Such preparations, in addition to bovine and ovine, are non-human, and may elicit immune reactions, possess endotoxin, or have some of the same defects as slaughterhouse derivations.

As an alternative to the existing animal-derived drugs, 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

Our objective is to develop and commercialize our first enzyme, recombinant human hyaluronidase (rHuPH20), as a medical device, drug enhancement agent, and therapeutic drug. Key aspects of our corporate strategy include the following:

Continue to commercialize Cumulase through our distributors;

Begin to commercialize Hylenex through our partner;

Complete Phase I/IIa trials for our oncology developmental product, Chemophase®;

Continue to conduct proof of concept clinical studies with our Enhanze™ Technology; and

Continue to seek partnerships for our Enhanze Technology;

Develop other early-stage opportunities in our pipeline.

Marketed Product and Product Development Programs

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

Product	Indication (Brief Description)	Development Status
Cumulase	In vitro fertilization	Marketed
Hylenex	Agent for drug and fluid infusion	NDA Approved

Chemophase	Chemoadjuvant for superficial bladder cancer	Phase I/IIa
Enhanze Technology	Agent for enhanced drug delivery	Phase I
HTI-101	Inflammation, oncology	Pre-Clinical

Cumulase

Cumulase is an *ex vivo* (used outside of the body) formulation of rHuPH20 to replace the bovine enzyme currently used for the preparation of oocytes (eggs) prior to IVF during the process of intracytoplasmic sperm injection (ICSI), in which the enzyme is an essential component. 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

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in December 2004, which allows the Company 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. Importantly, EASI for fluid replacement in terminal patients may be achieved with limited or no need for nursing assistance. Over 1.1 million subcutaneous fluid infusions are performed per year with hospice patients alone (Source: Company estimates based on National Hospice and Palliative Care Organization data, 2001). In addition, over 500 million infusion bags are utilized annually in the United States, some of which could potentially convert to EASI using Hylenex, giving rise to additional market potential (Source: B. Braun, 2003).

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 ($p<0.05$).

SC administration of morphine + 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.

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 SC injections with rHuPH20 vs. saline placebo.

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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. Chemophase is being developed for potential use in the treatment of patients with various solid tumor malignancies. 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 (bull) 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, Chemophase 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 extend the 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. During June 2005, we submitted an investigational new drug application (IND) in order to begin clinical testing of our Chemophase product candidate 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.

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[tm] Technology, a proprietary drug enhancement system using Halozyme s first approved enzyme, rHuPH20, is the company s broader technology opportunity that can potentially lead to proprietary partnerships with other pharmaceutical companies. When co-formulated with other injectable drugs, Enhanze Technology may act as a molecular machete to 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 perforated 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. Halozyme is 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.

Roche Agreement

In December 2006, we entered into a license and collaboration agreement with Roche for Enhanze Technology. Under the terms of the agreement, Roche will obtain 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. 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

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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, on December 5, 2006, an affiliate of Roche purchased 3,385,000 shares of common stock for an aggregate of approximately $11.1 million.

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 direct contact with target audiences, advertising in trade journals, presentations and booths at conferences and trade shows, mass mailings, Web initiatives, and brand-building efforts such as press releases and other public relations efforts. Direct contact could include communicating with key advocacy groups, meeting with regulatory officials, and attending specialty conferences.

One of the highest impact target audiences is the Society for Assisted Reproductive Technology (SART), which is the leading organization of professionals dedicated to the practice of assisted reproductive technologies in the United States. The organization includes over 370 members, which represents over 95% of the IVF clinics in the nation, and sponsors a highly-attended annual conference and exhibitor program. Likewise, the European Society of Human Reproduction and Embryology (ESHRE) is the leading non-profit organization for IVF in Europe and also sponsors an annual meeting. We plan on using efficacy and safety data to recruit key thought leaders and practitioners from this organization to help promote the use of Cumulase over existing preparations.

There are approximately eight known suppliers of IVF reagents and media, including micromanipulation media that contain hyaluronidase preparations. All of these suppliers sell animal-derived enzymes, and may benefit from having the opportunity to supply clinics with a human recombinant hyaluronidase. We are seeking to establish non-exclusive distribution agreements with a subset of these suppliers to serve the worldwide marketplace. We have signed worldwide distribution agreements with MediCult AS (MediCult), a Denmark-based distributor with strengths in the European Union (EU) market and MidAtlantic Diagnostics, Inc. (MidAtlantic), a New Jersey-based distributor with strengths in the United States market. These agreements are non-exclusive distribution agreements, having five-year terms with renewal options for an additional two or three years, and granting each of our distributors the right to purchase Cumulase from us and resell it to end users. During 2006, sales to MediCult for the EU were approximately $220,000 and sales to MidAtlantic were approximately $122,000, of which approximately $31,000 was to the EU.

Hylenex

The sales and marketing strategy for Hylenex consists of building a strong clinical foundation with post-marketing trials. 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 will market it. Clinical trials have inherent risk, and it is possible that not all trials will meet their endpoints. Examples of the trials include the completed INFUSE-LR study and the recently completed INFUSE-Morphine study, which is designed to determine the time to maximal blood levels of morphine after subcutaneous administration with and without Hylenex, maximal blood levels after intravenous administration of morphine, and to assess safety and tolerability. In addition, we plan to educate clinicians about the potential benefits of Hylenex by engaging key opinion leaders and enrolling clinical Centers of Excellence.

Baxter Agreements

In February 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20. Under the terms of these agreements, Baxter paid us an initial upfront payment of $10 million and, pending the successful completion of a series of regulatory and sales events, Baxter

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may make milestone payments which could potentially reach a value of up to $25 million. In addition, Baxter will pay royalties on the sales of products covered under the agreements. Baxter prepaid $1 million of these royalties in connection with the execution of the agreements and Baxter will be obligated to prepay $9 million of additional royalties 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 agreements. We will continue to supply Baxter with the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. Baxter will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, 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). Additionally, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. In addition, on February 13, 2007, an affiliate of Baxter purchased 2,070,394 shares of Halozyme s common stock for an aggregate of $20 million.

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 Halozyme 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 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, Vitrase®, Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase™, and Primapharm, Inc. also with a bovine hyaluronidase, Hydase™. 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 are 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, we anticipate that Hylenex will be priced at a significant premium to the animal-derived hyaluronidases currently in the marketplace. This anticipated price premium may slow market adoption of Hylenex and make market penetration difficult.

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 a potential competitive advantage for our inventions. Our patent portfolio includes six issued patents and a number of pending patent applications. Our technology is primarily based on an exclusive license with the University of Connecticut of the patent covering the DNA sequence that encodes human hyaluronidase. This patent expires in 2015. We believe our patent position

surrounding recombinant human hyaluronidases and their methods of manufacture presents 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

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policy is to require our employees, directors, consultants and 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 for 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 active pharmaceutical ingredient 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 not established and may not be able to establish arrangements with additional manufacturers for these ingredients or products should the existing supplies become unavailable or in the event that Avid is unable to adequately perform its responsibilities. 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 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, package and fill and finish 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 fill and finish Cumulase. We also utilize Baxter Pharmaceutical Solutions (BPS), a subsidiary of Baxter Healthcare Corporation, to fill and finish 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 financial condition.

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 are currently enrolling patients in our Phase I/IIa clinical trial for Chemophase. 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 2006, 2005 and 2004 totaled approximately $9.2 million, $10.2 million and $6.5 million, respectively. 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. In fiscal 2004, our research and development expenditures were primarily related to the development of

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our Cumulase and Hylenex products. We anticipate that we will have 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 s requirements for clinical trials are well established and we believe that we have planned and conducted our clinical trials in accordance with the FDA s applicable regulations and guidelines, these requirements, including requirements relating to testing the safety of drug candidates, may be subject to change as a result of recent announcements regarding safety problems with approved drugs. Additionally, we could be required to conduct additional trials beyond what we had planned due to the FDA s safety and/or efficacy concerns or due to differing interpretations of the meaning of our clinical data. (See 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

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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 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 under the caption, Executive Officers of the Registrant. This information is incorporated by reference into Part I of this report.

Human Resources

As of February 28, 2007, we had 40 full-time employees, including 24 engaged in research and clinical development activities. Nine employees hold Ph.D. or M.D. degrees. We currently anticipate hiring approximately 10 additional employees by the end of 2007. 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, 2006, we have incurred aggregate net losses of $41,099,240.

We may need 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 need to raise additional capital to complete 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 6.4 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 2.3 million of our outstanding warrants contain a call feature that, potentially, may allow us to raise funds from the holders of these warrants. If our common stock closes at a price equal to or greater than $2.00 per share for twenty consecutive trading days, we have the ability, at our sole discretion, to call warrants exercisable for up to approximately 1.9 million shares of common stock, provided that we have not exercised a call right in the preceding three months. Upon such a call, the holders of these warrants have thirty days to decide whether to either 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. If we need to raise funds in the future and we wish to utilize this call right, we will not be able to exercise the call right if we do not meet the minimum closing price condition and, even if we meet this condition, we

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cannot be sure of the amounts that will be raised by such a call because some or all warrant holders may decide not to exercise their warrants.

Considering our stage of development and the nature of our capital structure, when we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If we are successful in raising additional capital, a substantial number of additional shares will be issued and these shares will dilute the ownership interest of our investors.

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 and April 2005 FDA clearance for Cumulase, and the December 2005 FDA approval for Hylenex, none of our product candidates have 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.

In December 2005, we received FDA approval for Hylenex. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an ovine-derived hyaluronidase, Vitrase®, Amphastar Pharmaceuticals, Inc. (Amphastar), with a bovine-derived hyaluronidase, Amphadase™, and Primapharm, Inc. also with a bovine-derived hyaluronidase, Hydase™. 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 are established as distinctly different new chemical entities 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 processes for obtaining FDA approval are 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 also a long, expensive and uncertain process and a 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 justify 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;

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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 policies, act contrary to previous guidance, or adopt new regulations; or

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

If the FDA does not approve our product candidates in a timely fashion on commercially viable terms or 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 Chemophase, 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 procedure 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, 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;

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

product seizure; and

injunctions or the imposition of civil or criminal penalties.

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.

If we are unable to sufficiently develop our sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize 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 Healthcare Corporation (Baxter) to market and sell our Hylenex product candidate 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 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.

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If our sole contract manufacturer is unable to manufacture 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 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 according to product specifications. In addition, as a result of our Roche Agreement, we are required to scale up our active pharmaceutical ingredient production in order to meet our contractual demands. If Avid does not maintain its status as an FDA-approved manufacturing facility, is unable to successfully scale our active pharmaceutical ingredient production, or is unable to manufacture the active pharmaceutical ingredient used in our products and product candidates for any other reason, the commercialization of our products and the development of our product candidates will be delayed and our business will be adversely affected. We have not established and may not be able to establish 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 we rely on its ability to successfully manufacture Cumulase according to product specifications. In addition, one of our distributors, who utilizes our raw material for Cumulase in production of their proprietary product, is experiencing technical challenges integrating our raw material into their proprietary manufacturing process. If our third party manufacturer is unable to successfully manufacture Cumulase, or if our distributor is unable to resolve their technical issues, we may be unable to supply enough Cumulase product to meet demand. In addition, we currently utilize a subsidiary of Baxter Healthcare Corporation (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 could have a material adverse impact on our business and financial condition.

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 affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability

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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. 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-sized 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 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 Halozyme other than standard agreements relating to the vesting of stock options that every optionee of Halozyme 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 Our 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 10,461,943 shares of common stock at purchase prices ranging from $0.77 to $1.75 per share. Currently, approximately 3.7 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 2,709,542 shares of common stock at a purchase of $2.25 per share. 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 the Company s 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 Halozyme 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 stock prices during the twelve months ended February 28, 2007 were $9.70 and $2.15, 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 report 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 partnerships;

general negative conditions in the healthcare industry;

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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;

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

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; and

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

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.

Notwithstanding recent increases to the daily trading volume, our stock has historically traded at a lower daily trading volume. If current trading volumes do not continue and limited trading in our stock returns, 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 2.3 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 Halozyme, 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, record keeping, 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.

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

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

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.

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

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, technologies, products, personnel or operations of companies that we acquire;
- certain acquisitions may disrupt our relationship with existing customers who are competitive with the acquired business;
- 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 payers 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 payers 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.

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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.

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. (ISTA), Amphastar Pharmaceuticals, Inc., and Primapharm, Inc., 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 Pharmaceuticals, Inc. (ISTA), with an ovine-derived hyaluronidase, Vitrase®, Amphastar Pharmaceuticals, Inc., with a bovine-derived hyaluronidase, Amphadase™, and Primapharm, Inc., also with a bovine-derived hyaluronidase, Hydase™. 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.

We are exposed to product liability claims, and insurance against these claims may not be available to us on reasonable terms or at all.

We might incur substantial liability in connection with clinical trials or the sale of our products. Product liability insurance is expensive and in the future may not be available on commercially acceptable terms, or at all. We currently carry a limited amount of product liability insurance. A successful claim or claims brought against us in excess of our insurance coverage could materially harm our business and financial condition.

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

None.

Item 2. ***Properties.***

Our administrative offices and research facilities are currently located in San Diego, California. We lease an aggregate of approximately 18,400 square feet of office and research space for approximately $34,000 per month. We have two separate leases for our facilities, which expire in December 2007. We believe the space is adequate for our immediate needs, but additional space will likely be required soon and may be more costly as we expand our research and development activities. We do not foresee any significant difficulties in obtaining any required additional facilities.

Item 3. ***Legal Proceedings.***

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management s opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position.

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

There were no matters submitted to a vote of our security holders during the fourth quarter of fiscal 2006.

PART II

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

Market Information

Since November 1, 2004, our common stock has 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 2006	**High**	**Low**
First Quarter	$ 3.71	$ 1.79
Second Quarter	$ 3.59	$ 2.20
Third Quarter	$ 2.74	$ 2.15
Fourth Quarter	$ 8.70	$ 2.46

Fiscal Year 2005	**High**	**Low**
First Quarter	$ 2.24	$ 1.50
Second Quarter	$ 2.10	$ 1.60
Third Quarter	$ 2.22	$ 1.60
Fourth Quarter	$ 2.36	$ 1.70

On February 28, 2007, the closing sales price of our common stock was $8.29 per share. As of February 28, 2007, we had approximately 3,000 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 matches the cumulative 33-month total return of holders of our common stock with the cumulative total returns of the AMEX Composite index and the AMEX Biotechnology index. The graph assumes that the value of the investment in our common stock and in each of the indexes (including reinvestment of dividends) was $100 on March 12, 2004 and tracks it through December 31, 2006.

* $100 invested on 3/12/04 in stock or on 2/28/04 in index-including reinvestment of dividends.
Fiscal year ending December 31.

	3/12/04	3/04	6/04	9/04	12/04	3/05	6/05	9/05	12/05	3/06	6/06	9/06
cs Inc	100	105	77	54	53	40	44	51	44	83	65	64
nposite	100	101	98	101	115	118	125	143	142	159	156	155
echnology	100	96	98	97	103	95	111	130	136	133	125	130

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Recent Sales of Unregistered Securities

During October, November, and December, holders of various outstanding warrants exercised their rights to purchase 892,711 common shares for gross proceeds of approximately $979,064. 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 at December 31, 2006 and 2005, and for the fiscal years ended December 31, 2006, 2005 and 2004, 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 at December 31, 2004, 2003 and 2002, and for the years ended December 31, 2003 and 2002, 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:	**2006**	**2005**	**2004**	**2003**	**2002**
Total revenues	$ 981,746	$ 127,209	$	$	$
Net loss	$ (14,751,986)	$ (13,275,373)	$ (9,091,376)	$ (2,115,025)	$ (1,134,765)
Net loss per share, basic and diluted	$ (0.24)	$ (0.26)	$ (0.26)	$ (0.31)	$ (0.25)
Shares used in computing net loss per share, basic and diluted	62,610,265	50,317,021	35,411,127	6,826,109	4,599,591
Cash dividends declared per share	$	$	$	$	$

	December 31,				
Balance sheet data:	**2006**	**2005**	**2004**	**2003**	**2002**
Working capital	$ 41,343,010	$ 17,802,804	$ 14,566,209	$ 230,140	$ (521,230)
Total assets	$ 46,091,320	$ 20,510,255	$ 16,403,671	$ 647,247	$ 230,580
Deferred revenues	$ 19,981,537	$ 254,138	$	$	$
Total liabilities	$ 23,010,085	$ 2,303,368	$ 1,579,413	$ 273,440	$ 610,140
Stockholders (deficit) equity	$ 23,081,235	$ 18,206,887	$ 14,824,258	$ 373,807	$ (379,560)

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.