

HALOZYME THERAPEUTICS INC

Form 10QSB

May 13, 2005

**Table of Contents**

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

**FORM 10-QSB**

(Mark One)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **March 31, 2005**

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-49616

**HALOZYME THERAPEUTICS, INC.**

---

(Exact name of small business issuer as specified in its charter)

**Nevada**

**88-0488686**

---

(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

**11588 Sorrento Valley Road, Suite 17, San Diego, California 92121**

---

(Address of principal executive offices)

**(858) 794-8889**

---

(Issuer's telephone number)

**Not Applicable**

---

(Former name, former address and former fiscal year, if changed since last report )

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

**APPLICABLE ONLY TO CORPORATE ISSUERS**

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 49,922,468 shares issued and outstanding as of April 30, 2005.

Transitional Small Business Disclosure Format (Check one):

Yes  No

---

**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED BALANCE SHEET - UNAUDITED**  
**AS OF MARCH 31, 2005**

---

**ASSETS**

## CURRENT ASSETS:

Cash and cash equivalents	\$ 13,130,312
Inventory	47,145
Prepaid expenses and other current assets	362,967

Total current assets	13,540,424
----------------------	------------

PROPERTY AND EQUIPMENT, net	316,081
-----------------------------	---------

OTHER ASSETS	20,313
--------------	--------

Total Assets	\$ 13,876,818
--------------	---------------

**LIABILITIES AND STOCKHOLDERS EQUITY**

## CURRENT LIABILITIES:

Accounts payable	\$ 1,768,517
Accrued expenses	159,438

Total current liabilities	1,927,955
---------------------------	-----------

## COMMITMENTS AND CONTINGENCIES

## STOCKHOLDERS EQUITY:

Common stock, \$0.001 par value; 100,000,000 shares authorized; 49,922,468 shares issued and outstanding	49,922
Additional paid-in-capital	28,163,899
Deficit accumulated during the development stage	(16,264,958)

Total Stockholders Equity	11,948,863
---------------------------	------------

Total Liabilities and Stockholders Equity	\$ 13,876,818
-------------------------------------------	---------------

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



**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS - UNAUDITED**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004 AND FROM INCEPTION TO MARCH 31, 2005**

---

	<b>2005</b>	<b>2004</b>	<b>Cumulative from inception (February 26, 1998) to 2005</b>
OPERATING EXPENSES:			
Research and development	\$ 2,462,290	\$ 696,581	\$ 11,389,588
General and administrative	808,621	510,971	4,580,361
Total Operating Expenses	3,270,911	1,207,552	15,969,949
Other income (expense), net	77,834	(76,870)	(295,009)
LOSS BEFORE INCOME TAXES	(3,193,077)	(1,284,422)	(16,264,958)
Income Tax Expense (Benefit)			
NET LOSS	\$ (3,193,077)	\$ (1,284,422)	\$ (16,264,958)
Net loss per share, basic and diluted	\$ (0.06)	\$ (0.08)	
Shares used in computing net loss per share, basic and diluted	49,575,492	15,441,244	

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

---

**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY - UNAUDITED**  
**FROM INCEPTION (FEBRUARY 26, 1998) TO MARCH 31, 2005**

---

(All share information reflects post-split amounts)

	<b>Common Stock</b>		<b>Paid-In</b>	<b>Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>	<b>Accumulated</b>	<b>Stockholders</b>
				<b>During</b>	<b>Equity</b>
		\$	\$	<b>Development</b>	
				\$	\$
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)

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

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 - net	35,521,906	35,522	7,876,927		7,912,449
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
Exercise of stock options	409,885	410	163,445		163,855
Exercise of warrants	310,500	310	146,565		146,875
Issuance of common stock option to consultant			6,952		6,952
Net loss				(3,193,077)	(3,193,077)
 BALANCE, MARCH 31, 2005	 49,922,468	 \$ 49,922	 \$ 28,163,899	 \$ (16,264,958)	 \$ 11,948,863

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



**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS - UNAUDITED**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND 2004 AND FROM INCEPTION TO MARCH 31, 2005**

---

	<b>2005</b>	<b>2004</b>	<b>Cumulative from inception (February 26, 1998) to 2005</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (3,193,077)	\$ (1,284,422)	\$ (16,264,958)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	50,117	21,497	382,357
Issuance of common stock and stock options for goods and services	6,952		207,397
Issuance of common stock for license			2,330
Issuance of common stock for accrued interest on notes			99,764
Beneficial conversion feature on 2003 notes			306,754
Changes in operating assets and liabilities:			
Inventory	4,676		(47,145)
Prepaid expenses and other assets	(274,650)	(116,031)	(383,281)
Accounts payable and accrued expenses	348,542	500,057	1,921,841
Net cash provided by operating activities	(3,057,440)	(878,899)	(13,774,941)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(130,692)	(42,015)	(675,338)
Net cash used in investing activities	(130,692)	(42,015)	(675,338)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of notes			1,272,000
Proceeds from issuance of common stock			110,956
Proceeds from exercise of stock options - net	163,855		163,855
Proceeds from exercise of warrants - net	146,875		3,009,595
Contributed capital - net		7,870,146	10,307,310
Proceeds from issuance of common stock - net			12,716,875
Net cash provided by financing activities	310,730	7,870,146	27,580,591
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(2,877,402)</b>	<b>6,949,232</b>	<b>13,130,312</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b>16,007,714</b>	<b>503,580</b>	

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

CASH AND CASH EQUIVALENTS, end of period	\$ 13,130,312	\$ 7,452,812	\$ 13,130,312
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
Conversion of Series C preferred stock to common stock	\$	\$	\$ 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

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

---

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

Item 1. Financial Statements

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3. Controls and Procedures

**PART II OTHER INFORMATION**

Item 1. Legal Proceedings

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Item 3. Defaults Upon Senior Securities

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

Item 5. Other Information

Item 6. Exhibits

**SIGNATURES**

**EXHIBIT 31.1**

**EXHIBIT 31.2**

**EXHIBIT 32.1**

**EXHIBIT 32.2**

---

**Table of Contents**

**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**Halozyme Therapeutics, Inc.  
(A Development Stage Company)**

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

**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.

Halozyme was founded on February 26, 1998. 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.

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. On March 11, 2004, Global changed its name to Halozyme Therapeutics, Inc.

Although Global acquired Halozyme as a result of the Merger, the former shareholders of Halozyme held a majority of the voting interest in the combined enterprise as consideration for entering into the Merger. Additionally, the Merger resulted in Halozyme's management and Board of Directors assuming operational control of Global. The Merger has been treated as a re-capitalization of Halozyme. Accordingly, the financial statements reflect the historical activity of Halozyme with the capital structure of Global. Prior to the Merger, Global had limited operations.

**Basis of Presentation**

The accompanying unaudited 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 a quarterly report on Form 10-QSB. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for complete financial statements. The interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature.

Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2005 or for any future period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2004 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 11, 2005 and other regulatory reports and filings made with the Securities and Exchange Commission.

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.

---

**Table of Contents****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 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:

In Thousands	Three Months Ended	
	2005	2004
Net loss, as reported	\$ (3,193)	\$ (1,284)
Deduct: Total stock-based employee Compensation expense determined under Fair value based method for all awards	(346)	(249)
Pro forma net loss	\$ (3,539)	\$ (1,533)
Net loss per share, basic and diluted, as reported	\$ (0.06)	\$ (0.08)
Pro forma net loss per share, basic and diluted	\$ (0.07)	\$ (0.10)

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 three months ended March 31, 2005 and 2004: weighted-average risk-free interest rate of 3.4% and 3.0%; a dividend yield of 0%; a stock price volatility of 84% and 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.

---

**Table of Contents****2. Inventories**

Inventories are stated at the lower of cost or market and consist of raw materials of \$22,185 and work in process of \$24,960 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 and the United States or to be used in sampling programs.

**3. Property and Equipment**

	<b>March 2005</b>	<b>December 2004</b>
Research equipment	\$ 417,405	\$ 333,403
Office equipment and furniture	136,828	102,775
Leasehold improvements	144,205	131,567
	698,438	567,745
Less accumulated depreciation and amortization	(382,357)	(332,240)
	\$ 316,081	\$ 235,505

Depreciation and amortization expense totaled \$50,117 in 2005 and \$21,497 in 2004.

**4. Net Loss Per Common Share**

In accordance with SFAS No. 128, *Earnings Per Share*, and SEC Staff Accounting Bulletin (SAB) No. 98, basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Under SFAS No. 128, diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period. Such common equivalent shares have not been included in the Company's computation of net loss per share as their effect would have been anti-dilutive.

	<b>Three Months Ended</b>	
	<b>2005</b>	<b>2004</b>
Numerator - Net loss	\$ (3,193,077)	\$ (1,284,422)
Denominator - Weighted average shares outstanding	49,575,492	15,441,244
Net loss per share	\$ (0.06)	\$ (0.08)
Incremental common shares (not included because of their anti-dilutive nature)		
Stock options	8,395,512	6,530,397



Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

Stock warrants	11,675,846	11,742,665
Potential common equivalents	20,071,358	18,273,062

---

**Table of Contents**

**5. Commitments and Contingencies**

**Material Agreement** On March 24, 2005, Halozyme Therapeutics, Inc. (the Company ) entered into a Development and Supply Agreement (the Supply Agreement ) and a First Amendment to our existing Exclusive Distribution Agreement, dated August 13, 2004 (the Distribution Agreement ) with Baxter Healthcare Corporation ( Baxter ). The following descriptions of the agreements are a summary of the material terms of the agreements. The Company will supply Baxter the active pharmaceutical ingredient, and Baxter will fill and finish the Hylenex product and hold it for subsequent distribution, pending regulatory approval. The Supply Agreement provides for additional product development opportunities that the parties may mutually decide to pursue. In addition, Baxter has a right of first refusal on certain product line extensions and select new products. The First Amendment provides for specific and consistent definitions among the Supply Agreement and Distribution Agreement, modifies various covenants of Baxter relating to the definition of sales and marketing costs and amends Section 1.2, Territories , to provide for a European market.

Baxter's fill and finish facilities may require a pre-approval inspection (PAI). If Baxter fails this PAI, it could have a material adverse effect on our business. Difficulties in our relationship with Baxter or delays or interruptions in their fill and finish operations could limit or stop our ability to provide sufficient quantities of our products, on a timely basis, 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.

**Item 2. 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 Quarterly 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 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, with the exception of Cumulase, are either in the discovery, pre-clinical, or pre-NDA approval 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

\$16,264,958 from inception through March 31, 2005.

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.

---

## **Table of Contents**

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 2004, which allows the Company to market Cumulase in the European Union. In addition, we received FDA clearance for Cumulase in April 2005, which allows the Company to market Cumulase in the United States.

## ***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 Hylenex (formerly referred to as 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 rHuPH20 enzyme, and are currently conducting pre-clinical studies in animal models.

Since our inception through March 31, 2005, we have incurred research and development costs of \$11.4 million. From January 1, 2002 through March 31, 2005, 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 Hylenex 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, Hylenex, 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.

---

## **Table of Contents**

Clinical development timelines, likelihood of success, and total costs vary widely. Although we are currently focused primarily on advancing Cumulase, Hylenex, 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 received FDA clearance for our Cumulase product candidate in April 2005, and we filed an NDA for our Hylenex product candidate in March 2005, and we anticipate filing 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. For the prior year, 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 Three Months Ended March 31, 2005 and 2004**

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

**Research and Development** Research and development expenses were \$2,462,000 for the three months ended March 31, 2005 compared to \$697,000 for the three months ended March 31, 2004. 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 \$1,765,000 due primarily to the completion of Cumulase 510(k) requirements, the completion of Hylenex NDA requirements, 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. In addition, we incurred a \$250,000 expense for a milestone payment to the University of Connecticut related to the filing of our Hylenex NDA. 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.

---

**Table of Contents**

**General and Administrative** General and administrative expenses were \$809,000 for the three months ended March 31, 2005 compared to \$511,000 for the three months ended March 31, 2004. General and administrative expenses increased by \$298,000 due to the hiring of additional general and 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 income was \$78,000 for the three months ended March 31, 2005 compared to \$77,000 in other expense for the three months ended March 31, 2004. The increase in other income was due to an increase in interest income relating to our higher cash and cash equivalents. The other expense during the 2004 quarter was due to the assumption of Global's liabilities as a result of the Merger.

**Net Loss** Net loss for the three months ended March 31, 2005 was \$3,193,000, or \$0.06 per common share, compared to \$1,284,000, or \$0.08 per common share for the three months ended March 31, 2004. The increase in net loss was due to an increase in operating expenses, reflecting our increased research and development efforts and additional personnel.

**Liquidity and Capital Resources** As of March 31, 2005, cash and cash equivalents were \$13,130,000 versus \$16,007,000 as of December 31, 2004, a decrease of \$2,877,000. This decrease resulted primarily from net cash used in operations and for the purchase of property and equipment during the quarter.

Net cash used in operations was \$3,057,000 during the three months ended March 31, 2005 compared to \$879,000 of cash used in operations during the quarter ended March 31, 2004. This increased use of cash was due to an increase in our research and development efforts and additional personnel.

Net cash used in investing activities was \$131,000 during the three months ended March 31, 2005 compared to \$42,000 during the three months ended March 31, 2004. This was due to the increased purchase of property and equipment and leasehold improvements during 2005.

Net cash provided by financing activities was \$311,000 during the three months ended March 31, 2005 versus \$7,870,000 during the three months ended March 31, 2004. During the first quarter of 2005 we raised \$164,000 through the exercise of stock options and \$147,000 through the exercise of warrants. 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.

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.

---

## **Table of Contents**

**Off-Balance Sheet Arrangements** As of March 31, 2005, 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***

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 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.

## **RISK FACTORS**

*The following information sets forth factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this quarterly report and those we may make from time to time. For a more detailed discussion of the factors that could cause actual results to differ, see the Risk Factors section in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 11, 2005.*

### **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 March 31, 2005, we have incurred aggregate net losses of \$16,264,958.

**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 11.7 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

---

## **Table of Contents**

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 and April 2005 FDA clearance 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 March 2005, we filed an NDA for Hylenex. During April 2005, we received FDA clearance for Cumulase. 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 Hylenex would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Hylenex; but if the FDA later changes its determination and decides that either or both apply to Hylenex, 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 NDA application for Hylenex 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 other 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

---

**Table of Contents**

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

---

**Table of Contents**

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 Hylenex, which may require a pre-approval inspection. If Avid fails this pre-approval inspection, it could delay the potential approval of our Hylenex NDA and 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 and 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 and finish the products prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are economically acceptable to us, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a third party to fill and finish Cumulase. In addition, we currently utilize Baxter Healthcare Corporation ( Baxter ) to fill and finish Hylenex under a development and supply agreement. Baxter may receive a pre-approval inspection by the FDA. If Baxter fails this pre-approval inspection, the potential commercialization of Hylenex, will likely be delayed. This could have a material adverse effect on our business.

**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.**



## Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

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. We filed an

---

## **Table of Contents**

amendment to this registration statement on Form S-3 (Registration No. 333-114776), which was declared effective on April 1, 2005.

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 the last twelve months were \$4.60 and \$1.41, 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 167,000 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, packaging, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, Halozyne and its contract suppliers and manufacturers are subject to periodic inspection of its or their respective facilities, procedures and operations and/or

---

**Table of Contents**

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

---

## **Table of Contents**

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.

---

## **Table of Contents**

### **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 Hylenex would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Hylenex; but if the FDA later changes its determination and decides that either or both apply to Hylenex, 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 ending 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 3. 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**

---

**Table of Contents**

There have been no significant changes in our internal controls over financial reporting that occurred during the quarter ended March 31, 2005, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

During February 2005, existing shareholders exercised warrants to purchase 310,500 common shares for gross proceeds of \$146,875. The shares and underlying warrants were purchased for investment in a private placement exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.

**Item 3. Defaults Upon Senior Securities.**

None.

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

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

<b>Exhibit</b>	<b>Title</b>
2.1	Agreement of Merger between DeliaTroph Pharmaceuticals, Inc. and Registrant, dated January 28, 2004 (1)

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10QSB

- 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)
  - 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
-

**Table of Contents**

<b>Exhibit</b>	<b>Title</b>
	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)
10.13	DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder (7)
10.14	Nonstatutory Stock Option Agreement With Andrew Kim (7)
10.15*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (8)
10.16*	Development and Supply Agreement with Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
10.17*	First Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
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
<hr/>	
(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 Registration Statement on Form S-8 filed with the Commission on October 26, 2004.
(8)	Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 22, 2005.

(9) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 30, 2005.

\* 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.

**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 May 13, 2005.

Halozyme Therapeutics, Inc.,  
a Nevada corporation

Date: May 13, 2005

By: /s/ Jonathan E. Lim

Jonathan E. Lim, MD  
Its: President, Chief Executive Officer,  
Chairman of the Board  
(Principal Executive Officer)

Date: May 13, 2005

By: /s/ David A. Ramsay

David A. Ramsay  
Its: Secretary, Chief Financial Officer  
(Principal Financial and Accounting Officer)