

HALOZYME THERAPEUTICS INC

Form 10QSB

November 12, 2004

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**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 **September 30, 2004**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
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Commission file number 000-49616

**HALOZYME THERAPEUTICS, INC.**

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

**Nevada**

**88-0488686**

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(State or other jurisdiction of incorporation or organization)

(IRS Employer Identification No.)

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

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(Address of principal executive offices)

**(858) 794-8889**

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(Issuer's telephone number)

**Not Applicable**

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(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**

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 47,630,401 shares issued and outstanding as of November 8, 2004.

Transitional Small Business Disclosure Format (Check one):

Yes  No

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(A DEVELOPMENT STAGE COMPANY)****CONSOLIDATED BALANCE SHEET UNAUDITED  
AS OF SEPTEMBER 30, 2004****ASSETS****CURRENT ASSETS:**

Cash and cash equivalents	\$ 3,480,301
Prepaid expenses and other current assets	130,390

Total current assets	3,610,691
PROPERTY AND EQUIPMENT, net	159,322
OTHER ASSETS	15,106

Total Assets	\$ 3,785,119
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**LIABILITIES AND STOCKHOLDERS EQUITY****CURRENT LIABILITIES:**

Accounts payable	\$ 1,923,482
Accrued expenses	67,949

Total current liabilities	1,991,431
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**COMMITMENTS AND CONTINGENCIES****STOCKHOLDERS EQUITY:**

Common stock, \$0.001 par value; 100,000,000 shares authorized; 39,704,686 shares issued and outstanding	39,705
Additional paid-in-capital	12,346,752
Deficit accumulated during the development stage	(10,592,769)

Total Stockholders Equity	1,793,688
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Total Liabilities and Stockholders Equity	\$ 3,785,119
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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 AND NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003 AND FROM  
INCEPTION TO SEPTEMBER 30, 2004**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>Cumulative</b>
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>	<b>from inception</b>
					<b>(February 26,</b>
					<b>1998)</b>
					<b>to 2004</b>
<b>EXPENSES:</b>					
Research and development	\$ 2,598,335	\$ 254,903	\$ 4,816,492	\$ 764,007	\$ 7,226,536
General and administrative	664,896	153,327	1,743,417	268,489	2,944,562
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Total Expenses	3,263,231	408,230	6,559,909	1,032,496	10,171,098
Other income (expense), net	10,086	(30,784)	(52,355)	(80,985)	(421,671)
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
<b>LOSS BEFORE INCOME TAXES</b>	<b>(3,253,145)</b>	<b>(439,014)</b>	<b>(6,612,264)</b>	<b>(1,113,481)</b>	<b>(10,592,769)</b>
Income Tax Expense	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
<b>NET LOSS</b>	<b>\$ (3,253,145)</b>	<b>\$ (439,014)</b>	<b>\$ (6,612,264)</b>	<b>\$ (1,113,481)</b>	<b>\$ (10,592,769)</b>
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net loss per share, basic and diluted	\$ (0.08)	\$ (0.05)	\$ (0.21)	\$ (0.14)	
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	
Shares used in computing net loss per share, basic and diluted	39,573,312	8,196,362	31,512,015	8,196,362	
	<u>                    </u>	<u>                    </u>	<u>                    </u>	<u>                    </u>	

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 NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003 AND FROM INCEPTION TO  
SEPTEMBER 30, 2004**

	<b>2004</b>	<b>2003</b>	<b>Cumulative from inception (February 26, 1998) to 2004</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(6,612,264)	\$(1,113,481)	\$(10,592,769)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	84,002	55,295	292,892
Issuance of common stock for goods and services	33,000	5,000	135,245
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:			
Prepaid expenses and other assets	(132,733)	(18,369)	(145,496)
Accounts payable and accrued expenses	1,717,991	120,617	1,991,431
	<hr/>	<hr/>	<hr/>
Net cash provided by operating activities	(4,910,004)	(950,938)	(7,909,849)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	(112,420)	(59,168)	(429,115)
	<hr/>	<hr/>	<hr/>
Net cash used in investing activities	(112,420)	(59,168)	(429,115)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of notes		923,870	1,272,000
Proceeds from exercise of warrants	128,999		128,999
Contributed capital net	7,870,146		10,418,266
	<hr/>	<hr/>	<hr/>
Net cash provided by financing activities	7,999,145	923,870	11,819,265
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>2,976,721</b>	<b>(86,236)</b>	<b>3,480,301</b>
<b>CASH AND CASH EQUIVALENTS, beginning of period</b>	<b>503,580</b>	<b>88,910</b>	<b><hr/></b>
	<hr/>	<hr/>	<hr/>
<b>CASH AND CASH EQUIVALENTS, end of period</b>	<b>\$ 3,480,301</b>	<b>\$ 2,674</b>	<b>\$ 3,480,301</b>
	<hr/>	<hr/>	<hr/>



SUPPLEMENTAL DISCLOSURES OF CASH  
FLOW INFORMATION:

Cash paid for income taxes	\$	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>
Interest paid	\$	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>
Non cash investing and financing activities:			
Conversion of contributed capital to common stock	\$ 7,870,146	\$	\$ 10,418,266
	<u>          </u>	<u>          </u>	<u>          </u>
Conversion of notes payable to common stock	\$	\$	\$ 1,272,000
	<u>          </u>	<u>          </u>	<u>          </u>
Common stock issued for property and equipment	\$	\$	\$ 3,099
	<u>          </u>	<u>          </u>	<u>          </u>
Series A preferred stock issued for property and equipment	\$	\$	\$ 20,000
	<u>          </u>	<u>          </u>	<u>          </u>

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

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**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, pursuant to the Agreement and Plan of Merger (the *Merger Agreement*), dated January 28, 2004, among privately held DeliaTroph Pharmaceuticals, Inc. dba Hyalozyme Therapeutics, Inc. (*Halozyme*), Global Yacht Services, Inc. (*Global*), a publicly traded Nevada corporation and Hyalozyme Acquisition Corporation (*Merger Sub*), a wholly owned subsidiary of Global, the *Merger Sub* merged with and into Halozyme, with Halozyme the survivor for accounting purposes.

Although Global acquired Halozyme as a result of the Merger, the shareholders of Halozyme held a majority of the voting interest in the combined enterprise. Additionally, the Merger resulted in Halozyme'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 Merger Agreement, Halozyme raised equity capital of approximately \$8.1 million.

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

A total of 4,296,362 shares of Global's outstanding common stock were redeemed by Global from three shareholders in exchange for \$42,303, or approximately \$0.01 per share.

Global's shareholders owned approximately 10% of the issued and outstanding shares of Halozyme's common stock, 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 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. On March 11, 2004, Global changed its name to Halozyme Therapeutics, Inc.

**Table of Contents****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 and nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2004 or for any future period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2003 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 30, 2004 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.

**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		Nine Months Ended	
	2004	2003	2004	2003

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Net loss, as reported	\$ (3,253)	\$ (439)	\$ (6,612)	\$ (1,113)
Deduct: Total stock-based employee Compensation expense determined under Fair value based method for all awards	(599)		(1,395)	

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<b>In Thousands</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Pro forma net loss	\$ (3,852)	\$ (403)	\$ (8,007)	\$ (1,113)
Net loss per share, basic and diluted, as reported	\$ (0.08)	\$ (0.05)	\$ (0.21)	\$ (0.14)
Pro forma net loss per share, basic and diluted	\$ (0.10)	\$ (0.05)	\$ (0.25)	\$ (0.14)

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 and nine months ended September 30, 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.

**2. Property and Equipment**

	<b>September</b>	<b>December</b>
	<b>2004</b>	<b>2003</b>
Research equipment	\$ 233,669	\$ 195,534
Office equipment and furniture	86,978	59,687
Leasehold improvements	131,567	84,573
	<hr/>	<hr/>
	452,214	339,794
Less accumulated depreciation and amortization	(292,892)	(208,890)
	<hr/>	<hr/>
	\$ 159,322	\$ 130,904
	<hr/>	<hr/>

### **3. 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.

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	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Numerator Net loss	\$ (3,253,145)	\$ (439,014)	\$ (6,612,264)	\$ (1,113,481)
Denominator Weighted average shares outstanding	39,573,312	8,196,362	31,512,015	8,196,362
Net loss per share	\$ (0.08)	\$ (0.05)	\$ (0.21)	\$ (0.14)
Incremental common shares (not included because of their anti-dilutive nature)				
Employee stock options	7,013,397		7,013,397	
Warrants to outside parties	51,334		51,334	
Warrants on notes	658,349		658,349	
Series B warrants	288,259		288,259	
Series C warrants	10,461,943		10,461,943	
Potential common equivalents	18,473,282		18,473,282	

**4. Subsequent Event**

On October 12, 2004, the Company entered into definitive securities purchase agreements with certain institutional and accredited investors for a \$13.9 million private placement of newly issued shares of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock. On October 13, 2004, the transaction closed and the Company received net proceeds of approximately \$12.9 million. Our September 30, 2004 pro forma cash and cash equivalents were \$16.4 million and pro forma stockholders' equity was \$14.7 million as a result of this private placement.

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

*The following discussion, including, without limitation, statements concerning our market opportunities, expected development goals and priorities, and expense trends and capital resource requirements, contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption Risk Factors. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2003 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 30, 2004 and other regulatory reports and filings made with the Securities and Exchange Commission.*



**Overview** Halozyme was founded on February 26, 1998. 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 products 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 and we have had operating and net losses each year since inception. We have accumulated a deficit of \$10,592,769 from inception through September 30, 2004.

Our technology is based on recombinant human PH20 (rHuPH20), a human synthetic version of hyaluronidase that

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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 product 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 product 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.

## ***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 September 30, 2004, we incurred research and development costs of \$7.2 million. From January 1, 2002 through September 30, 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.

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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 recently 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** Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., or GAAP for interim information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. We state these accounting policies in the notes to the financial statements in our Annual Report on Form 10-KSB for the year ended December 31, 2003. Actual results may differ from these estimates under different assumptions or conditions.

## **Results of Operations Comparison of Three Months Ended September 30, 2004 and 2003**

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

**Research and Development** Research and development expenses were \$2,598,000 for the three months ended September 30, 2004 compared to \$255,000 for the three months ended September 30, 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 \$2,343,000 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 \$665,000 for the three months ended September 30, 2004 compared to \$153,000 for the three months ended September 30, 2003. General and administrative expenses increased by \$512,000 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

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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 \$10,000 for the three months ended September 30, 2004 compared to \$31,000 in other expense for the three months ended September 30, 2003. The increase in other income was due to an increase in interest income relating to our higher cash and cash equivalents resulting from the completion of an \$8.1 million capital investment during January 2004. The interest expense during the 2003 quarter was due to interest expense on outstanding notes payable.

**Net Loss** Net loss for the three months ended September 30, 2004 was \$3,253,000, or \$0.08 per common share, compared to \$439,000, or \$0.05 per common share for the three months ended September 30, 2003. The increase in net loss was due to an increase in operating expenses, reflecting our increased research and development efforts and additional personnel.

**Comparison of Nine Months Ended September 30, 2004 and 2003**

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

**Research and Development** Research and development expenses were \$4,816,000 for the nine months ended September 30, 2004 compared to \$764,000 for the nine months ended September 30, 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 \$4,052,000 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 \$1,743,000 for the nine months ended September 30, 2004 compared to \$268,000 for the nine months ended September 30, 2003. General and administrative expenses increased by \$1,475,000 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 \$52,000 for the nine months ended September 30, 2004 compared to \$81,000 for the nine months ended September 30, 2003. The increase in other expense was due to the assumption of \$84,000 in liabilities as a result of the Merger offset by an increase in interest income relating to our higher cash and cash equivalents resulting from the completion of an \$8.1 million capital investment during January, 2004. The interest expense during 2003 was due to interest expense on outstanding notes payable.

**Net Loss** Net loss for the nine months ended September 30, 2004 was \$6,612,000, or \$0.21 per common share, compared to \$1,113,000, or \$0.14 per common share for the nine months ended September 30, 2003. 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 September 30, 2004, cash and cash equivalents were \$3,480,000 versus \$504,000 as of December 31, 2003, an increase of \$2,976,000. This increase resulted primarily from the sale of common stock for approximately \$7,999,000, net of issuance costs during the nine months ended September 30, 2004, offset by our net loss for the nine months ended September 30, 2004.

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Net cash used in operations was \$4,910,000 during the first nine months of 2004 compared to \$951,000 of cash used in operations during the first nine months of 2003. This increase was due to an increase in personnel and our increased research and development efforts.

Net cash used in investing activities was \$112,000 during the first nine months of 2004 compared to \$59,000 during the first nine months of 2003. This was due to the increased purchase of property and equipment and leasehold improvements during 2004.

Net cash provided by financing activities was \$7,999,000 during the first nine months of 2004 versus \$924,000 during the first nine months of 2003. In January, 2004, we sold common stock for approximately \$8,057,000, or \$7,670,000 net of issuance costs. Additionally, we received approximately \$329,000 in proceeds from stock option and warrant exercises during the first nine months of 2004. During the first nine months of 2003, we received \$924,000 from the issuance of notes and the related accrued interest on those notes.

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.

On October 12, 2004, the Company entered into definitive securities purchase agreements with certain institutional and accredited investors for a \$13.9 million private placement of newly issued shares of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock. On October 13, 2004, the transaction closed and the Company received net proceeds of approximately \$12.9 million. We believe that our current cash and cash equivalents will be sufficient to fund our operations until at least the end of 2005. 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 September 30, 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.

## **Caution on Forward-Looking Statements**



Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as believe, may, could, will, estimate, continue, anticipate, seek, plan, expect, should, or would. Among the factors that could cause actual results to differ materially from indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation, difficulties or delays in development, testing, obtaining

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regulatory approvals, manufacturing and marketing our product candidates; the progress and timing of our clinical trials; potential unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates that could delay or prevent product development or commercialization, or that could result in product recalls or product liability claims; the scope and validity of patent protection for our products and our ability to commercialize our product candidates without infringing the patent rights of others; competition from other pharmaceutical or biotechnology companies; our ability to obtain additional financing to support our operations; and other risks detailed in our Annual Report on Form 10-KSB for the year ended December 31, 2003 filed with the Securities and Exchange Commission on March 30, 2004 and our amended SB-2 Registration Statement filed with the Securities and Exchange Commission on July 23, 2004 and the discussions set forth below under the caption Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

## **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 30, 2004 and in our amended SB-2 Registration Statement filed with the Securities and Exchange Commission on July 23, 2004.*

### **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 revenues from product sales in the future. 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 September 30, 2004, we have incurred aggregate net losses of \$10,592,769.

**We may need to raise funds in the next twelve months, and our current capital structure may make us less attractive to investors.**

During the next twelve months we may need to raise additional capital to complete the steps required to obtain FDA 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 collaborative agreements, private financings, and various other equity or debt financings. Our capital structure is fairly complex, due largely to the fact that we have issued warrants to purchase up to 14,146,703 shares of our common stock. We may redeem 8,094,829 of these warrants for \$0.01 per share under certain circumstances. 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.**

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.

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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. 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 our 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.**

A number of factors may affect the market acceptance of any of our existing products 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.

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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 an agreement with Avid Bioservices Incorporated, a contract manufacturing organization, to produce bulk recombinant human enzyme product for clinical use. Our contract manufacturer will produce the active pharmaceutical ingredient under current good manufacturing practices for commercial scale validation 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 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.

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

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. If we were to lose either 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 following the registration of shares we issued in our most recent financing, may negatively affect our stock price.**

As a result of our January 2004 private financing transaction, the private investors received approximately 19.0 million shares of common stock. The shares of common stock issued in connection with this financing transaction represent approximately 48% of our outstanding common stock. In connection with the financing

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transaction, we also issued warrants to the private investors that are exercisable for the purchase of up to an aggregate of 10.5 million shares of common stock based upon a purchase price ranging from \$0.77 to \$1.75 per share. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise. These shares and the shares issuable upon exercise of the warrants have been registered for resale.

In October 2004, we entered into definitive securities purchase agreements with certain institutional and accredited investors for a \$13.9 million private placement of newly issued shares of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock. On November 11, 2004 we filed a registration statement 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 Halozyyme common stock.

Sales of substantial amounts of shares of our common stock, or even the potential for such sales, 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 for the last twelve months are \$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.**

The merger between Global and Halozyyme was concluded on March 11, 2004. On March 12, 2004, our common stock began trading. During the last ninety days, our average daily trading volume has been approximately 120,000 shares. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

### **Short selling common stock by selling security holders may drive down the market price of our stock.**

Any selling security holders who holds warrants may sell shares of our common stock on the market before exercising the warrant. The stock is usually offered at or below market since the warrant holders receive stock at a discount to market. Once the sale is completed the holders exercise a like dollar amount of shares. If the stock sale lowered the market price, upon exercise, the holders would receive a greater number of shares than they would have absent the short sale. This pattern may result in a reduction of our common stock's market price.

### **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;

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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.

## **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 products 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

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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. and foreign 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.

**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.

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### **We face intense competition and rapid technological change that could result in the development of products by others that are superior to 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 may 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. In particular, ISTA is developing ovine derived hyaluronidase (Vitrace®) for intraocular use. On May 5, 2004 the FDA approved ISTA's Vitrace® for use as a spreading agent, the same indication we plan to seek for Enhanze SC . On September 3, 2004, the FDA made public that it had granted Vitrace three years of marketing exclusivity. On October 26, 2004, the FDA approved Amphastar Pharmaceutical's Amphadase , a bovine hyaluronidase. On October 28, 2004, ISTA announced that the FDA had extended the exclusivity from three years to five years, granting Vitrace® new chemical entity status. While we do not believe that the Vitrace® marketing exclusivity will apply to Enhanze SC , if the FDA decides that it does apply to Enhanze SC , it 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.

## **Item 3. Controls and Procedures.**

### **Evaluation of Disclosure Controls and Procedures**

Our Chief Executive Officer and Chief Financial Officer have, as of the end of the period covered by this Report, reviewed our process of gathering, analyzing and disclosing information that is required to be disclosed in our periodic reports (and information that, while not required to be disclosed, may bear upon the decision of management as to what information is required to be disclosed) under the Exchange Act of 1934, including information pertaining to the condition of, and material developments with respect to, our business, operations and finances. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our process provides for timely collection and evaluation of information that may need to be disclosed to investors.

### **Changes in Internal Controls Over Financial Reporting**

There have been no significant changes in the Company's internal controls over financial reporting that occurred during the quarter ended September 30, 2004, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.



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**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. 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. Changes in Securities.**

On July 28, 2004, a shareholder exercised warrants to purchase 31,590 common shares for gross proceeds of \$15,000. On August 11, 2004, a shareholder exercised warrants to purchase 53,380 common shares for gross proceeds of \$24,000. And on September 8, 2004, a shareholder exercised warrants to purchase 131,086 common shares for gross proceeds of \$60,000. These shares 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 and Reports on Form 8-K.**

**(a) Exhibits:**

<b>Exhibit</b>	<b>Title</b>
3.1	Articles of Incorporation (1)
3.2	Certificate of Amendment to Articles of Incorporation (1)
3.3	Bylaws (1)
3.4	Certificate of Amendment to Articles of Incorporation (2)



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- 4.1 Form of Common Stock Certificate (3)
- 4.2 Form of Callable Stock Purchase Warrant (4)
- 10.7 2004 Stock Plan and Form of Option Agreement thereunder (4)
- 10.8 Form of Indemnity Agreement for Directors and Executive Officers (4)
- 10.9\* Exclusive Distribution Agreement between Baxter Healthcare Corp. and Registrant, dated August 13, 2004
- 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 Registration Statement on Form SB-2 filed with the Commission on September 21, 2001.
- (2) Incorporated by reference to the Registrant's Information Statement on Schedule 14C filed with the Commission on February 17, 2004.
- (3) Incorporated by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on April 23, 2004.

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<b>Exhibit</b>	<b>Title</b>
(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.
*	Confidential treatment has been granted for certain portions of this exhibit. These portions have been omitted from this agreement and have been filed separately with the Securities and Exchange Commission.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on November 12, 2004.

Halozyme Therapeutics, Inc.,  
a Nevada corporation

Date: November 12, 2004

By: /s/ Jonathan E. Lim

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

Date: November 12, 2004

By: /s/ David A. Ramsay

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