

HALOZYME THERAPEUTICS INC

Form 10-Q

May 10, 2007

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2007**

**OR**

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

**For the transition period from**

**to**

**Commission File Number 000-49616**

**HALOZYME THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation or organization)

**88-0488686**

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

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

(Address of principal executive offices)

**92121**

(Zip Code)

**(858) 794-8889**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of May 4, 2007 was 71,944,186.

**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. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

**PART II OTHER INFORMATION**

Item 1. Legal Proceedings

Item 1A. Risk Factors

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**

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**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS    UNAUDITED**  
**AS OF MARCH 31, 2007 AND DECEMBER 31, 2006**

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 70,970,875	\$ 44,189,403
Accounts receivable	552,789	370,068
Inventory	475,185	442,492
Prepaid expenses and other assets	1,295,675	591,587
Total current assets	73,294,524	45,593,550
PROPERTY AND EQUIPMENT, net	572,026	497,770
Total Assets	\$ 73,866,550	\$ 46,091,320
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,072,178	\$ 2,017,395
Accrued expenses	1,187,146	1,011,153
Deferred revenue	2,896,932	1,221,992
Total current liabilities	5,156,256	4,250,540
Deferred revenue, net of current portion	27,806,645	18,759,545
<b>COMMITMENTS AND CONTINGENCIES (NOTE 9)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.001 par value; 500,000 shares authorized; none issued and outstanding		
Common stock, \$0.001 par value; 150,000,000 and 100,000,000 shares authorized; 71,531,197 and 68,736,993 shares issued and outstanding as of March 31, 2007 and December 31, 2006, respectively	71,531	68,737
Additional paid-in-capital	85,288,662	64,111,738
Accumulated deficit	(44,456,544)	(41,099,240)
Total Stockholders' Equity	40,903,649	23,081,235
Total Liabilities and Stockholders' Equity	\$ 73,866,550	\$ 46,091,320

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

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**Table of Contents****HALOZYME THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS    UNAUDITED  
FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006**

	<b>2007</b>	<b>2006</b>
REVENUES:		
Product sales	\$ 187,086	\$ 73,281
Revenue under collaborative agreements	623,129	
 Total Revenues	 810,215	 73,281
 EXPENSES:		
Cost of sales	76,228	22,959
Research and development	2,829,364	2,192,070
Selling, general and administrative	1,985,034	1,531,292
 Total Expenses	 4,890,626	 3,746,321
 LOSS FROM OPERATIONS	 (4,080,411)	 (3,673,040)
Interest income	723,107	182,846
 NET LOSS	 \$ (3,357,304)	 \$ (3,490,194)
 Net loss per share, basic and diluted	 \$ (0.05)	 \$ (0.06)
 Shares used in computing net loss per share, basic and diluted	 69,984,931	 60,456,462

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

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**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS    UNAUDITED**  
**FOR THE THREE MONTHS ENDED MARCH 31, 2007 AND 2006**

	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,357,304)	\$ (3,490,194)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	86,635	52,985
Share-based compensation expense	415,480	273,092
Issuance of common stock and stock options for goods and services		9,323
Changes in operating assets and liabilities:		
Accounts receivable	(182,721)	320,240
Inventory	(32,693)	(7,231)
Prepaid expenses and other assets	(704,088)	(350,229)
Accounts payable and accrued expenses	(769,224)	389,899
Deferred revenue	10,722,040	
Net cash provided by (used in) operating activities	6,178,125	(2,802,115)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(160,891)	(38,879)
Net cash used in investing activities	(160,891)	(38,879)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock    net	19,946,411	
Proceeds from exercise of stock options	459,918	
Proceeds from exercise of warrants	357,909	1,279,301
Net cash provided by financing activities	20,764,238	1,279,301
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>26,781,472</b>	<b>(1,561,693)</b>
CASH AND CASH EQUIVALENTS, beginning of period	44,189,403	19,132,194
CASH AND CASH EQUIVALENTS, end of period	\$ 70,970,875	\$ 17,570,501

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

**Table of Contents**

**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

**1. Organization and Business**

Halozyme Therapeutics, Inc. ( Halozyme, we or the Company ) is a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the drug delivery, palliative care, oncology, and infertility markets.

Our operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing our technology and undertaking product development for our existing products and for a limited number of product candidates. In June 2005, we launched our first product, Cumulase<sup>®</sup>, a product used for in vitro fertilization, and transitioned from a development-stage organization to a commercial entity.

**2. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ( U.S. GAAP ) and with the rules and regulations of the Securities and Exchange Commission related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP 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, 2007 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2007 or for any future period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2006 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2007 and other regulatory reports and filings made with the Securities and Exchange Commission.

The preparation of financial statements in conformity with U.S. GAAP 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. The unaudited condensed consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc. All intercompany accounts and transactions have been eliminated.

**3. Summary of Significant Accounting Policies**

***Revenue Recognition***

We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 104, *Revenue Recognition* and Emerging Issues Task Force Issue ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured.

***Product Sales*** We recognize Cumulase revenue when the transfer of ownership occurs, upon shipment to the distributor. Accounts receivable is recorded net of an allowance for doubtful accounts. Currently, the allowance for doubtful accounts is zero as the collectibility of accounts receivable is reasonably assured. We are not obligated to accept returns for products that have reached their expiration date. Thus, no allowance for product returns has been established.



**Table of Contents**

On February 13, 2007, we amended certain agreements with Baxter Healthcare Corporation ( Baxter ) (the Baxter Agreement ) for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20. Under the terms of the Baxter Agreement, we will supply Baxter the active pharmaceutical ingredient ( API ) for Hylenex at our fully burdened cost plus a margin and Baxter will fill and finish Hylenex and hold it for subsequent distribution. Because of our continued involvement in the development and production process of Hylenex under the terms of the Baxter Agreement, the earnings process is not considered to be complete. Accordingly, we defer revenue and the related product costs resulting from transfers of the active pharmaceutical ingredient for Hylenex to Baxter until the product is filled, finished, packaged and released.

**License and Collaborative Arrangement** Revenues from licensing agreements are recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Non-refundable upfront fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. In February 2007, we entered into the Baxter Agreement which consists of non-refundable upfront license fees, reimbursements of research and development services and various performance or sales milestones and future product royalty payments. Due to our ongoing involvement obligation, we recorded the non-refundable upfront license fee received under the Baxter Agreement as deferred revenue when received in February 2007 and will recognize it over the term of the contract.

Reimbursements of research and development services are recognized as revenues during the period in which the services are performed. Payments related to substantive, performance-based milestones in a collaborative agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the license agreements.

**Cost of Sales**

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

**Clinical Trial and Contract Research Expenses**

Research and development expenditures are charged to operations as incurred in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 2 *Accounting for Research and Development Costs*. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions, clinical research organizations, and other vendors that conduct and manage clinical trials on our behalf.

**Share-Based Compensation Expense**

On January 1, 2006, we adopted the provisions of revised SFAS No. 123 ( SFAS 123(R) ), *Share-Based Payment*, including the provisions of Staff Accounting Bulletin No. 107 ( SAB 107 ), using the modified prospective transition method to account for our employee share-based awards. Under SFAS 123(R), share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. We have no awards with market or performance conditions. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ).

Total compensation expense related to all of our employee share-based awards, recognized under SFAS 123(R), for the three months ended March 31, 2007 and 2006 was comprised of the following:

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**Table of Contents**

	2007	2006
Research and development	\$ 145,322	\$ 98,580
Selling, general and administrative	270,158	174,512
Share-based compensation expense before taxes	415,480	273,092
Related income tax benefits		
Share-based compensation expense	\$ 415,480	\$ 273,092
Net share-based compensation expense per basic and diluted share	\$ 0.01	\$ 0.00
Share-based compensation expense from:		
Stock options	\$ 360,480	\$ 273,092
Restricted stock awards	55,000	
Total	\$ 415,480	\$ 273,092

**4. Inventory**

Inventory consists of our Cumulase product and our Hylenex API as of March 31, 2007 and December 31, 2006 as follows:

	2007	2006
Raw materials	\$ 399,407	\$ 337,344
Work in process	63,576	76,257
Finished goods	12,202	28,891
	\$ 475,185	\$ 442,492

Inventories are used in the manufacture of the Company's Cumulase and Hylenex products and are stated at the lower of cost or market.

**5. Property and Equipment**

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

	2007	2006
Research equipment	\$ 907,225	\$ 805,077
Computer and office equipment	238,508	217,418
Leasehold improvements	215,592	179,822
	1,361,325	1,202,317
Less accumulated depreciation	(789,299)	(704,547)
	\$ 572,026	\$ 497,770

Depreciation and amortization expense totaled \$86,635 and \$52,985, for the three months ended March 31, 2007 and 2006, respectively.

**6. Deferred Revenue**

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

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	2007	2006
Collaborative agreements	\$ 29,552,337	\$ 19,918,965
Prepaid royalties	1,000,000	
Product sales	151,240	62,572
	30,703,577	19,981,537
Less: current portion	2,896,932	1,221,992
Long-term portion	\$ 27,806,645	\$ 18,759,545

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**Table of Contents**

**Roche Agreement** On December 5, 2006, we entered into a license and collaborative agreement with F. Hoffmann-La Roche Ltd ( LTD ) and Hoffmann-La Roche Inc. ( INC ) (LTD and INC, collectively, Roche ) (the Roche Agreement ). Under the terms of the Roche Agreement, Roche will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid us \$20 million in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. Due to our continuing involvement obligations, revenue from the \$20 million upfront payment was deferred and is being recognized over the term of the agreement. We recognized \$289,854 in revenue from license fees in the three months ended March 31, 2007.

**Baxter Agreements** On February 13, 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20. Under the terms of these agreements, Baxter paid us an initial upfront payment of \$10 million. In addition, Baxter will pay royalties on the sales of products covered under the agreements. Baxter prepaid \$1 million of these royalties in connection with the execution of the agreements and Baxter will be obligated to prepay \$9 million of additional royalties on or prior to January 1, 2009. Due to our continuing involvement obligations, revenue from the \$10 million upfront payment was deferred and is being recognized over the term of the agreement. We recognized \$76,774 in revenue from license fees in the three months ended March 31, 2007. In addition, the \$1 million royalty prepayment was also deferred and will be recognized as revenue as we earn royalties from the sales of Hylenex.

**7. Net Loss Per Common Share**

In accordance with SFAS No. 128, *Earnings Per Share*, and 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 March 31,</b>	
	<b>2007</b>	<b>2006</b>
Numerator Net loss	\$ (3,357,304)	\$ (3,490,194)
Denominator Weighted average shares outstanding	69,984,931	60,456,462
Net loss per share	\$ (0.05)	\$ (0.06)
Incremental common shares (not included because of their anti-dilutive nature)		
Stock options and awards	8,650,443	8,599,833
Stock warrants	6,204,006	10,458,548
Potential common equivalents	14,854,449	19,058,381

**Table of Contents****8. Stockholders Equity**

During January, February and March 2007, holders of the Company's various outstanding warrants exercised rights to purchase 510,397 common shares for gross proceeds of approximately \$357,909. Warrants to purchase approximately 6.2 million shares of our common stock are outstanding as of March 31, 2007. During January, February, and March 2007, holders of the Company's various outstanding options exercised their rights to purchase 283,260 common shares for gross proceeds of approximately \$459,918. Options to purchase approximately 8.7 million shares of our common stock are outstanding as of March 31, 2007. During February 2007, an affiliate of Baxter purchased 2,070,394 shares of Halozyme's common stock for an aggregate of \$20 million.

**9. Commitments and Contingencies**

**Operating Leases** Our administrative offices and research facilities are currently located in San Diego, California. We lease 18,400 square feet of office and research space for approximately \$34,000 per month. We have two separate leases for our facilities, which expire in December 2007. In February 2007, we leased an additional 2,540 square feet of office space in the same building, commencing on February 22, 2007 and expiring on December 31, 2007. Additionally we lease certain office equipment under operating leases. Rent expense totaled \$95,000 and \$62,000 for the three months ended March 31, 2007 and 2006, respectively.

**Material Agreements** On February 13, 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20. Under the terms of these agreements, Baxter paid us an initial upfront payment of \$10 million and, pending the successful completion of a series of regulatory and sales events, Baxter may make milestone payments which could potentially reach a value of up to \$25 million. In addition, Baxter will pay royalties on the sales of products covered under the agreements. Baxter prepaid \$1 million of these royalties in connection with the execution of the agreements and Baxter will be obligated to prepay \$9 million of additional royalties on or prior to January 1, 2009. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the agreements. We will continue to supply Baxter with the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. Baxter will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, with Baxter hydration fluids and generic small molecule drugs (with the exception of combinations with (i) bisphosphonates, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, the rights to which have been retained by us). Additionally, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. In addition, on February 13, 2007, an affiliate of Baxter purchased 2,070,394 shares of Halozyme's common stock for an aggregate of \$20 million.

On December 5, 2006, we entered into a license and collaboration Agreement with Roche for Enhance Technology. Under the terms of the agreement, Roche will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid us \$20 million as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory, and sales events, Roche may pay us further milestones which could potentially reach a value of up to \$111 million. In addition, Roche may pay us royalties on potential product sales for these first three targets. Over the next ten years, Roche will also have the option to exclusively develop and commercialize rHuPH20 with an additional ten targets to be identified by Roche, provided that Roche will be obligated to pay continuing exclusivity maintenance fees to us in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche may pay us further upfront and milestone payments of up to \$47 million per target as well as royalties on potential product sales for each of these additional ten targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets. In addition, on December 5, 2006, an affiliate of Roche purchased 3,385,000 shares of common stock for an aggregate of approximately \$11.1 million. On December 15, 2006, we amended our Commercial Supply Agreement (the "Amendment") with Avid Bioservices, Inc. ("Avid") that was originally entered into on February 16, 2005. Under the terms of the Amendment, we are committed to certain minimum annual purchases equal to two quarters of forecasted supply of Active Pharmaceutical Ingredient ("API"). In addition, Avid will have the right to manufacture and supply a certain percentage of the API that will be used in our Cumulase and Hylenex products.



**Table of Contents**

On December 30, 2005, we entered into a First Amendment to a November 15, 2002 license agreement (the Agreement ) with the University of Connecticut Health Center ( UCHC ). The original license agreement provided for certain payments to be made to UCHC in connection with the development and commercialization of certain products defined in the Agreement. The First Amendment to the License Agreement (the First Amendment ) calls for payments of a one time Supplemental License Fee of \$25,000, a \$250,000 Technology Access Fee and a Technology Fee of \$2,500,000 to be paid to UCHC in annual installments of \$250,000 payable in February each year commencing with 2006 and ending 2015. Other terms of the amendment include a termination clause which allows us to discontinue commercialization of certain products covered under the Agreement and to cease making the annual \$250,000 payment with a one time termination fee of \$250,000. The annual technology fee payments are recognized to expense on a straight-line basis.

**Legal Contingencies** In the ordinary course of business, we may face various claims brought by third parties, including claims relating to the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Currently we are not involved in any litigation.

**10. Segment Information**

We operate in one segment, which is the research, development and commercialization of recombinant human enzymes for the drug delivery, palliative care, oncology, and infertility markets. The chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

**11. New Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, established a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 157 to significantly affect our financial condition or results of operations.

The Emerging Issues Task Force ( EITF ) has two issues currently under consideration that may impact the Company. EITF 07-01, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* , is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-3, *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* , is focused on whether non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. The Company will continue to monitor the development of these EITF s and evaluate the effects on its financial statements and disclosures.

**12. Income Taxes**

On July 13, 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* An Interpretation of FASB Statement No. 109 ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with FASB Statement No. 109, *Accounting for*

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**Table of Contents**

Income Taxes and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN 48 on January 1, 2007. The total amount of unrecognized tax benefits as of the date of adoption is not material. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. During the three months ended March 31, 2007 and 2006, the Company has not recognized any interest or penalties. Upon adoption of FIN 48 on January 1, 2007, the Company did not record any interest or penalties.

The Company is subject to taxation in the US and various state jurisdictions. The Company's tax years for 1998 and forward are subject to examination by the US and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At January 1, 2007, we had net deferred tax assets of \$17.8 million. The deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carryforwards and federal and state research and development ( R&D ) credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset our net deferred tax asset. Additionally, the future utilization of our NOL and R&D credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. We have not yet determined whether such an ownership change has occurred, however, the Company plans to complete a Section 382 analysis regarding the limitation of the net operating losses and research and development credits. When this project is completed, the Company plans to update their unrecognized tax benefits under FIN 48. Therefore, the Company expects that the unrecognized tax benefits may change within 12 months of this reporting date. At this time, the Company cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

**13. Subsequent Events**

On April 23, 2007, Halozyme Therapeutics, Inc. ( Halozyme ), and New River Management V, LP ( New River ), entered into a definitive stock purchase agreement (the Purchase Agreement ). Under the terms of the Purchase Agreement New River will purchase 3,500,000 newly-issued shares of Halozyme's common stock for an aggregate price of \$32,095,000. The sale of the shares is contingent upon the satisfaction of customary closing conditions, including the receipt of anti-trust clearance. If the necessary closing conditions are not met on or before July 6, 2007, then either party will have the right to not proceed with the transaction. The Company anticipates that the sale of the shares will be completed in late May 2007. Shareholder approval is not required for the sale of the Shares. The Company will not immediately file a registration statement with the Securities and Exchange Commission (the SEC ) covering the resale of the shares, but we have agreed to file a registration statement with the SEC on or before November 1, 2007, covering the resale of the shares.

**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.*



## **Table of Contents**

### ***Overview***

We are a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes for the drug delivery, palliative care, oncology, and infertility markets. Our existing products and our products under development are based on intellectual property covering the family of human enzymes known as hyaluronidases. Hyaluronidases are enzymes (proteins) that break down hyaluronic acid, which is a naturally occurring substance in the human body. Our technology is based on recombinant human PH20 (rHuPH20), a human synthetic version of hyaluronidase that degrades hyaluronic acid, a space-filling, gel-like substance that is a major component of tissues throughout the body, such as skin and cartilage. The PH20 enzyme is a naturally occurring enzyme that digests hyaluronic acid to temporarily break down the gel, thereby facilitating the penetration and diffusion of other drugs and fluids that are injected under the skin or in the muscle. It also degrades the cumulus matrix surrounding oocytes (eggs) facilitating in vitro fertilization (IVF).

Currently, we have only limited revenue from Cumulase product sales, the sale of the active pharmaceutical ingredient ( API ) for Hylenex, and revenue from collaborative agreements with Baxter and Roche. All of our potential products, with the exception of Cumulase and Hylenex, are either in the research, pre-clinical, or clinical stage. It may be years, if ever, before we are able to obtain the regulatory approvals necessary to generate meaningful revenue from the sale of these product candidates. In addition, we have only generated minimal revenue from our biopharmaceutical operations and we have had operating and net losses each year since inception, with an accumulated deficit of \$44,456,544 as of March 31, 2007.

We currently have an effective universal shelf registration statement which will permit us, from time to time, to offer and sell up to \$32.5 million of additional equity or debt securities. Sales of substantial amounts of shares of our common stock pursuant to this registration statement or in connection with other transactions, or even the potential for such sales through the exercise of currently outstanding warrants, could lower the market price of our common stock and impair the Company's ability to raise capital through the sale of equity securities. In the future, we may also issue additional options, warrants or other derivative securities convertible into Halozyme common stock to fund the continued development of our product candidates and other general corporate purposes.

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

We currently have two FDA-approved products, Cumulase and Hylenex. We also have one product candidate, Chemophase, which is currently in clinical development. All of our other product candidates are in the research or pre-clinical stage of development. We received a CE (European Conformity) Mark for Cumulase in December 2004 and FDA clearance in April 2005. We launched Cumulase in the European Union and in the United States in June 2005.

During March 2005, we filed a new drug application ( NDA ) for the spreading agent Hylenex. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. ( ISTA ), with an ovine (ram) hyaluronidase, Vitrase®, Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase , and Primapharm, Inc. also with a bovine hyaluronidase, Hydase . The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. As each of these products is established as distinctly different new chemical entities, the marketing exclusivity granted does not prohibit the marketing of the products. During December 2005, we received FDA approval for our Hylenex NDA.

During June 2005, we submitted an investigational new drug application ( IND ) in order to begin clinical testing of our Chemophase® product candidate. We received authorization to initiate clinical testing of Chemophase in August 2005, and we commenced patient enrollment in our initial clinical protocol under this IND in October 2005. In March 2006, we completed enrollment in our Chemophase Phase I clinical trial. In April 2006, we commenced patient enrollment in our Chemophase Phase I/IIa clinical trial.

**Table of Contents*****Roche Agreement***

In December 2006, we entered into a license and collaboration Agreement with Roche for Enhance Technology. Under the terms of the agreement, Roche will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid us \$20 million as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. Pending the successful completion of a series of clinical, regulatory, and sales events, Roche may pay us further milestones which could potentially reach a value of up to \$111 million. In addition, Roche may pay us royalties on potential product sales for these first three targets. Over the next ten years, Roche will also have the option to exclusively develop and commercialize rHuPH20 with an additional ten targets to be identified by Roche, provided that Roche will be obligated to pay continuing exclusivity maintenance fees to us in order to maintain its exclusive development rights for these targets. For each of the additional ten targets, Roche may pay us further upfront and milestone payments of up to \$47 million per target as well as royalties on potential product sales for each of these additional ten targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets. In addition, on December 5, 2006, an affiliate of Roche purchased 3,385,000 shares of common stock for an aggregate of approximately \$11.1 million.

***Baxter Agreements***

In February 2007, we amended certain agreements with Baxter for Hylenex and entered into a new agreement for kits and co-formulations with rHuPH20. Under the terms of these agreements, Baxter paid us an initial upfront payment of \$10 million and, pending the successful completion of a series of regulatory and sales events, Baxter may make milestone payments which could potentially reach a value of up to \$25 million. In addition, Baxter will pay royalties on the sales of products covered under the agreements. Baxter prepaid \$1 million of these royalties in connection with the execution of the agreements and Baxter will be obligated to prepay \$9 million of additional royalties on or prior to January 1, 2009. Baxter will also now assume all development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the agreements. We will continue to supply Baxter with the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. Baxter will obtain a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, our proprietary recombinant human hyaluronidase, with Baxter hydration fluids and generic small molecule drugs (with the exception of combinations with (i) bisphosphonates, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, the rights to which have been retained by us). Additionally, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. In addition, on February 13, 2007, an affiliate of Baxter purchased 2,070,394 shares of Halozyme's common stock for an aggregate of \$20 million.

***Revenues***

Product revenue will depend on our ability to develop, manufacture, 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. In June 2005, Cumulase was launched in the European Union and United States. In December 2005, we received FDA approval for Hylenex.

Revenues from collaborative and licensing agreements are recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Non-refundable upfront fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. In December 2006, we entered into the Roche Agreement which consists of non-refundable upfront license fees, reimbursements of research and development services and various performance or sales milestones and future product royalty payments. Due to our ongoing involvement obligation, we recorded the non-refundable upfront license fee received under the Roche Agreement as deferred revenue when received in December 2006 and recognized over the term of the contract.

**Table of Contents**

In addition, in February 2007, we entered into the Baxter Agreement which consists of non-refundable upfront license fees, reimbursements of research and development services and various performance or sales milestones and future product royalty payments. Due to our ongoing involvement obligation, we recorded the non-refundable upfront license fee received under the Baxter Agreement as deferred revenue when received in February 2007 and recognized over the term of the contract.

***Costs and Expenses***

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

*Research and Development.* Our research and development expenses consist primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, clinical trials, facility costs, and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our Chemophase and Hylenex product candidates which are both based on our recombinant human PH20 (rHuPH20) enzyme, a human synthetic version of hyaluronidase. We completed enrollment in our Chemophase Phase I clinical trial in March 2006 and commenced patient enrollment in our Chemophase Phase I/IIa clinical trial in April 2006.

Since our inception through March 31, 2007, we have incurred research and development costs of \$31.1 million. From January 1, 2002 through March 31, 2007, approximately 51% 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 products and approximately 15% of our research and development costs were associated with the development of our Chemophase product candidate. Due to the uncertainty in obtaining FDA approval, our reliance on third parties, and competitive pressures, we are unable to estimate with any certainty the additional costs we will incur in the continued development of our Hylenex product and our Chemophase product candidate for commercialization. However, we expect our research and development costs to increase substantially if we are able to advance our product candidates into later stages of clinical development.

Clinical development timelines, likelihood of success, and total costs vary widely. Although we are currently focused primarily on advancing Chemophase, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific and clinical progress of each product candidate and other market and regulatory developments.

Product candidate completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals, and the subsequent compliance with applicable regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We received FDA approval for our Hylenex product candidate in December 2005. We submitted an IND for our Chemophase product candidate in June 2005, and initiated Phase I clinical trials in October 2005. In March 2006, we completed enrollment in our Chemophase Phase I clinical trial. In April 2006, we commenced patient enrollment in our Chemophase Phase I/IIa clinical trial. We cannot be certain when or if our Chemophase product candidate, or any of our other product candidates, will receive regulatory approval or whether any net cash inflow from our Chemophase product candidate, or any of our other product candidates, or development projects, will commence.

*Selling, General and Administrative.* Selling, general and administrative expenses consist primarily of compensation and other expenses related to our corporate operations and administrative employees, accounting and legal fees, other professional services expenses, marketing expenses, as well as other expenses associated with operating as a publicly traded company. We anticipate continued increases in selling, general and administrative expenses as our operations continue to expand.

*Interest Income.* Interest income consists primarily of income earned on our cash and cash equivalents. We anticipate increases in interest income due to increases in our cash and cash equivalents.

**Table of Contents**

***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 U.S. generally accepted accounting principles, or U.S. GAAP. 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 ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

***Revenue Recognition***

We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 104, *Revenue Recognition* and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured.

***Product Sales***

Cumulative revenue is recognized when the transfer of ownership occurs, upon shipment to the distributor. Accounts receivable is recorded net of an allowance for doubtful accounts. Currently, the allowance for doubtful accounts is zero as the collectibility of accounts receivable is reasonably assured. We are not obligated to accept returns for products that have reached their expiration date. Thus, no allowance for product returns has been established.

Under the terms of our Baxter Agreement, we will supply Baxter the active pharmaceutical ingredient for Hylenex at our fully burdened cost plus a margin and Baxter will fill and finish Hylenex and hold it for subsequent distribution. Because of our continued involvement in the development and production process of Hylenex under the terms of the Baxter Agreement, the earnings process is not considered to be complete. Accordingly, we defer revenue and the related product costs resulting from transfers of the active pharmaceutical ingredient for Hylenex to Baxter until the product is filled, finished, packaged and released.

***Revenues under Collaborative Agreements***

Revenues from collaborative and licensing agreements are recognized based on the performance requirements of the agreement. Revenue is deferred for fees received before earned. Non-refundable upfront fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. In February 2007, we entered into the Baxter Agreement which consists of non-refundable upfront license fees, reimbursements of research and development services and various performance or sales milestones and future product royalty payments. Due to our ongoing involvement obligation, we recorded the non-refundable upfront license fee received under the Baxter Agreement as deferred revenue when received in February 2007 and recognized over the term of the contract.

Reimbursements of research and development services are recognized as revenues during the period in which the services are performed. Payments related to substantive, performance-based milestones in a collaborative agreement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process. Royalty revenue from licensed products will be recognized when earned in accordance with the terms of the license agreements.

**Table of Contents*****Share-based Compensation Expense***

We grant options to purchase our common stock to our employees, directors and consultants under our stock option plans. The benefits provided under these plans are share-based payments subject to the provisions of revised Statement of Financial Accounting Standards No. 123, *Share-Based Payment* ( SFAS 123(R) ). Effective January 1, 2006, we adopted SFAS 123(R), including the provisions of the SEC's Staff Accounting Bulletin No. 107 ( SAB 107 ) and use the fair value method to account for share-based payments with a modified prospective application which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods are not revised for comparative purposes. Total compensation cost for our share-based payments recognized for the three months ended March 31, 2007 was \$415,000. Selling, general and administrative expense and research and development expense for the three months ended March 31, 2007 included share-based compensation of \$270,000 and \$145,000, respectively. As of March 31, 2007, \$3.0 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 2.0 years.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ( Black-Scholes model ) that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of our common stock and our peer group. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience and those of our peer group.

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS 123(R). Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, values may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS 123(R) and the SEC's Staff Accounting Bulletin No. 107 ( SAB 107 ) using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

***Clinical Trial and Contract Research Expenses***

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions, clinical research organizations, and other vendors that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates accordingly on a prospective basis.

In addition, we have several contracts that extend across multiple reporting periods, including our largest contract representing a \$260,000 development contract. We recognize expenses as the services are provided pursuant to

management's assessment of the progress that has been made to date. Such contracts require an assessment of the work that has been completed during the period, including measurement of progress, analysis of data that justifies the progress and management's judgment. Based on Company experience and management's

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**Table of Contents**

intimate involvement with these outsourced contracts, it is reasonably likely that we may experience a 3% variance in our estimate of the work completed. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by \$7,800, which would not represent a material change to historically reported results of operations.

***Inventory***

Inventory consists of our Cumulase product and our Hylenex API. Inventory primarily represents raw materials used in production, work in process, and finished goods inventory on hand, valued at actual cost. Inventories are reviewed periodically for slow-moving or obsolete status. If a launch of a new product is delayed, inventory may not be fully utilized and could be subject to impairment, at which point we would record a reserve to adjust inventory to its net realizable value.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. Please see our audited financial statements and notes thereto included elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2006, which contain accounting policies and other disclosures required by U.S. GAAP.

**Results of Operations Comparison of Three Months Ended March 31, 2007 and 2006**

**Revenues** Product sales were \$187,000 for the three months ended March 31, 2007 compared to \$73,000 for the three months ended March 31, 2006, an increase of \$114,000, or 156%. Cumulase product sales were \$171,000 and \$73,000 and sales of the API for Hylenex were \$16,000 and \$0 for the three months ended March 31, 2007 and 2006, respectively.

Revenues under collaborative agreements were \$623,000 for the three months ended March 31, 2007 compared to \$0 for the three months ended March 31, 2006. Revenues under collaborative agreements primarily consist of the amortization of upfront fees received from Baxter and Roche of \$367,000 and research and development payments from Baxter and Roche of \$256,000.

**Cost of Sales** Cost of sales were \$76,000 for the three months ended March 31, 2007 compared to \$23,000 for the three months ended March 31, 2006, an increase of \$53,000, or 230%. This was due to the increase in product sales for Cumulase and the API for Hylenex.

**Research and Development** Research and development expenses were \$2.8 million for the three months ended March 31, 2007 compared to \$2.2 million for the three months ended March 31, 2006. 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, and depreciation. Research and development expenses increased by \$637,000 primarily due to increased clinical trial costs of \$344,000, higher compensation costs of \$232,000 and increased share-based compensation costs of \$47,000. We expect research and development costs to increase in future periods as we increase our research efforts, expand our clinical trials, and continue to develop and manufacture our product candidates.

**Selling, General and Administrative** Selling, general and administrative expenses were \$2.0 million for the three months ended March 31, 2007 compared to \$1.5 million for the three months ended March 31, 2006. Selling, general and administrative expenses increased by \$454,000 primarily due to increased compensation costs of \$222,000, increased share-based compensation expenses of \$96,000, increased professional fees of \$85,000, which were primarily associated with higher audit and consulting fees related to internal controls documentation and testing under the Sarbanes-Oxley Act of 2002, and increased marketing costs of \$50,000.

**Table of Contents**

**Share-Based Compensation** Through 2005, we accounted for our stock plans using the intrinsic value method and recorded no stock based compensation for options granted to employees. Effective at the beginning of 2006, we adopted Statement of Financial Accounting Standards No. 123(R) ( SFAS 123(R) ), *Share-Based Payment*, and elected to adopt the modified prospective application method. SFAS No. 123(R) requires us to use a fair-valued based method to account for share-based compensation. Accordingly, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employees' requisite service period. Total compensation cost for our share-based payments for the three months ended March 31, 2007 was \$415,000 compared to \$273,000 for the three months ended March 31, 2006. Selling, general and administrative expense and research and development expense for the three months ended March 31, 2007 include share-based compensation of \$270,000 and \$145,000, respectively. As of March 31, 2007, \$3.0 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 2.0 years. See Note 3, Summary of Significant Accounting Policies Share-Based Compensation in the Notes to Condensed Consolidated Financial Statements for further discussion.

**Interest Income** Interest income was \$723,000 for the three months ended March 31, 2007 compared to \$183,000 for the three months ended March 31, 2006. The increase in interest income was a result of maintaining higher average cash balances during 2007. We anticipate continued increases in interest income due to increases in our cash and cash equivalents.

**Net Loss** Net loss for the three months ended March 31, 2007 was \$3.4 million, or \$0.05 per common share, compared to \$3.5 million, or \$0.06 per common share for the three months ended March 31, 2006. The decrease in net loss was due to an increase in revenues and interest income partially offset by an increase in operating expenses.

**Liquidity and Capital Resources**

As of March 31, 2007, cash and cash equivalents were \$71.0 million versus \$44.2 million as of December 31, 2006, an increase of \$26.8 million. This increase resulted primarily from the \$10 million initial up front payment received from Baxter, \$1 million in prepaid royalties received from Baxter, \$20.0 million in net proceeds from the sale of common stock to Baxter, and net proceeds from the exercise of warrants and stock options of \$0.8 million during the three months ended March 31, 2007, offset by our net cash used in operations and for the purchase of property and equipment for the three months ended March 31, 2007.

*Operating activities*

Net cash provided by operations was \$6.2 million during the three months ended March 31, 2007 compared to \$2.8 million of cash used in operations during the three months ended March 31, 2006. This change was due to the \$11 million initial up front payments received from Baxter in 2007 of which \$10.9 million was recorded as deferred revenue.

*Investing activities*

Net cash used in investing activities was \$161,000 during the three months ended March 31, 2007 compared to \$39,000 during the three months ended March 31, 2006. This was due to the increased purchase of property and equipment during the three months ended March 31, 2007.

*Financing activities*

Net cash provided by financing activities was \$20.8 million during the three months ended March 31, 2007 compared to \$1.3 million during the three months ended March 31, 2006. In February 2007, we sold common stock for approximately \$20 million, net of issuance costs. Additionally, we received approximately \$0.8 million in net proceeds from warrant and stock option exercises during the three months ended March 31, 2007.

We expect our cash requirements to increase significantly as we continue to increase our research and development for, seek regulatory approvals of, and develop and manufacture our current product candidates. As we expand our research and development efforts and pursue additional product opportunities, we anticipate significant cash requirements for hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure. The amount and timing of cash requirements will depend on the research, development, manufacture, regulatory and market acceptance of our product candidates, if any, and the resources we devote to researching, developing, manufacturing, commercializing and supporting our product candidates.





## Table of Contents

We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months. 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 Roche and Baxter collaborations. We may finance future cash needs through the sale of other equity securities, the exercise of our callable warrants, strategic collaboration agreements, debt financing, or any combination of the foregoing. On June 10, 2005, we filed a shelf registration statement on Form S-3 (Registration No. 333-125731), which was declared effective on June 17, 2005, which initially allowed us, from time to time, to offer and sell up to \$50 million of equity or debt securities. We have previously sold common stock under this registration statement for an aggregate of approximately \$17.5 million, so we currently have the ability to issue debt and equity securities for an aggregate of \$32.5 million. We cannot be certain that our existing cash and cash equivalents will be adequate for our anticipated needs or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs or delay the launch of our product candidates. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders could result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

**Off-Balance Sheet Arrangements** As of March 31, 2007, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we 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.

### **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-K filed with the Securities and Exchange Commission on March 9, 2007.*

### **Risks Related To Our Business**

**We have generated only minimal revenue from product sales to date; we have a history of net losses and negative cash flow, and we may never achieve or maintain profitability.**

We have generated only minimal revenue from product sales to date and may never generate significant revenues from future product sales. Even if we do achieve significant revenues from product sales, licensing revenues and milestone payments, we expect to incur significant operating losses over the next several years. We have never been profitable, and we may never become profitable. Through March 31, 2007, we have incurred aggregate net losses of \$44,456,544.

**We may need to raise funds in the next twelve months, and there can be no assurance that such funds will be available.**

During the next twelve months we may need to raise additional capital to complete the steps required to continue development of our product candidates and to fund general operations. If we engage in acquisitions of companies, products, or technology in order to execute our business strategy, we may need to raise additional capital. We may be required to raise additional capital in the future through the public offering of securities, collaborative agreements, private financings and various other equity or debt financings, including calling outstanding warrants to purchase our common stock.

**Table of Contents**

Currently, warrants to purchase approximately 5.9 million shares of our common stock are outstanding and this amount of outstanding warrants may make us a less desirable candidate for investment for some potential investors. Approximately 2.1 million of our outstanding warrants contain a call feature that, potentially, may allow us to raise funds from the holders of these warrants. If our common stock closes at a price equal to or greater than \$2.00 per share for twenty consecutive trading days, we have the ability, at our sole discretion, to call warrants exercisable for up to approximately 1.9 million shares of common stock, provided that we have not exercised a call right in the preceding three months. Upon such a call, the holders of these warrants have thirty days to decide whether to either exercise their warrants at a price of \$1.75 per share or receive \$0.01 from us for each share of common stock that is not exercised. If we need to raise funds in the future and we wish to utilize this call right, we will not be able to exercise the call right if we do not meet the minimum closing price condition and, even if we meet this condition, we 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 may be issued and these shares will dilute the ownership interest of our current investors.

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

With the exception of the December 2004 receipt of a CE (European Conformity) Mark and April 2005 FDA clearance for Cumulase, and the December 2005 FDA approval for Hylenex, none of our product candidates have received regulatory approval from the FDA or from any similar national regulatory agency or authority in any other country in which we intend to do business. Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States. Most other countries in which we may do business have similar requirements.

In December 2005, we received FDA approval for Hylenex. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. ( ISTA ), with an ovine-derived hyaluronidase, Vitrase Amphastar Pharmaceuticals, Inc. ( Amphastar ), with a bovine-derived hyaluronidase, Amphadase , and Primapharm, Inc. also with a bovine-derived hyaluronidase, Hydase . The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are each distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. For so long as each of these products are established as distinctly different new chemical entities the marketing exclusivity granted does not prohibit the marketing of any of these products, including Hylenex. If the FDA changes its earlier determination that Hylenex is a distinct new chemical entity, our ability to market Hylenex will be materially impaired.

The processes for obtaining FDA approval are extensive, time-consuming and costly, and there is no guarantee that the FDA will approve any NDAs that we intend to file with respect to any of our product candidates, or that the timing of any such approval will be appropriate for our product launch schedule and other business priorities, which are subject to change. We have not currently begun the NDA approval process for any of our other potential products, and we may not be successful in obtaining such approvals for any of our potential products.

**We may not receive regulatory approvals for our product candidates for a variety of reasons, including unsuccessful clinical trials.**

Clinical testing of pharmaceutical products is also a long, expensive and uncertain process and a failure of a clinical trial can occur at any stage. Even if initial results of pre-clinical studies or clinical trial results are promising, we may obtain different results that fail to show the desired levels of safety and efficacy, or we may not obtain FDA approval for a variety of other reasons. The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from obtaining regulatory approval and commercializing the product. FDA approval can be delayed, limited or not granted for many reasons, including, among others:

**Table of Contents**

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

FDA officials may not find that the data from pre-clinical testing and clinical trials justify approval, or they may require additional studies that would make it commercially unattractive to continue pursuit of approval;

the FDA may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;

the cost of a clinical trial may be greater than what we originally anticipate, and we may decide to not pursue FDA approval for such a trial;

the FDA may not approve our manufacturing processes or facilities, or the processes or facilities of our contract manufacturers or raw material suppliers;

the FDA may change its formal or informal approval policies, act contrary to previous guidance, or adopt new regulations; or

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

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

We intend to market certain of our products, and perhaps have certain of our products manufactured, in foreign countries. The process of obtaining regulatory approvals in foreign countries is subject to delay and failure for many of the same reasons set forth above as well as for reasons that vary from jurisdiction to jurisdiction. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

**If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.**

Any approved products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements. The cGMP regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of our products. We are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements.

Later discovery of previously unknown problems with our products, manufacturing processes or failure to comply with regulatory requirements, may result in any of the following:

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**Table of Contents**

restrictions on our products or manufacturing processes;

warning letters;

withdrawal of the products from the market;

voluntary or mandatory recall;

fines;

suspension or withdrawal of regulatory approvals;

suspension or termination of any of our ongoing clinical trials;

refusal to permit the import or export of our products;

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

product seizure; and

injunctions or the imposition of civil or criminal penalties.

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

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

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

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

our ability to fund our sales and marketing efforts;

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

the effectiveness of our sales and marketing efforts; and

the introduction of generic competitors.

If our products do not gain market acceptance, we may not be able to fund future operations, including the development or acquisition of new product candidates and/or our sales and marketing efforts for our approved products, which would cause our business to suffer.

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

**If we are unable to sufficiently develop our sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize products.**

We may not be successful in marketing and promoting our existing product candidates or any other products we develop or acquire in the future. We are currently in the process of developing our sales, marketing and distribution capabilities. However, our current capabilities in these areas are very limited. In order to commercialize



**Table of Contents**

any products successfully, we must internally develop substantial sales, marketing and distribution capabilities, or establish collaborations or other arrangements with third parties to perform these services. We do not have extensive experience in these areas, and we may not be able to establish adequate in-house sales, marketing and distribution capabilities or engage and effectively manage relationships with third parties to perform any or all of such services. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, whose efforts may not meet our expectations or be successful.

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

We depend upon the efforts of these third parties to promote and sell our current products, but there can be no assurance that the efforts of these third parties will meet our expectations or result in any significant product sales.

**If our sole contract manufacturer is unable to manufacture our products, our product development and commercialization efforts could be delayed or stopped.**

We have signed a commercial supply agreement with Avid Bioservices, Inc. ( Avid ), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. Avid will produce the active pharmaceutical ingredient used in each of Cumulase, Hylenex, Chemophase, and Enhanze Technology under cGMP for commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. Avid has only limited experience manufacturing our active pharmaceutical ingredient batches and we rely on its ability to successfully manufacture these batches according to product specifications. In addition, as a result of our Roche Agreement, we are required to scale up our active pharmaceutical ingredient production in order to meet our contractual demands. If Avid does not maintain its status as an FDA-approved manufacturing facility, is unable to successfully scale our active pharmaceutical ingredient production, or is unable to manufacture the active pharmaceutical ingredient used in our products and product candidates for any other reason, the commercialization of our products and the development of our product candidates will be delayed and our business will be adversely affected. We have not established and may not be able to establish arrangements with additional manufacturers for these ingredients or products should the existing supplies become unavailable or in the event that our sole contract manufacturer is unable to adequately perform its responsibilities. Any delays or interruptions in the supply of materials by Avid could cause the delay of clinical trials and could delay or prevent the commercialization of product candidates that may receive regulatory approval. Such delays or interruptions would have a material adverse effect on our business and financial condition.

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

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, fill, finish, and package the products prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are economically acceptable to us, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a third-party to prepare, fill, finish, and package Cumulase. This third party has only limited experience manufacturing Cumulase batches and we rely on its ability to successfully manufacture Cumulase according to product specifications. In addition, one of our distributors, who utilizes our raw material for Cumulase in production of their proprietary product, is experiencing technical challenges integrating our raw material into their proprietary manufacturing process. If our third party manufacturer is unable to successfully manufacture Cumulase, or if our distributor is unable to resolve their technical issues, we may be unable to supply enough Cumulase product to meet demand. In addition, we currently utilize a subsidiary of Baxter to prepare, fill, finish, and package Hylenex under a development and supply





## **Table of Contents**

agreement. Baxter has only limited experience manufacturing Hylenex batches and we rely on its ability to successfully manufacture Hylenex batches according to product specifications. Any delays or interruptions in Baxter's ability to manufacture Hylenex batches could have a material adverse impact on our business and financial condition.

### **Developing and marketing pharmaceutical products for human use involves product liability risks, for which we currently have limited insurance coverage.**

The testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us.

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

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. In addition, we rely on the expertise and guidance of independent directors to develop business strategies and to guide our execution of these strategies. Due to changes in the regulatory environment for public companies over the past few years, the demand for independent directors has increased and it may be difficult for us, due to competition from both like-sized and larger companies, to recruit qualified independent directors.

Furthermore, if we were to lose key management personnel, particularly Jonathan Lim, M.D., our chief executive officer, or Gregory Frost, Ph.D., our chief scientific officer, then we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained. For example, Dr. Frost has been with us from soon after our inception, and he possesses a substantial amount of knowledge about our development efforts. If we were to lose his services, we would experience delays in meeting our product development schedules. We have not entered into any retention or other agreements specifically designed to motivate officers or other employees to remain with Halozyme other than standard agreements relating to the vesting of stock options that every optionee of Halozyme must enter into as a condition of receiving an option grant.

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

## **Risks Related To Our Stock**

### **Future sales of shares of our common stock upon the exercise of currently outstanding securities or pursuant to our universal shelf registration statement may negatively affect our stock price.**

As a result of our January 2004 private financing transaction, we issued warrants to private investors for the purchase of 10,461,943 shares of common stock at purchase prices ranging from \$0.77 to \$1.75 per share. Currently, approximately 3.3 million shares of common stock remain issuable upon the exercise of these warrants. As a result of our October 2004 financing transaction, we issued warrants for the purchase of 2,709,542 shares of common stock at a purchase of \$2.25 per share. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise which could negatively affect our stock price.

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**Table of Contents**

We currently have the ability, from time to time, to offer and sell up to \$32.5 million of additional equity or debt securities under a currently effective universal shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair the Company's ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into Halozyyme common stock.

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

We participate in a highly dynamic industry, which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low stock prices during the twelve months ended March 31, 2007 were \$9.70 and \$2.15, respectively. We expect our stock price to continue to be subject to significant volatility and, in addition to the other risks and uncertainties described elsewhere in this report and all other risks and uncertainties that are either not known to us at this time or which we deem to be immaterial, any of the following factors may lead to a significant drop in our stock price:

our failure, or the failure of one of our third-party partners, to comply with the terms of our partnerships;

general negative conditions in the healthcare industry;

general negative conditions in the financial markets;

the failure, for any reason, to obtain FDA approval for any of our products;

the failure, for any reason, to secure or defend our intellectual property position;

for those products that are approved by the FDA, the failure of the FDA to approve such products in a timely manner consistent with the FDA's historical approval process;

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

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

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

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

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

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

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

Notwithstanding recent increases to the daily trading volume, our stock has historically traded at a lower daily trading volume. If current trading volumes do not continue and limited trading in our stock returns, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

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

We may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 2.1 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.



**Table of Contents**

**Risks Related To Our Industry**

**Compliance with the extensive government regulations to which we are subject is expensive and time consuming, and may result in the delay or cancellation of product sales, introductions or modifications.**

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including Halozyme, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration ( DEA ) and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, Halozyme and its contract suppliers and manufacturers are subject to periodic inspection of its or their respective facilities, procedures and operations and/or the testing of products by the FDA, the DEA and other authorities, which conduct periodic inspections to confirm that Halozyme and its contract suppliers and manufacturers are in compliance with all applicable regulations. The FDA also conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems, or our contract suppliers and manufacturers processes, are in compliance with cGMP and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

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

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

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

Regulatory requirements applicable to pharmaceutical products make the substitution of suppliers and manufacturers costly and time consuming. We have no internal manufacturing capabilities and are, and expect to be in the future, entirely dependent on contract manufacturers and suppliers for the manufacture of our products and for their active and other ingredients. The disqualification of these manufacturers and suppliers through their failure to comply with regulatory requirements could negatively impact our business because the delays and costs in obtaining and qualifying alternate suppliers (if such alternative suppliers are available, which we cannot assure) could delay clinical trials or otherwise inhibit our ability to bring approved products to market, which would have a material adverse effect on our business and financial condition.

**We may be required to initiate or defend against legal proceedings related to intellectual property rights, which may result in substantial expense, delay and/or cessation of the development and commercialization of our products.**

We rely on patents to protect our intellectual property rights. The strength of this protection, however, is uncertain. For example, it is not certain that:

our patents and pending patent applications cover products and/or technology that we invented first;

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**Table of Contents**

we were the first to file patent applications for these inventions;

others will not independently develop similar or alternative technologies or duplicate our technologies;

any of our pending patent applications will result in issued patents; and

any of our issued patents, or patent pending applications that result in issued patents, will be held valid and infringed in the event the patents are asserted against others.

We currently own or license several U.S. patents and also have pending patent applications. There can be no assurance that our existing patents, or any patents issued to us as a result of our pending patent applications, will provide a basis for commercially viable products, will provide us with any competitive advantages, or will not face third-party challenges or be the subject of further proceedings limiting their scope or enforceability. Such limitations in our patent portfolio could have a material adverse effect on our business and financial condition. In addition, if any of our pending patent applications do not result in issued patents, this could have a material adverse effect on our business and financial condition.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. In addition, costly litigation could be necessary to protect our patent position. We also rely on trademarks to protect the names of our products. These trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation that we seek to protect with confidentiality agreements with employees, consultants and others with whom we discuss our business. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and we might not be able to resolve these disputes in our favor.

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

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

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

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

an acquisition may negatively impact our results of operations because it may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;

we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire;

certain acquisitions may disrupt our relationship with existing customers who are competitive with the acquired business;



**Table of Contents**

acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs;

an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;

acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and

key personnel of an acquired company may decide not to work for us.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results. We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market will not view such acquisitions positively.

**If third-party reimbursement and customer contracts are not available, our products may not be accepted in the market.**

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health insurers, managed care organizations and other healthcare providers.

Third-party payers are increasingly attempting to limit both the coverage and the level of reimbursement of new drug products to contain costs. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Third-party payers may not establish adequate levels of reimbursement for the products that we commercialize, which could limit their market acceptance and result in a material adverse effect on our financial condition.

Customer contracts, such as with group paying organizations and hospital formularies, will often not offer contract or formulary status without either the lowest price or substantial proven clinical differentiation. If our products are compared to animal-extracted hyaluronidases by these entities, it is possible that neither of these conditions will be met, which could limit market acceptance and result in a material adverse effect on our financial condition.

**The rising cost of healthcare and related pharmaceutical product pricing has led to cost-containment pressures that could cause us to sell our products at lower prices, resulting in less revenue to us.**

Any of our products that have been or in the future are approved by the FDA may be purchased or reimbursed by state and federal government authorities, private health insurers and other organizations, such as health maintenance organizations and managed care organizations. Such third-party payors increasingly challenge pharmaceutical product pricing. The trend toward managed healthcare in the United States, the growth of such organizations, and various legislative proposals and enactments to reform healthcare and government insurance programs, including the Medicare Prescription Drug Modernization Act of 2003, could significantly influence the manner in which pharmaceutical products are prescribed and purchased, resulting in lower prices and/or a reduction in demand. Such cost containment measures and healthcare reforms could adversely affect our ability to sell our products. Furthermore, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could negatively and materially impact our revenues and financial condition. We anticipate that we will encounter similar regulatory and legislative issues in most other countries outside the United States.

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## **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, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc. (ISTA), Amphastar Pharmaceuticals, Inc., and Primapharm, Inc., among others. These competitors may develop technologies and products that are more effective, safer, or less costly than our current or future product candidates or that could render our technologies and product candidates obsolete or noncompetitive. Many of these competitors have substantially more resources and product development, manufacturing and marketing experience and capabilities than we do. In addition, many of our competitors have significantly greater experience than we do in undertaking pre-clinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. ( ISTA ), with an ovine-derived hyaluronidase, Vitrase<sup>®</sup> Amphastar Pharmaceuticals, Inc., with a bovine-derived hyaluronidase, Amphadase , and Primapharm, Inc., also with a bovine-derived hyaluronidase, Hydase . The FDA has determined that Amphadase, Hydase, Hylenex and Vitrase are distinct new chemical entities and hence afforded five years of market exclusivity. The five year market exclusivity precludes identical new chemical entity products from being marketed for a period of five years. As each of these products is established as distinctly different new chemical entities the marketing exclusivity granted does not prohibit the marketing of the products.

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

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. An immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio; therefore, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

### **Item 4. 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 Quarterly Report.

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

There have been no significant changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2007, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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**Table of Contents****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 1A. Risk Factors**

A description of the risk factors associated with our business is included under "Risk Factors" in "Management's Discussion and Analysis of Financial Condition and Results of Operations", contained in Item 2 of Part I of this report. This description includes any changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1 of our 2006 Annual Report on Form 10-K and is incorporated herein by reference. There are no material changes to the risk factors described in our Form 10-K.

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

During January, February, and March 2007, holders of the Company's various outstanding warrants exercised rights to purchase 510,397 common shares for gross proceeds of approximately \$358,000. The shares and underlying warrants were purchased for investment in a private placement exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

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

Not applicable.

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

<b>Exhibit</b>	<b>Title</b>
3.1	Amended and Restated Articles of Incorporation, as filed with the Nevada Secretary of State on May 4, 2006 (1)
3.2	Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock (1)
3.3	Bylaws as Amended (2)
4.1	Rights Agreement between Corporate Stock Transfer, as rights agent, and Registrant, dated May 4, 2006 (1)
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)

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- 10.4\* Distribution Agreement between MediCult AS and Registrant, dated February 9, 2004 (3)
  - 10.5 2004 Stock Plan and Form of Option Agreement thereunder (4)
  - 10.6 Form of Indemnity Agreement for Directors and Executive Officers (4)
  - 10.7 Form of Callable Stock Purchase Warrant (4)
  - 10.8 Form of Common Stock Purchase Warrant (5)
  - 10.9 DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder (6)
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**Table of Contents**

<b>Exhibit</b>	<b>Title</b>
10.10	Nonstatutory Stock Option Agreement With Andrew Kim (6)
10.11*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (7)
10.12	Halozyme Therapeutics, Inc. 2005 Outside Directors Stock Plan (8)
10.13	Placement Agent Agreement, dated as of December 12, 2005 between Registrant, SG Cowen & Co., LLC, Rodman & Renshaw, LLC and Roth Capital Partners, LLC (9)
10.14	Placement Agent Agreement, dated as of December 13, 2005 between Registrant, SG Cowen & Co., LLC, Rodman & Renshaw, LLC and Roth Capital Partners, LLC (10)
10.15	First Amendment to the License Agreement between University of Connecticut and Registrant, dated January 9, 2006 (11)
10.16	Halozyme Therapeutics, Inc. 2006 Stock Plan (13)
10.17	First Amendment to Standard Industrial Net Lease between Registrant and Sorrento Square, dated as of July 1, 2006 (14)
10.18	Second Amendment to Standard Industrial Net Lease between Registrant and Sorrento Square, dated as of July 1, 2006 (14)
10.19	Form of Stock Option Agreement (2005 Outside Directors Stock Plan) (15)
10.20	Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan) (15)
10.21	Form of Stock Option Agreement (2006 Stock Plan) (15)
10.22	Form of Restricted Stock Agreement (2006 Stock Plan) (15)
10.23*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006 (16)
10.24	Stock Purchase Agreement between Roche Finance Ltd and Registrant, dated December 5, 2006 (16)
10.25*	First Amendment to the Commercial Supply Agreement between Avid Bioservices, Inc. and Registrant, dated December 15, 2006 (17)
10.26*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 13, 2007 (18)
10.27*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 13, 2007 (18)

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- 10.28\* License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 13, 2007 (18)
  - 10.29 Stock Purchase Agreement between Baxter International, Inc. and Registrant, dated February 13, 2007 (18)
  - 10.30 Stock Purchase Agreement between New River Management V, LP and Registrant, dated April 23, 2007 (19)
  - 21.1 Subsidiaries of Registrant (12)
  - 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 Current Report on Form 8-K, filed May 8, 2006.
- (2) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 14, 2004, and Exhibit 99.2 of Registrant's Current Report on Form 8-K, filed July 6, 2005.
- (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 Current Report on Form 8-K, filed October 15, 2004.
- (6) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the Commission on October 26, 2004.
- (7) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed February 22, 2005.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed July 6, 2005.

(9)

Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 13, 2005.

(10) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 14, 2005.

(11) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2006.

(12) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.

(13) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.

(14) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed August 8, 2006.

(15)

Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2006.

(16) Incorporated by reference to the Registrant's Current Report on Form 8-K/A, filed December 15, 2006.

(17) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 21, 2006.

(18) Incorporated by reference to the Registrants Current Report on Form 8-K/A, filed February 20, 2007.

(19) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed April 24, 2007.

\* Confidential treatment has been requested for certain portions of this exhibit. These portions have been omitted



from this  
agreement and  
have been filed  
separately with  
the Securities  
and Exchange  
Commission.

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**Table of Contents**

**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 10, 2007.

Halozyme Therapeutics, Inc.,  
a Nevada corporation

Date: May 10, 2007

By: /s/ Jonathan E. Lim  
Jonathan E. Lim, MD  
Its: President, Chief Executive Officer,  
(Principal Executive Officer)

Date: May 10, 2007

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