

HALOZYME THERAPEUTICS INC

Form 10KSB

March 11, 2005

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form 10-KSB**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2004**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from            to**

**Commission File Number: 000-49616**

**Halozyme Therapeutics, Inc.**

*(Exact name of registrant as specified in its charter)*

**Nevada**

*(State or other jurisdiction of incorporation or organization)*

**88-0488686**

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

**11588 Sorrento Valley Road, Suite 17,  
San Diego, California**

*(Address of principal executive offices)*

**92121**

*(Zip Code)*

**(858) 794-8889**

**(Registrant's Telephone Number, Including Area Code)**

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

**Title of Each Class Registered:**

**Name of Each Exchange on Which Registered:**

None

None

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

**Common Stock, Par Value \$.001**

*(Title of Class)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. No

State issuer's revenues for its most recent fiscal year: \$0.

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10KSB

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.) As of February 15, 2005, approximately \$91,522,400.

As of February 15, 2005, there were 49,502,083 shares of the issuer'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 2005 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, 2004.

Transitional Small Business Disclosure format (check one):    Yes             No

---

## PART I

### Item 1. Description of Business.

*This Annual Report contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as expects, anticipates, intends, plans, believes, seeks, estimates and 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.

### **The Company**

We are a development stage biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the infertility, ophthalmology, and oncology 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 a limited number of product candidates. As the Company has not begun principal operations of commercializing a product candidate, the financial statements have been presented as a development stage company.

DeliaTroph Pharmaceuticals, Inc. ( DeliaTroph ), our predecessor company, was incorporated on February 26, 1998. Effective March 11, 2004, DeliaTroph (which was doing business at the time as Hyalozyme Therapeutics, Inc.), Global Yacht Services, Inc. ( Global ), a publicly traded Nevada corporation and Hyalozyme Acquisition Corporation ( Merger Sub ), a wholly owned subsidiary of Global, completed a transaction in which Merger Sub merged with and into DeliaTroph (the Merger ), with DeliaTroph surviving as a wholly owned subsidiary of Global.

Although Global acquired DeliaTroph as a result of the Merger, the former shareholders of DeliaTroph received a majority of the voting interest in the combined enterprise as consideration for entering into the Merger. Additionally, the Merger resulted in DeliaTroph's management and Board of Directors assuming operational control of Global.

The following summary lists the structure of the Merger and matters completed in connection therewith:

On January 28, 2004, pursuant to an investment round completed simultaneously with the signing of the definitive Merger agreement, DeliaTroph raised equity capital of approximately \$8.1 million.

The stockholders of Global amended and restated Global's Articles of Incorporation to change Global's corporate name to Halozyme Therapeutics, Inc., increased the authorized number of shares of common stock to 100 million, and authorized 20 million shares of preferred stock.

Global, now named Halozyme Therapeutics, Inc., issued 35,521,906 shares of its restricted common stock, 6,380,397 options and 11,742,665 warrants to purchase shares of its common stock to the

shareholders of DeliaTroph in exchange for 100% of their issued and outstanding common stock, options and warrants to purchase DeliaTroph's common stock.

A total of 4,296,362 shares of Global, now named Halozyme Therapeutics, Inc., outstanding common stock were redeemed by Global from three stockholders in exchange for \$42,303, or approximately \$0.01 per share.

Upon completion of the Merger, the pre-Merger stockholders of Global owned approximately 10% of the issued and outstanding shares of Halozyme Therapeutics, Inc., based on 39,421,906 shares outstanding after the Merger.

The full text of the definitive Merger agreement may be found in Exhibit A to our definitive Schedule 14C Information Statement, as filed with the Securities and Exchange Commission on February 17, 2004. The Merger has been treated as a re-capitalization of DeliaTroph and, accordingly, our financial statements reflect the historical activity of DeliaTroph with the capital structure of Global, furthermore, the historical information presented in this Annual Report reflects the pre-merger activities of DeliaTroph and does not include information relating to the activities of Global prior to the Merger unless otherwise indicated. Prior to the Merger, Global had limited operations.

In addition, on October 13, 2004, we announced the closing of a private placement in which we sold an aggregate of 7,925,715 shares of our common stock and warrants to purchase an additional 2,609,542 shares of our common stock for aggregate gross proceeds of approximately \$13.9 million.

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

### **Technology**

Our 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 that are injected in the skin or in the muscle.

Bovine and ovine-derived hyaluronidases have been used in multiple therapeutic areas, including in vitro fertilization and ophthalmology, where a FDA-approved bovine version was used as a drug delivery agent to enhance dispersion of local anesthesia for cataract surgery 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 less than 1-5% pure.

*Prion disease:* Cattle testes are an organ with the highest concentration of hyaluronidase, but also with the highest levels of a protein implicated in the development of neurodegenerative disorders associated with prion disease, such as Mad Cow Disease.

*Immunogenicity:* Hyaluronidases can also be found in bacteria, leeches, certain venoms, and marine organisms. We believe that very few companies are pursuing clinical development of any of these enzymes. Regardless, all such preparations are non-human, and may elicit potent immune reactions, possess endotoxin, or have some of the same defects as slaughterhouse derivations.

There have been successes in replacing animal-derived drugs with human recombinant biologics, as in the case of insulin, Pulmozyme and human growth hormone. Our objective is to execute this recombinant human

enzyme replacement strategy by applying our products under development to key markets in multiple therapeutic areas, beginning with in vitro fertilization (IVF) and ophthalmology.

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 which 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 opportunities to capture market share.

### Strategy

We are pursuing a recombinant human enzyme replacement strategy to replace animal-derived hyaluronidase enzymes currently on the market. Our objective is to develop and commercialize our first enzyme, recombinant human hyaluronidase (rHuPH20), as a medical device, drug enhancement agent, and therapeutic biologic. Key aspects of our corporate strategy include the following:

Obtain United States Food and Drug Administration (FDA) regulatory approval of our developmental product, Cumulase<sup>tm</sup>, as a medical device;

If approved, commercialize Cumulase through our distributors;

File a NDA for our developmental product, Enhanze SC<sup>tm</sup>;

File an IND for our developmental product, Chemophase<sup>tm</sup>.

### Product Development Programs

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

Product	Indication	Development Status
Cumulase	In vitro fertilization	510(k) filed
Enhanze SC	Spreading factor for anesthesia	Pre-NDA
Chemophase	Chemoadjuvant for solid tumors	Pre-clinical
HTI-101	Inflammation, lysosomal storage disorders	Discovery
HTI-201	Inflammation, oncology	Discovery
HTI-401	Central nervous system trauma and disorders, wound healing	Discovery

#### *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 in December of 2004, which allows the Company to market Cumulase in the European Union. The total ICSI market consists of an estimated 500,000 intracytoplasmic sperm injection cycles worldwide in 2005 (Source: CDC, 2001; ESHRE, 2002).

#### *Enhanze SC*

Enhanze SC is a local formulation of rHuPH20 to replace Wydase®, Wyeth's discontinued bovine enzyme previously used for over 50 years as a drug delivery agent to enhance dispersion of local anesthesia for ophthalmic surgery, particularly in cataract surgery. Its value as a spreading agent for local anesthesia in cataract surgery is the result of its ability to break down hyaluronic acid. When injected into 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 plan to submit a New Drug Application (NDA) in the first



quarter of 2005. The market consists of approximately 6.4 million local anesthesia procedures (or 45% of the 14.2 million total estimated cataract surgery procedures) worldwide in 2004 (Source: Medtech Insight, 2002; Marketscope, 2001; Review of Ophthalmology, 2003).

Enhance SC is the first product in the company's broader technology platform called Enhance<sup>®</sup> Technology, a proprietary drug enhancement system. When co-formulated with other injectable drugs, Enhance 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 perforated extracellular matrix which recovers its normal density within 24 hours, leading to a drug delivery platform which does not permanently alter the architecture of the skin. Halozyme intends to seek partnerships with pharmaceutical companies that market drugs requiring injection via the subcutaneous or intramuscular routes that could benefit from this technology.

*Local anesthesia and other small molecule drugs:* A natural extension of Enhance SC would be applying this technology, used as a spreading factor for local anesthetics around the eye, to other areas of the body. For example, lidocaine and bupivacaine are administered for most minor surgical operations requiring local anesthesia.

*Subcutaneous Fluid Replacement (SFR):* Our Enhance SC may also facilitate a procedure known as hypodermoclysis, which allows subcutaneous delivery of fluids up to one liter without the need for intravenous access. Importantly, fluid replacement in terminal patients may be achieved without the need for nursing assistance. This method of fluid replacement was an approved indication of Wydase, the product that Enhance SC is designed to replace. Over 1.1 million SFR infusions are performed per year with hospice patients alone (Source: Company estimates based on National Hospice and Palliative Care Organization data, 2001). However, over 500 million infusion bags are utilized annually in the United States alone, many of which could potentially convert to SFR using Enhance SC, giving rise to additional market potential (Source: B. Braun, 2003).

### ***Chemophase***

Chemophase, our third product candidate, is a chemoadjuvant designed to enhance the transport of chemotherapeutic agents to tumor tissue, increasing diffusion in distal tissues without affecting vascular permeability. Chemophase is intended 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 diffusion of current or future chemotherapeutics. Previous clinical trials of bovine (bull) PH20 in patients showed 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 Enhance SC. 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 significant time and cost savings by leveraging our current manufacturing process and toxicology package to support a clinical program for a local oncology application. We are refining the clinical targets for Chemophase and plan to file an investigational new drug (IND) application with the FDA in oncology during the second quarter of 2005.



***HTI-101***

Our HTI-101 discovery program is focused on the development of new clinical applications for our second patented enzyme. We intend to leverage our knowledge of this family of enzymes to develop new indications for HTI-101 in the fields of inflammation and lysosomal storage diseases.

***HTI-201***

We have a patented discovery program surrounding another enzyme for use in inflammation and oncology. We intend to leverage our recombinant protein expression capacity to develop this technology.

***HTI-401***

HTI-401 is a fourth patented enzyme in our portfolio that has unique substrate specificity. We intend to develop manufacturing systems for HTI-401 to explore its use in central nervous system trauma and wound healing.

**Collaborations**

We have collaborations underway using our recombinant hyaluronidase technology for gene therapy delivery and for solid tumor chemosensitization. Our research collaboration with the Schering-Plough Research Institute involves the testing of rHuPH20 hyaluronidase for enhanced gene therapy delivery. The research collaboration with the Ludwig Boltzmann Institute of Clinical Oncology in Vienna, Austria is exploring the effects of rHuPH20 on the sensitivity of tumor cells to chemotherapeutic agents. These programs are collaborative research programs supplying recombinant enzyme with partners that have expertise in relevant pre-clinical models or have drugs that may benefit from our Enhance Technology programs.

**Sales and Marketing**

***Cumulase***

Our sales and marketing strategy in the IVF market will consist of a multi-channel approach that targets patients, clinicians, suppliers, and regulators. We will 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 FDA officials, and attending specialty conferences.

One of the highest impact target audiences will be 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 ART clinics in the nation. 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 would benefit greatly 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 three such worldwide distribution agreements with key suppliers serving this market. The agreements are with MediCult AS, a Denmark-based distributor with strengths in the European market, MidAtlantic Diagnostics, Inc., a New Jersey-based distributor with strengths in the North American market, and Cook Ob/ Gyn Incorporated, an Indiana-based distributor with strengths in the worldwide market. These three 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.

***Enhanze SC***

During August 2004, we signed an exclusive sales and marketing agreement with Baxter Healthcare Corporation ( Baxter ) to market, distribute and sell Enhanze SC in the United States and Puerto Rico. Baxter and Halozyme are equal partners in the commercialization of Enhanze SC and may mutually agree to pursue other territories and dosage forms and indications.

**Competition**

***Cumulase***

A strong 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 (bovine products) in the US, and MediCult (ovine) and Vitrolife (bovine) outside the US.

***Enhanze SC***

Some commercial pharmacies now compound hyaluronidase preparations for institutions and physicians. However, there are several 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. The American Academy of Ophthalmology therefore recommends that compounded ophthalmic products be used within 30 days of preparation to minimize bacterial overgrowth and drug decomposition. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. ( ISTA ), with an ovine-derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase™. The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Enhanze SC would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Enhanze SC; but if the FDA later changes its determination and decides that either or both apply to Enhanze SC, then such a decision could have a material adverse impact on our operations.

**Patents and Proprietary Rights**

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 four issued patents and a number of pending patent applications. 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 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 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 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, if our products are approved, could limit or stop 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/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/finish and package Cumulase. We also utilize another third party to fill/finish and package Enhanze SC under an agreement that is terminable by either party, but we are currently negotiating with this third party on a long-term agreement. If we fail to finalize an agreement with this third party, the clinical trial progress, and potential commercialization of Enhanze SC, will likely be delayed.

### **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. Our research and development activities are primarily focused on the development of our Cumulase and Enhanze SC product candidates, but we are also developing Chemophase, and are currently conducting pre-clinical studies in animal models. 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 2004 and 2003 totaled approximately \$6.5 million and \$1.1 million, respectively. Research and development expenditures in fiscal 2004 and 2003 were primarily related to the development of our Cumulase and Enhanze SC product candidates, and, to a lesser extent, Chemophase. We anticipate that we will have significant research and development expenses in the future in connection with the commercialization of our current products and development of new products.

### **Human Resources**

As of February 15, 2005, we had 24 full-time employees, including 17 engaged in research and clinical development activities. Seven employees hold Ph.D. or M.D. degrees. We anticipate hiring five to ten additional employees by the end of 2005. We believe our relationship with our employees is good.

## Risks Related To Our Business

***We have not generated any revenue from product sales to date; we have a history of net losses and negative cash flow, and may never achieve or maintain profitability.***

We have not generated any 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, we expect to incur significant operating losses over the next several years. We have never been profitable, and may never become profitable. Through December 31, 2004, we have incurred aggregate net losses of \$13,071,881.

***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 obtain FDA or other regulatory approval for any of our products. 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 11.8 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 5.9 million of our outstanding warrants contain a call feature that, potentially, will 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 1,971,000 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 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, if we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If we are successful in raising additional capital, a substantial number of additional shares will be outstanding and would 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 for Cumulase, 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. Many other countries including major European countries and Japan have similar requirements.

During September, 2004, we filed a 510(k) application for Cumulase and we intend to file a NDA for Enhanze SC in the first quarter of 2005. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. ( ISTA ), with an ovine-derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase™. The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Enhanze SC would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Enhanze SC; but if the FDA later changes its determination and decides that either or both apply to Enhanze SC, then such a decision could have a material adverse impact on our operations.

The processes for obtaining FDA approval are extensive, time-consuming and costly, and there is no guarantee that the FDA will approve our recently filed 510(k) application or 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 potential products, and we may not be successful in obtaining such approvals for any of our potential products.

***If we are unsuccessful in our clinical trials, we will not receive regulatory approvals for our product candidates.***

Clinical testing of pharmaceutical products is also a long, expensive and uncertain process. Even if initial results of pre-clinical studies or clinical trial results are positive, we may obtain different results in later stages of drug development, including failure to show desired safety and efficacy.

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 to merit an 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 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 approval policies or adopt new regulations; and

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.

In addition, we intend to market certain of our products, and perhaps have certain of our products manufactured, in foreign countries. The process of obtaining approvals in foreign countries is subject to delay and failure for similar reasons.

***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 effectiveness of our sales and marketing efforts; and

the introduction of generic competitors.



We have never successfully marketed any products, and we may not be successful in marketing and promoting our existing product candidates or any other products we develop or acquire in the future.

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, as well as market acceptance and the commercial potential of our products may be negatively affected.

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.

***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 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 be successful.

***If we have problems with our sole contract manufacturer, our product development and commercialization efforts for our product candidates could be delayed or stopped.***

We have signed a commercial supply agreement with Avid Bioservices Incorporated ( Avid ), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical use. Avid will produce the active pharmaceutical ingredient under current good manufacturing practices for commercial scale production and will provide support for chemistry, manufacturing and controls sections for FDA regulatory filings. The active pharmaceutical ingredient is used in Enhance SC, which may require a pre-approval inspection. If Avid fails this pre-approval inspection, it could have a material adverse effect on our business. 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. Difficulties in our relationship with Avid or delays or interruptions in Avid's supply of its requirements could limit or stop our ability to provide sufficient quantities of our products, on a timely basis, for clinical trials and, if our products are approved, could limit or stop commercial sales, which would have a material adverse effect on our business and financial condition.

***If we have problems with the third parties that prepare, package and fill/ finish 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, package and fill/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/finish and package Cumulase. In addition, we currently utilize a third party to fill/finish and package Enhance SC under an agreement that is terminable by either party, but we are currently negotiating with this third party on a long-term agreement. If we fail to finalize an agreement with this third party, the clinical trial progress, and potential commercialization of Enhance SC, will likely be delayed.

***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 also 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, MD, our chief executive officer, or Gregory Frost, PhD, 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 our Company from soon after its 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 employment agreements with any of our employees or officers, including Dr. Lim and Dr. Frost. We do not have key man life insurance policies on the lives of any of our employees, including Dr. Lim and Dr. Frost.

***Future sales of shares of our common stock, including sales of shares issued in our most recent financings, may negatively affect our stock price.***

As a result of our January 2004 private financing transaction, we issued 19,046,721 shares of common stock to certain private investors. In connection with this transaction we also issued warrants to the 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, 8.3 million shares of common stock remain issuable upon exercise of these warrants. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise. We filed a registration statement on Form SB-2 (Registration No. 333-114776), which was declared effective on August 12, 2004, covering the 29,508,664 shares issued to the private investors and issuable upon exercise of the warrants.

As a result of our October 2004 financing transaction, we issued 7,925,715 shares of common stock to certain institutional and accredited investors for \$13.9 million in gross proceeds. In connection with this transaction, we also issued warrants for the purchase of 2,609,542 shares of common stock. We filed a registration statement on Form S-3 (Registration No. 333-120448), which was declared effective on November 26, 2004, covering the 10,535,257 shares issued to the private investors and issuable upon exercise of the warrants. In the future, we may issue additional options, warrants or other derivative securities convertible into Halozyme common stock.

Sales of substantial amounts of shares of our common stock, or even the potential for such sales through the exercise of warrants, could lower the market price of our common stock and impair the Company's ability to raise capital through the sale of equity securities.

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

Our stock price is subject to significant volatility. Overall market conditions, in addition to other risks and uncertainties described in this section and elsewhere in this report, may cause the market price of our common stock to fall. 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 2004 were \$4.75 and \$0.02, respectively. Fluctuations in the price of our common stock may be exacerbated by conditions in the healthcare and technology industry segments or conditions in the financial markets generally.



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

During the last ninety days, our average daily trading volume was approximately 164,000 shares. If limited trading in our stock continues, 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.***

As discussed above in the Risk Related to Our Business titled *We may need to raise funds in the next twelve months, and there can be no assurance that such funds will be available* we may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 5.9 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 by 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, packing, 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 current good manufacturing practices and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

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

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

***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 affect 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 such 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.

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. While we have not ever been and are currently not involved in any litigation, in the event we become involved, 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 remain competitive, 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 is 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. If we succeed in bringing one or more of our product candidates to market, third-party payers may not establish adequate levels of reimbursement for our products, which could limit their market acceptance and result in a material adverse effect on our financial condition.

***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 Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc. (ISTA), and Allergan, Inc., among others. These competitors may develop technologies and products that are more effective 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®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase™. The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Enhanze SC would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Enhanze SC; but if the FDA later changes its determination and decides that either or both apply to Enhanze SC, then such a decision could have a material adverse impact on our operations.

***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.

***We may have difficulty implementing in a timely manner the internal controls over financial reporting necessary to allow our management to report on the effectiveness of our internal controls over financial reporting, and we may incur substantial costs in order to comply with the requirements of the Sarbanes-Oxley Act of 2002.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to furnish a report of management's assessment of the effectiveness of our internal controls over financial reporting as part of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006. Our registered public accountant will then be required to attest to, and report on, our assessment. In order to issue our report, our management must document both the design for our internal controls over financial reporting and the testing processes that support management's evaluation and conclusion. There can be no assurance that we will be able to complete the work necessary for our management to issue its management report in a timely manner, or that management will be able to report that our internal controls over financial reporting are effective.

**Item 2. *Description of Property.***

Our administrative offices and research facilities are located in San Diego, California. We lease an aggregate of approximately 10,800 square feet of office and research space for approximately \$20,000 per month. We have two separate leases for our facilities that expire on June 30, 2005 (5,700 square feet) and June 30, 2006 (5,100 square feet), respectively. We believe the space is adequate for our immediate needs, but additional space may be required 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, Halozyme may be involved in litigation relating to claims arising out of its 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. Halozyme currently is 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 security holders of Halozyme during the fourth quarter of fiscal 2004.

## PART II

### Item 5. *Market for Common Equity and Related Stockholder Matters.*

Since November 1, 2004, our common stock has traded under the symbol HTI on The American Stock Exchange (the AMEX ). From March 12, 2004 through October 31, 2004 our common stock traded under the symbol HZYM on the Over-the-Counter Bulletin Board. Prior to the effectiveness of the merger between Global Yacht Services, Inc. and our predecessor company DeliaTroph Pharmaceuticals, Inc. on March 11, 2004, our common stock traded under the symbol GYHT on the Over-the-Counter Bulletin Board. The following table sets forth the high and low sales prices per share of our common stock:

Fiscal Year 2004	High	Low
First Quarter	\$ 4.75	\$ 0.02
Second Quarter	\$ 4.68	\$ 2.55
Third Quarter	\$ 3.35	\$ 1.41
Fourth Quarter	\$ 3.10	\$ 1.80

Fiscal Year 2003	High	Low
First Quarter	n/a	n/a
Second Quarter	\$ 0.12	\$ 0.05
Third Quarter	\$ 0.10	\$ 0.05
Fourth Quarter	\$ 0.10	\$ 0.02

On February 15, 2005, the closing sales price of Common Stock was \$2.03 per share. As of February 15, 2005, we had approximately 610 shareholders 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.

### Item 6. *Management's Discussion and Analysis of Financial Condition and Results of Operations.*

*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** DeliaTroph Pharmaceuticals, Inc. ( DeliaTroph ), the predecessor company to Halozyme, was founded on February 26, 1998. On March 11, 2004, DeliaTroph merged with a publicly traded corporation, Global Yacht Services, Inc. ( Global ), to form Halozyme. Although Global (which changed its name to Halozyme Therapeutics, Inc. in connection with the Merger) acquired DeliaTroph as a result of the merger, the former shareholders of DeliaTroph held a majority of the voting interest in the combined enterprise immediately after the Merger. Additionally, the Merger resulted in DeliaTroph's management and Board of Directors assuming operational control of Halozyme Therapeutics, Inc. Accordingly, the Merger has been treated as a re-capitalization of DeliaTroph and the financial information presented here and elsewhere in this Annual Report reflects the historical activity of DeliaTroph, unless otherwise indicated. Global conducted limited operations prior to the merger in a line of business wholly unrelated to biopharmaceutical operations, and the results of Global's operations are not reflected in the financial information of Halozyme.

We are a development stage biopharmaceutical company dedicated to the development and planned commercialization of recombinant human enzymes for the infertility, ophthalmology, and oncology communities. 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. Currently, we have no product revenue and all of our potential products are

either in the discovery, pre-clinical, pre-NDA or pre-510(k) stage. It may be years, if ever, before we are able to obtain the necessary regulatory approvals necessary to generate meaningful revenue from the sale of these potential products. In addition, we have never generated any revenue from our

biopharmaceutical operations and we have had operating and net losses each year since inception. We have accumulated a deficit of \$13,071,881 from inception through December 31, 2004.

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 the skin and eyes. 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 that are injected in the skin or in the muscle.

Bovine and ovine-derived hyaluronidases have been used in multiple therapeutic areas, including in vitro fertilization and ophthalmology, where a FDA-approved bovine version was used as a drug delivery agent to enhance dispersion of local anesthesia for cataract surgery 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 less than 1-5% pure.

*Prion disease:* Cattle testes are an organ with the highest concentration of hyaluronidase, but also with the highest levels of a protein implicated in the development of neurodegenerative disorders associated with prion disease, such as Mad Cow Disease.

*Immunogenicity:* Hyaluronidases can also be found in bacteria, leeches, certain venoms, and marine organisms. Very few companies are pursuing clinical development of any of these enzymes. Regardless, all such preparations are non-human, and are therefore likely to elicit potent immune reactions, possess endotoxin, or have some of the same defects as slaughterhouse derivations.

There have been successes in replacing animal-derived drugs with human recombinant biologics, as in the case of insulin, Pulmozyme and human growth hormone. Our objective is to execute this recombinant human enzyme replacement strategy by applying our products under development to key markets in multiple therapeutic areas, beginning with in vitro fertilization and ophthalmology.

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 which encodes human hyaluronidase, may both expand existing markets and create new ones. Gaps in existing hyaluronidase offerings may create demand for our solution.

#### **Revenues**

We have not generated any revenues from product sales since our inception on February 26, 1998. Product revenue will depend on our ability to obtain regulatory approvals for and successfully commercialize our product candidates. We received a CE (European Conformity) Mark for Cumulase in December of 2004, which allows the Company to market Cumulase in the European Union.

#### **Costs and Expenses**

*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, facility costs, amortization and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our Cumulase and Enhance SC product candidates which are both based on our recombinant human PH20 (rHuPH20) enzyme, a human synthetic version of hyaluronidase. We are also developing Chemophase, which is also based on our recombinant PH20 enzyme, and are currently conducting pre-clinical studies in animal models.

Since our inception through December 31, 2004, we have incurred research and development costs of \$8.9 million. From January 1, 2002 through December 31, 2004, approximately 90% of our research and





development costs were associated with the research and development of our recombinant human PH20 enzyme used in our Cumulase and Enhanze SC product candidates. 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 Cumulase, Enhanze SC, and Chemophase product candidates for commercialization. However, we expect our research and development costs to increase substantially if we are able to advance our product candidates into later stages of clinical development.

Clinical development timelines, likelihood of success, and total costs vary widely. Although we are currently focused primarily on advancing Cumulase, Enhanze SC, and 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 on-going basis in response to the scientific and clinical progress of each product candidate and other market 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. While we have filed a 510(k) application for our Cumulase product candidate in September 2004, and we anticipate filing a NDA for our Enhanze SC product candidate in the first quarter of 2005, and an IND for our Chemophase product candidate in the second quarter of 2005, we cannot be certain when or if any net cash inflow from these products or any of our other development projects will commence.

*General and Administrative.* General and administrative expenses consist primarily of compensation and other expenses related to our corporate operations and administrative employees, legal fees and other professional services expenses.

*Other Income and Expense, Net.* Other income and expense, net consists primarily of interest income earned on our cash and cash equivalents and interest expense associated with our short-term notes payable. Other income and expense, net, also includes the liabilities assumed as a result of the Merger.

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

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact the Company in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. While we have not yet recorded any revenue to date, our critical accounting policy regarding revenue recognition is to record revenue when the transfer of ownership occurs, upon shipment to the distributor. Our critical accounting policies also include estimating the useful lives of fixed assets and the resulting depreciation expense and the amount and valuation of inventory.

#### **Results of Operations Comparison of Year Ended December 31, 2004 and 2003**

**Revenues** Halozyme has generated no revenues since its inception on February 26, 1998.

**Research and Development** Research and development expenses were \$6,517,000 for the year ended December 31, 2004 compared to \$1,145,000 for the year ended December 31, 2003. 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 increased by \$5,372,000 due primarily to completion of Cumulase 510(k) requirements, the substantial completion of Enhanze SC chemistry manufacturing and controls

(CMC) and toxicology work, the hiring of additional research and development personnel, and contract manufacturing costs for development and production of our rHuPH20 enzyme for research, clinical, and potential commercial use. We expect research and development costs to continue to increase in future periods as we increase our research efforts and continue to develop and manufacture our first two product candidates.

**General and Administrative** General and administrative expenses were \$2,571,000 for the year ended December 31, 2004 compared to \$576,000 for the year ended December 31, 2003. General and administrative expenses increased by \$1,995,000 due to the hiring of additional administrative personnel and the increased legal and accounting fees associated with becoming a public reporting entity. We anticipate that compliance with provisions of the Sarbanes-Oxley Act of 2002, including Section 404 relating to audits of our internal controls, will increase our general and administrative costs in future periods.

**Other Income and Expense** Other expense was \$4,000 for the year ended December 31, 2004 compared to \$393,000 for the year ended December 31, 2003. The decrease in other expense was due to interest expense incurred in 2003 from outstanding notes payable, which were converted to common stock in October 2003.

**Net Loss** Net loss for the year ended December 31, 2004 was \$9,091,000, or \$0.26 per common share, compared to \$2,115,000, or \$0.26 per common share for the year ended December 31, 2003. The increase in net loss was due to an increase in operating expenses, reflecting our increased research and development efforts and additional personnel costs.

**Liquidity and Capital Resources** As of December 31, 2004, cash and cash equivalents were \$16,007,000 versus \$504,000 as of December 31, 2003, an increase of \$15,503,000. This increase resulted primarily from the sale of common stock and warrants to purchase common stock for approximately \$23,450,000, net of issuance costs during the year ended December 31, 2004, offset by our net cash used in operations and for the purchase of property and equipment for the year ended December 31, 2004.

Net cash used in operations was \$7,718,000 during the year ended December 31, 2004 compared to \$1,459,000 of cash used in operations during the year ended December 31, 2003. This increase was due to an increase in our research and development efforts and additional personnel.

Net cash used in investing activities was \$228,000 during the year ended December 31, 2004 compared to \$72,000 during the year ended December 31, 2003. This was due to the increased purchase of property and equipment and leasehold improvements during 2004.

Net cash provided by financing activities was \$23,450,000 during the year ended December 31, 2004 versus \$1,946,000 during the year ended December 31, 2003. In January 2004, we sold common stock and warrants to purchase common stock for approximately \$8,057,000, or \$7,670,000 net of issuance costs. In October 2004, we sold common stock and warrants to purchase common stock for approximately \$13,870,000, or \$12,717,000 net of issuance costs. Additionally, we received approximately \$2,863,000 in proceeds from warrant exercises for the year ended December 31, 2004. During the year ended December 31, 2003, we received \$942,000 from the issuance of promissory notes, which are no longer outstanding, and the issuance of common stock upon the exercise of stock options.

We expect our cash requirements to increase significantly in the foreseeable future 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 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 into 2006. 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 from our recent private financing. We



may finance future cash needs through the sale of other equity securities, the exercise of our callable warrants, strategic collaboration agreements and debt financing. We cannot be certain that our existing cash and cash equivalents will be adequate 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 would likely 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, 2004, 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 do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

**Recent Accounting Pronouncements**

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

**Item 7. Financial Statements.**

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

**Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.**

On March 12, 2004, our Board of Directors voted to replace the independent accountant that had reported on the financial statements for Global Yacht Services, Inc., Hall & Company ( Hall ). We retained the accounting firm of Cacciamatta Accountancy Corporation ( Cacciamatta ) on March 12, 2004, to make an examination of the financial statements for the 2002 and 2003 fiscal years. This examination by Cacciamatta reflected our post-merger structure and our activities as a biopharmaceutical corporation. We authorized Hall to respond fully to any inquiries from Cacciamatta and to make Hall s work papers available to Cacciamatta. We did not have any disagreements with Hall nor did Hall s prior reports contain adverse opinions or disclaimers of opinions. Hall did not make any negative report regarding our internal controls, management or prior financial statements prior to its dismissal.

**Item 8A. 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 Controls Over Financial Reporting**

There have been no significant changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2004, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**Item 8B. Other Information.**

None.

### PART III

#### **Item 9. Directors and Executive Officers.**

The information required by this item regarding directors is incorporated by reference to our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with our 2005 Annual Meeting of Stockholders (the Proxy Statement) 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 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 Ethics contained in our Proxy Statement.

#### **Executive Officers**

**Jonathan E. Lim, MD (33)**, 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 software company; 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 member of the strategic planning committee of the American Medical Association. He 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, PhD (33)**, Vice President & Chief Scientific Officer and Director. Dr. Frost joined Halozyme in 1999 and has spent more than ten 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 13 scientific peer-reviewed and invited articles in the Hyaluronidase field and is an inventor on numerous 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 PhD in the department of Pathology at the University of California, San Francisco, where he was an ARCS-Scholar.

**David A. Ramsay, MBA (40)**, Vice President & Chief Financial Officer. Mr. Ramsay joined Halozyme in 2003 and brings 17 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, a multinational, specialty pharmaceutical company. Mr. Ramsay joined ICN in 1998 from ARCO, where he spent four years in various financial roles, most recently serving as Manager of Financial Planning & Analysis for the company's 1,700-station West Coast Retail Marketing Network. Prior to ARCO, he served as Vice President, Controller for Security Pacific Asian Bank, a subsidiary of Security Pacific Corporation. He began his career as an Auditor at Deloitte & Touche, where he obtained his CPA license. Mr. Ramsay also serves on the Board of Directors for Axxora Life Sciences, Inc., a privately held, worldwide research reagent company. 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.

**Don A. Kennard (58)**, 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 and a Regulatory Affairs Certificate.

**Carolyn M. Rynard, PhD (50)**, Vice President of Product Development & Manufacturing. Dr. Rynard joined Halozyme in 2003. Dr. Rynard's career in drug development spans 20 years in the pharmaceutical and biotech industries. Her broad experience includes project management, formulation, manufacturing, clinical supplies, validation, medical devices, and quality systems. From 2001 to 2003, Dr. Rynard was Vice President of Product Development at Medinox, Inc., where she was directly responsible for Medinox's Chemistry, Manufacturing, and Control, formulation, analytical methods, and specification development. From 1994 to 2001, she worked for Amylin Pharmaceuticals, Inc., a San Diego, California-based pharmaceutical company where she held various positions of increasing responsibility, serving most recently as Senior Director of Product Development. At Amylin, Dr. Rynard managed seven functional areas and wrote CMC sections for US NDAs and investigational new drug applications; European marketing authorization applications and clinical trial exemptions; as well as device 510(k) and CE mark technical files. Prior to joining Amylin, Dr. Rynard held various R&D positions at Baxter Healthcare and at DuPont. Dr. Rynard earned her BSc degree in Chemistry and Biochemistry from the University of Toronto, and her PhD in Physical and Organic Chemistry from Stanford University.

**Mark S. Wilson, MBA (44)**, Vice President of Business Development. Mr. Wilson joined Halozyme in 2003 and has spent more than 15 years in the biotechnology/pharmaceutical industry, having most recently served as Founder and CEO of Biophysica Science, Inc. and Director of Strategic External Alliance Management at Pfizer Global R&D La Jolla from 2001 to 2003. From 1996 to 2001, Mr. Wilson was Associate Director of Materials at Agouron Pharmaceuticals, Inc., where he identified and negotiated international supply agreements in excess of \$120 million annually and served as Materials Manager for the launch of Viracept. From 1991 to 1996, Mr. Wilson was an Associate Director at Gensia Laboratories, Ltd., where he directed a wide range of business operations. Prior experience also includes various management and operational roles at Hybritech, Ferro Corporation, and TRW, Inc. Mr. Wilson earned his BS degree in engineering from the University of California, Berkeley, and his MBA degree at the Anderson Graduate School of Management at the University of California, Los Angeles.

#### **Item 10. 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.

**Item 11. 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 12. Certain Relationships and Related Transactions.**

The information required by this item is incorporated by reference to the information under the caption Certain Relationships and Related Transactions contained in the Proxy Statement.

**Item 13. Exhibits.**

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

**(a) Financial Statements:**

	<b>Page</b>
Report of Independent Registered Accounting Firm	F-1
Consolidated Balance Sheet at December 31, 2004	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2004 and 2003 and from Inception to December 31, 2004	F-3
Consolidated Statements of Stockholders Equity from Inception to December 31, 2004	F-4
Consolidated Statements of Cash Flows for the Years Ended December 31, 2004 and 2003 and from Inception to December 31, 2004	F-5
Notes to Consolidated Financial Statements	F-6

**(b) Exhibits:**

<b>Exhibit</b>	<b>Title</b>
2.1	Agreement of Merger between DeliaTroph Pharmaceuticals, Inc. and Registrant, dated January 28, 2004(1)
3.1	Amended and Restated Articles of Incorporation(1)
3.2	Bylaws(2)
10.1	License Agreement between University of Connecticut and Registrant, dated November 15, 2002(3)
10.2*	Agreement for Services between Avid Bioservices, Inc. and Registrant, dated November 19, 2003(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*	Distribution Agreement between Cook Ob/Gyn Incorporated and Registrant, dated April 13, 2004(3)
10.6	2004 Stock Plan and Form of Option Agreement thereunder(4)



Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10KSB

- 10.7 Form of Indemnity Agreement for Directors and Executive Officers(4)
- 10.8\* Exclusive Distribution Agreement between Baxter Healthcare and Registrant, dated August 13, 2004(5)
- 10.9 Form of Callable Stock Purchase Warrant(4)
- 10.10 Securities Purchase Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004(6)
- 10.11 Form of Common Stock Purchase Warrant(6)
- 10.12 Registration Rights Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004(6)

<b>Exhibit</b>	<b>Title</b>
10.13*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005(7)
31.1	Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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 Information Statement on Schedule 14C filed on February 17, 2004.
- (2) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 14, 2004.
- (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 Current Report on Form 8-K, filed February 22, 2005.  
\* 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.

**Item 14. *Principal Accountant Fees and Services.***

The information required by this item is incorporated by reference to the information under the caption **Principal Accountant Fees and Services** contained in the Proxy Statement.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on March 11, 2005.

Halozyme Therapeutics, Inc.,  
a Nevada corporation  
By: /s/ Jonathan E. Lim

Jonathan E. Lim, MD  
President, Chief Executive Officer,  
Chairman of the Board

Date: March 11, 2005

**POWER OF ATTORNEY**

Know all persons by these presents, that each person whose signature appears below constitutes and appoints Jonathan E. Lim and David A. Ramsay, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Annual Report has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Jonathan E. Lim, M.D. Jonathan E. Lim, M.D.	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 11, 2005
/s/ David A. Ramsay David A. Ramsay	Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2005
/s/ Gregory I. Frost, Ph.D. Gregory I. Frost, Ph.D.	Vice President and Chief Scientific Officer, Director	March 11, 2005
/s/ Kenneth J. Kelley Kenneth J. Kelley	Director	March 11, 2005
/s/ Robert L. Engler, M.D. Robert L. Engler, M.D.	Director	March 11, 2005
/s/ John S. Patton, Ph.D.	Director	March 11, 2005

John S. Patton, Ph.D.

**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 (a development stage company) (the Company) as of December 31, 2004, 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, 2004, and for the period from inception (February 26, 1998) to December 31, 2004. 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, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2004, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2004, and for the period from inception (February 26, 1998) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ CACCIAMATTA ACCOUNTANCY  
CORPORATION

Irvine, California  
February 18, 2005

F-1

---

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED BALANCE SHEET**  
**As of December 31, 2004**

<b>ASSETS</b>	
<b>CURRENT ASSETS:</b>	
Cash and cash equivalents	\$ 16,007,714
Inventory	51,821
Prepaid expenses and other current assets	86,087
Total current assets	16,145,622
PROPERTY AND EQUIPMENT, net	235,505
OTHER ASSETS	22,544
Total Assets	\$ 16,403,671
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>	
<b>CURRENT LIABILITIES:</b>	
Accounts payable	\$ 1,487,243
Accrued expenses	92,170
Total current liabilities	1,579,413
<b>COMMITMENTS AND CONTINGENCIES</b>	
<b>STOCKHOLDERS EQUITY:</b>	
Common stock, \$0.001 par value; 100,000,000 shares authorized; 49,202,083 shares issued and outstanding	
	49,202
Additional paid-in-capital	27,846,937
Deficit accumulated during the development stage	(13,071,881)
Total Stockholders Equity	14,824,258
Total Liabilities and Stockholders Equity	\$ 16,403,671

The accompanying notes are an integral part of these financial statements.

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**For the Years Ended December 31, 2004 and 2003 and**  
**From Inception to December 31, 2004**

	<b>2004</b>	<b>2003</b>	<b>Cumulative from Inception (February 26, 1998) to 2004</b>
<b>EXPENSES:</b>			
Research and development	\$ 6,517,254	\$ 1,145,420	\$ 8,927,298
General and administrative	2,570,595	576,452	3,771,740
Total Expenses	9,087,849	1,721,872	12,699,038
Other income (expense), net	(3,527)	(393,153)	(372,843)
<b>LOSS BEFORE INCOME TAXES</b>	(9,091,376)	(2,115,025)	(13,071,881)
Income Tax Expense			
<b>NET LOSS</b>	\$ (9,091,376)	\$ (2,115,025)	\$ (13,071,881)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.26)	
Shares used in computing net loss per share, basic and diluted	35,411,127	8,196,362	

The accompanying notes are an integral part of these financial statements.

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**From Inception (February 26, 1998) to December 31, 2004**

	Common Stock		Paid-In Capital	Deficit Accumulated During Development	Total Shareholders Equity
	Shares	Amount			
(All share information reflects post-split amounts)					
Initial capitalization		\$	\$ 10,956	\$	\$ 10,956
Contributed capital net			132,819		132,819
Net loss				(41,884)	(41,884)
BALANCE,					
DECEMBER 31, 1999			143,775	(41,884)	101,891
Contributed capital net			78,473		78,473
Net loss				(125,210)	(125,210)
BALANCE,					
DECEMBER 31, 2000			222,248	(167,094)	55,154
Issuance of common stock for cash, February 22, 2001	4,275,000	4,275			4,275
Issuance of common stock for cash, May 4, 2001	21,376	21			21
Issuance of common stock for cash, May 25, 2001	1,187,498	1,188			1,188
Contributed capital net			796,225		796,225
Net loss				(563,621)	(563,621)
BALANCE,					
DECEMBER 31, 2001	5,483,874	5,484	1,018,473	(730,715)	293,242
Issuance of common stock for cash, May 10, 2002	2,712,488	2,712	124,188		126,900
Contributed capital net			335,063		335,063
Net loss				(1,134,765)	(1,134,765)
BALANCE,					
DECEMBER 31, 2002	8,196,362	8,196	1,477,724	(1,865,480)	(379,560)
Contributed capital net			2,868,392		2,868,392
Net loss				(2,115,025)	(2,115,025)
BALANCE,					
DECEMBER 31, 2003	8,196,362	8,196	4,346,116	(3,980,505)	373,807
Redemption of common stock, March 10, 2004	(4,296,362)	(4,296)	(38,007)		(42,303)
Issuance of shares for Merger with DeliaTroph	35,521,906	35,522	7,876,927		7,912,449



Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10KSB

net					
Exercise of warrants	282,780	283	128,716		128,999
Exercise of callable warrants, net	1,571,682	1,571	2,726,036		2,727,607
Issuance of common stock for cash, net	7,925,715	7,926	12,708,949		12,716,875
Issuance of common stock options to consultants			98,200		98,200
Net loss				(9,091,376)	(9,091,376)
 BALANCE, DECEMBER 31, 2004	 49,202,083	 \$ 49,202	 \$ 27,846,937	 \$ (13,071,881)	 \$ 14,824,258

The accompanying notes are an integral part of these financial statements.

F-4

---

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the Years Ended December 31, 2004 and 2003 and**  
**From Inception to December 31, 2004**

	2004	2003	Cumulative from Inception (February 26, 1998) to 2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (9,091,376)	\$ (2,115,025)	\$ (13,071,881)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	123,350	75,726	332,240
Issuance of common stock for goods and services	98,200	85,388	200,445
Issuance of common stock for license			2,330
Issuance of common stock for accrued interest on notes		87,510	99,764
Beneficial conversion feature on 2003 notes		306,754	306,754
Changes in operating assets and liabilities:			
Inventory	(51,821)		(51,821)
Prepaid expenses and other assets	(95,868)	(5,263)	(108,631)
Accounts payable and accrued expenses	1,299,859	105,554	1,573,299
Net cash provided by operating activities	(7,717,656)	(1,459,356)	(10,717,501)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(227,951)	(72,460)	(544,646)
Net cash used in investing activities	(227,951)	(72,460)	(544,646)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of notes		842,000	1,272,000
Proceeds from issuance of common stock		100,000	110,956
Proceeds from exercise of warrants net	2,862,720		2,862,720
Contributed capital net	7,870,146	1,004,486	10,307,310
Proceeds from issuance of common stock net	12,716,875		12,716,875
Net cash provided by financing activities	23,449,741	1,946,486	27,269,861
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>			
	15,504,134	414,670	16,007,714
	503,580	88,910	

**CASH AND CASH EQUIVALENTS,  
beginning of period**

CASH AND CASH EQUIVALENTS, end of period	\$ 16,007,714	\$ 503,580	\$ 16,007,714
--	---------------	------------	---------------

**SUPPLEMENTAL DISCLOSURES OF  
CASH FLOW INFORMATION:**

Cash paid for income taxes	\$	\$	\$
----------------------------	----	----	----

Interest paid	\$	\$	\$
---------------	----	----	----

**Non cash investing and financing activities:**

Conversion of contributed capital to common stock	\$ 7,870,146	\$	\$ 10,307,310
---	--------------	----	---------------

Conversion of notes payable to common stock	\$	\$ 1,371,764	\$ 1,371,764
---	----	--------------	--------------

Conversion of Series C preferred stock to common stock	\$ 1,004,486	\$	\$ 1,004,486
--	--------------	----	--------------

Common stock issued for property and equipment	\$	\$	\$ 3,099
--	----	----	----------

Series A preferred stock issued for property and equipment	\$	\$	\$ 20,000
--	----	----	-----------

Accrued cost for redemption of unexercised callable warrants	\$ 6,114	\$	\$ 6,114
--	----------	----	----------

The accompanying notes are an integral part of these financial statements.

**Halozyme Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

**1. Organization and Business**

Halozyme is a development stage biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the infertility, ophthalmology, and oncology 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 a limited number of product candidates. As the Company has not begun principal operations of commercializing a product candidate, the financial statements have been presented as a development stage company.

DeliaTroph Pharmaceuticals, Inc. ( DeliaTroph ), our predecessor company, was incorporated on February 26, 1998. Effective March 11, 2004, DeliaTroph (which was doing business at the time as Hyalozyme Therapeutics, Inc.), Global Yacht Services, Inc. ( Global ), a publicly traded Nevada corporation and Hyalozyme Acquisition Corporation ( Merger Sub ), a wholly owned subsidiary of Global, completed a transaction in which Merger Sub merged with and into DeliaTroph (the Merger ), with DeliaTroph surviving as a wholly owned subsidiary of Global.

Although Global acquired DeliaTroph as a result of the Merger, the former shareholders of DeliaTroph received a majority of the voting interest in the combined enterprise as consideration for entering into the Merger. Additionally, the Merger resulted in DeliaTroph's management and Board of Directors assuming operational control of Global.

The following summary lists the structure of the Merger and matters completed in connection therewith:

On January 28, 2004, pursuant to an investment round completed simultaneously with the signing of the definitive Merger agreement, DeliaTroph raised equity capital of approximately \$8.1 million.

The stockholders of Global amended and restated Global's Articles of Incorporation to change Global's corporate name to Halozyme Therapeutics, Inc., increased the authorized number of shares of common stock to 100 million, and authorized 20 million shares of preferred stock.

Global, now named Halozyme Therapeutics, Inc., issued 35,521,906 shares of its restricted common stock, 6,380,397 options and 11,742,665 warrants to purchase shares of its common stock to the shareholders of DeliaTroph in exchange for 100% of their issued and outstanding common stock, options and warrants to purchase DeliaTroph's common stock.

A total of 4,296,362 shares of Global, now named Halozyme Therapeutics, Inc., outstanding common stock were redeemed by Global from three stockholders in exchange for \$42,303, or approximately \$0.01 per share.

Upon completion of the Merger, the pre-Merger stockholders of Global owned approximately 10% of the issued and outstanding shares of Halozyme Therapeutics, Inc., based on 39,421,906 shares outstanding after the Merger. The full text of the Merger Agreement may be found in Exhibit A to Global Yacht's definitive Schedule 14C Information Statement, as filed with the Securities and Exchange Commission on February 17, 2004.

The Merger has been treated as a re-capitalization of DeliaTroph and, accordingly, the financial statements reflect the historical activity of DeliaTroph with the capital structure of Global. Prior to the Merger, Global had limited operations.

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

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. and with the rules and regulations of the Securities and Exchange Commission related to an annual report on Form 10-KSB.

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosures of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Certain amounts in the prior year financial statements have been reclassified to conform to the current year presentation.

***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.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist of cash and cash equivalents. The Company maintains its cash balances with one major commercial bank. The balances are insured by the Federal Deposit Insurance Corporation up to \$100,000.

***Inventory***

Inventories are stated at lower of cost or market and consist of raw materials and work in process used in the manufacture of the Company's Cumulase product. Inventories are valued using a standard cost approach that approximates the first-in, first-out method. The inventory of work in process represents those units the Company expects to sell in the European Union or to be used in sampling programs.

***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 Statements 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, 2004, the Company believes there has been no impairment of the value of such assets.

***Research and Development Costs***

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with FASB statement No. 2, *Accounting for Research and Development Costs*.

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

***Stock-Based Compensation***

In December 2002, Statement of Financial Accounting Standards ( SFAS ) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123* was issued. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation from the intrinsic value-based method of accounting prescribed by Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. The Company adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting prescribed in APB No. 25 and, accordingly, does not recognize compensation expense for stock option grants made to employees at an exercise price equal to or in excess of the fair value of the stock at the date of grant. Deferred compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options.

Had compensation cost for the Company s outstanding employee stock options been determined based on the fair value at the grant dates for those options consistent with SFAS No. 123, the Company s net loss and basic and diluted net loss per share, would have been changed to the following pro forma amounts:

	<b>Year Ended</b>	
	<b>2004</b>	<b>2003</b>
	<b>In thousands</b>	
Net loss, as reported	\$ (9,091)	\$ (2,115)
Deduct: Total stock-based employee Compensation expense determined under Fair value based method for all awards	(1,619)	(149)
Pro forma net loss	\$ (10,710)	\$ (2,264)
Net loss per share, basic and diluted, as reported	\$ (0.26)	\$ (0.26)
Pro forma net loss per share, basic and diluted	\$ (0.30)	\$ (0.28)

SFAS No. 123 pro forma information regarding net loss is required by SFAS No. 123, and has been determined as if the Company had accounted for its stock-based employee compensation under the fair value method prescribed in SFAS No. 123. The fair value of the options was estimated at the date of grant using the Black-Scholes pricing model with the following assumptions for the year ended December 31, 2004 and 2003: weighted-average risk-free interest rate of 3.0%; a dividend yield of 0%; a stock price volatility of 100%; and a weighted-average life of the option of 48 months.

The effects of applying SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed over their respective vesting periods.

The Company accounts for options issued to nonemployees under SFAS No. 123 and Emerging Issues Task Force ( EITF ) Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. As such, the value of such options is periodically remeasured and income or expense is recognized during their vesting terms.

***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

F-8

---

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

(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 Company's computation of net loss per share as their effect would have been anti-dilutive.

		<b>Year Ended</b>	
		<b>2004</b>	<b>2003</b>
Numerator	Net loss	\$ (9,091,376)	\$ (2,115,025)
Denominator	Weighted average shares outstanding	35,411,127	8,196,362
Net loss per share		\$ (0.26)	\$ (0.26)
Incremental common shares (not included because of their anti-dilutive nature)			
	Stock options	8,700,397	21,697,371
	Stock warrants	11,886,346	11,316,033
Potential common equivalents		20,586,743	33,013,404

***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, 2004 and 2003, the Company has no reportable differences between net loss and comprehensive loss.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States 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 the Company 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 the Company's estimates.

***Recent Accounting Pronouncements***

On December 16, 2004 the FASB issued SFAS No. 123R, Share-Based Payment, which is an amendment to SFAS No. 123, Accounting for Stock-Based Compensation. This new standard eliminates the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and generally requires such transactions be accounted for using a fair-value-based method and the resulting cost recognized in our financial statements. This new standard is effective for awards that are granted, modified or settled in cash in interim and annual periods beginning after June 15, 2005, December 15, 2005 for small business issuers. In addition, this statement will apply to unvested options granted prior to the effective date. The Company will adopt this new standard effective for the first fiscal quarter of 2006 and it has not yet determined what impact this standard will have on its financial position or results of operations.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs: an amendment of ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after





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

June 15, 2005. We do not believe the provisions of SFAS No. 151, when applied, will have a material impact on our financial position or results of operations.

**3. Inventories**

Inventories are stated at the lower of cost or market and consist of raw materials of \$22,870 and work in process of \$28,951 used in the manufacture of the Company's Cumulase product. Inventories are valued using a standard cost approach that approximates the first-in, first-out method. The inventory of work in process represents those units the Company expects to sell in the European Union or to be used in sampling programs.

**4. Property and Equipment**

	2004	2003
Research equipment	\$ 333,403	\$ 195,534
Office equipment and furniture	102,775	59,687
Leasehold improvements	131,567	84,573
	567,745	339,794
Less accumulated depreciation and amortization	(332,240)	(208,890)
	\$ 235,505	\$ 130,904

Depreciation and amortization expense totaled \$123,350 in 2004 and \$75,726 in 2003.

**5. Accrued Expenses**

	2004	2003
Other accrued expenses	20,065	11,000
Accrued vacation payable	72,105	39,162
	\$ 92,170	\$ 50,162

**6. Stockholders Equity**

*Issuance of Common Stock* In March 1999, the Company issued 2,078,662 shares of common stock for \$10,956 in goods and services. In January 2000, the Company issued 2,078,662 shares of common stock for \$10,956 in cash. In August 2000, the Company issued 442,267 shares of common stock in exchange for a license valued at \$2,330. Of the common stock 4,157,324 shares were sold to founders of the Company.

In January 2004, the purchasers of the Series C stock exercised their option and the Company issued 15,304,804 shares of common stock in a private placement, at \$0.4647 per share, generating approximately \$7.1 million in gross proceeds. In addition, the Company sold 756,286 shares of common stock for \$1.25 per share, or \$0.9 million in gross proceeds. Net proceeds from this transaction totaled approximately \$7.9 million. In March 2004, the Company issued 3,900,000 shares of common stock as a result of the reverse Merger. In October 2004, the Company issued 7,925,715 shares of common stock in a private placement at a price per share of \$1.75, generating approximately \$12.7 million in net proceeds.

*Issuance of Common Stock Options for Services* In September 2002, the Company issued 7,897 common stock options for consulting services valued at \$500. In January 2003, the Company issued 39,488 common stock options

for consulting services valued at \$2,500. In April 2003, the Company issued 39,488 common stock options for consulting services valued at \$2,500. In October 2003, the Company issued 39,488 common stock options for consulting services valued at \$2,500. In November 2003, the Company issued 24,712 common stock options for consulting services valued at \$9,638. In December 2003, the Company

F-10

---

**Halozyme Therapeutics, Inc.**

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

issued 100,000 common stock options to two former Board members and 75,000 common stock options to members of its Scientific Advisory Board. 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, totaling \$68,250, was recorded as a noncash stock issuance cost by the Company.

In July 2004, the Company issued 10,000 common stock options to members of its Scientific Advisory Board valued at \$33,000. In November 2004, the Company issued 20,000 common stock options for consulting services valued at \$45,000. In December 2004, the Company issued 10,000 common stock options for consulting services valued at \$20,200. 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 issuance cost by the Company.

*Series A, B and C Convertible Preferred Stock* In January 2001, the Company completed an 8 for 1 stock split of its outstanding common stock and Series A preferred stock. In November 2001, the Company completed a 2 for 1 stock split for the Series B preferred stock and warrants. In October 2003, the Company completed a 1 for 1.266199 reverse stock split of all its common stock. All share numbers and per share dollar values in the accompanying financial statements and footnotes have been restated for all periods presented to reflect the stock splits.

From March 1999 to January 2000, the Company sold 3,803,507 shares of Series A convertible preferred stock ( Series A ) for \$198,006 (\$178,006 in cash and \$20,000 in goods and services), net of issuance costs. From March 2001 to May 2002, the Company sold 2,743,121 shares of Series B convertible preferred stock ( Series B ) for \$1,254,672 in cash, net of issuance costs. During October 2003, the Company sold 2,367,114 shares of Series C convertible preferred stock ( Series C ) for \$1,004,486, net of issuance costs. In addition, in connection with the Series C financing, the Company issued an option to purchasers of the Series C to buy an additional 15,304,804 shares of the Company's common stock for \$0.4647 per share or \$7,112,142. In connection with the Series C financing, 289,482 additional shares of Series B stock were issued to the Series B investors as a result of anti-dilution provisions.

Upon closing the Series C investment, the Series A and Series B were all converted to common stock. The liquidation preference of the Series C is \$0.4647 per share and is payable in preference to the common stock. Following this distribution, upon liquidation, any remaining assets of the Company shall be distributed ratably to holders of the common stock. Upon closing the Company's January 2004 private placement, the Series C stock converted to common stock.

*Warrants* In November and December of 2001, the Company granted warrants to purchase 252,721 shares of common stock at an exercise price of \$0.4748 per share to purchasers of the Series B. From January to May 2002, the Company granted warrants to purchase 109,248 shares of common stock at an exercise price of \$0.4748 per share to purchasers of the Series B. These warrants are exercisable until February 15, 2005. In June 2002, the Company granted, to outside parties for services, warrants to purchase 67,129 shares of common stock at an exercise price of \$0.13 per share. These warrants were fully exercisable and fully vested on the date of grant and shall expire in ten years based on the terms of the warrants. The fair value of these warrants, totaling \$8,500, was recorded as a non-cash stock issuance cost by the Company.

In connection with the notes issued in 2002 and 2003 (see Note 4), the Company granted warrants to purchase 867,419 shares of common stock at an exercise price of \$0.4496 per share. These warrants are exercisable until October 20, 2007. In October 2003, in conjunction with the issuance of its Series C convertible preferred stock, 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.

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

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 connection with the October 2004 private placement, the Company issued warrants to purchase 2,609,542 shares of common stock at an exercise price of \$2.25 per share. These warrants are exercisable until October 12, 2009. In December the Company called the first tranche of the **Callable Warrants**. 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.

**7. Stock Option Plan**

The Company's 2004 Stock Plan (the **Plan**) and 2001 Stock Plan, as amended, provide for the granting of non-statutory or incentive stock options to acquire shares of the Company's common stock to employees of the Company. The Plan is administered by the Board of Directors and permits the issuance of options for the purchase of up to 10,000,000 shares, as amended, of the Company's common stock at exercises prices of not less than the fair market value of the underlying shares on the date of grant. Options granted under the Plan generally vest over a four-year period and expire up to a maximum of 10 years from the date of grant.

The following table summarizes stock option activity for the periods indicated:

	Shares Underlying Stock Options	Weighted Average Option Price per Share
Outstanding, January 1, 2002		
Granted	60,573	\$ 0.06
Canceled	(10,327)	\$ 0.06
Outstanding, December 31, 2002	50,246	\$ 0.06
Granted	6,603,426	\$ 0.38
Exercised	(256,410)	\$ 0.39
Canceled	(4,695)	\$ 0.06
Outstanding, December 31, 2003	6,392,567	\$ 0.38
Granted	2,814,240	\$ 2.01
Exercised	(506,410)	\$ 0.39
Outstanding, December 31, 2004	8,700,397	\$ 0.91

The following table summarizes information for outstanding and exercisable options as of December 31, 2004:

Options Outstanding			Options Exercisable	
Number	Weighted Average Remaining Contractual	Weighted Average Exercise	Number Vested and	Weighted Average Exercise

<b>Exercise Price</b>	<b>Outstanding</b>	<b>Life in Years</b>	<b>Price</b>	<b>Exercisable</b>	<b>Price</b>
\$0.06	164,015	5.5	\$ 0.06	153,198	\$ 0.06
\$0.39 \$0.43	6,216,382	8.1	\$ 0.40	2,194,834	\$ 0.40
\$1.25	150,000	9.1	\$ 1.25		
\$2.02 \$2.25	1,687,000	9.8	\$ 2.04	430,000	\$ 2.04
\$3.30 \$4.10	483,000	9.4	\$ 3.81	68,332	\$ 3.98
	8,700,397	8.5	\$ 0.91	2,846,364	\$ 0.71

F-12

---

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

**8. Income Taxes**

Income taxes are recorded in accordance with SFAS No. 109, *Accounting for Income Taxes*. This statement 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 financial statements or tax returns. Measurement of the deferred items is based on enacted tax laws. In the event the future consequences of differences between financial reporting bases and tax bases of the Company's assets and liabilities result in a deferred tax asset, SFAS No. 109 requires an evaluation of the probability of being able to realize the future benefits indicated by such assets. A valuation allowance related to a deferred tax asset is recorded when it is more likely than not that some portion or the entire deferred tax asset will not be realized. The Company had combined federal and state deferred tax assets of approximately \$5,500,000 at December 31, 2004 and \$1,400,000 at December 31, 2003, consisting primarily of net operating loss carryforwards. The Company has recorded a full valuation allowance for all net deferred tax assets generated to date. The deferred tax assets and valuation allowance increased approximately \$4,100,000 in 2004. The federal and state net operating losses total approximately \$12,200,000, and begin to expire in 2018 and 2008, respectively.

**9. Commitments and Contingencies**

*Operating Leases* On May 20, 2003, the Company signed a two-year lease for 5,728 square feet of office and lab space in a building located at 11588 Sorrento Valley Road, San Diego, California, commencing on June 1, 2003. On October 28, 2004, the Company signed an 18-month lease for an additional 5,060 square feet of office and lab space in the same building, commencing on January 1, 2005. Additionally, the Company leases certain office equipment under operating leases. Rent expense totaled \$147,638 and \$123,110 for the years ended December 31, 2004 and 2003, respectively.

Future minimum payments, by year and in the aggregate, required under the Company's non-cancelable operating lease obligations consist of the following:

**Year Ending December 31**

2005	\$ 159,134
2006	47,364
	206,498

*Material Agreement* In February 2005, we entered into a Commercial Supply Agreement with Avid Bioservices, Inc. (Avid). Avid will manufacture under current good manufacturing practices our first recombinant human enzyme on a non-exclusive basis over the next two years. This enzyme will be used in Cumulase<sup>tm</sup> and Enhanze SC<sup>tm</sup>, our first two product candidates, as well as in other products currently in development. Avid will produce up to seven batches per year of the enzyme under the terms of the Agreement. The enzyme is used in Enhanze SC, which may require a pre-approval inspection (PAI). If Avid fails this PAI, it could have a material adverse effect on our business. 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. Difficulties in our relationship with our manufacturer or delays or interruptions in such manufacturer's supply of its requirements could limit or stop our ability to provide sufficient quantities of our products, on a timely basis, for clinical trials and, if our products are approved, could limit or stop commercial sales, which would have a material adverse effect on our business and financial condition.

*Legal Contingencies* In the ordinary course of business, we may face various claims brought by third parties, including claims relating to the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different





**Halozyme Therapeutics, Inc.**

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

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 operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

F-14