

HALOZYME THERAPEUTICS INC

Form 10-Q

November 09, 2006

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**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 September 30, 2006**

**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 October 31, 2006 was 64,449,455.

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**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS    UNAUDITED**  
**AS OF SEPTEMBER 30, 2006 AND DECEMBER 31, 2005**

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,100,911	\$ 19,132,194
Receivables	384,206	413,829
Inventory	233,767	278,958
Prepaid expenses	613,150	281,191
Total current assets	17,332,034	20,106,172
Property and equipment, net	460,834	381,248
Other assets	18,835	22,835
Total assets	\$ 17,811,703	\$ 20,510,255
<b>LIABILITIES AND STOCKHOLDERS    EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,428,044	\$ 1,379,932
Accrued expenses	1,206,630	669,298
Deferred revenue	122,365	254,138
Total current liabilities	2,757,039	2,303,368
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000,000 shares authorized, 64,449,455 and 60,246,997 shares issued and outstanding as of September 30, 2006 and December 31, 2005, respectively	64,449	60,247
Additional paid-in-capital	51,711,492	44,493,894
Accumulated deficit	(36,721,277)	(26,347,254)
Total stockholders' equity	15,054,664	18,206,887
Total liabilities and stockholders' equity	\$ 17,811,703	\$ 20,510,255

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



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**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS UNAUDITED**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Revenues:				
Product sales	\$ 362,477	\$ 25,644	\$ 555,420	\$ 71,347
Expenses:				
Cost of sales	356,093	10,091	395,591	31,115
Research and development	2,429,016	3,106,983	6,536,011	7,579,311
Selling, general and administrative	1,403,405	674,368	4,537,869	2,443,287
Total expenses	4,188,514	3,791,442	11,469,471	10,053,713
Loss from operations	(3,826,037)	(3,765,798)	(10,914,051)	(9,982,366)
Other income, net	175,000	65,322	540,028	220,480
Net loss	\$ (3,651,037)	\$ (3,700,476)	\$ (10,374,023)	\$ (9,761,886)
Net loss per share, basic and diluted	\$ (0.06)	\$ (0.07)	\$ (0.17)	\$ (0.20)
Shares used in computing net loss per share, basic and diluted	62,731,254	49,978,696	61,669,201	49,834,695

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

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**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS    UNAUDITED**  
**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005**

	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net loss	\$ (10,374,023)	\$ (9,761,886)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	172,702	155,070
Loss (gain) on disposal of equipment	3,168	(1,200)
Share-based compensation expense	911,815	
Issuance of common stock and stock options for goods and services	9,322	146,802
Changes in operating assets and liabilities:		
Accounts receivable	29,623	(19,114)
Inventory	45,191	6,468
Prepaid expenses and other assets	(327,959)	(151,366)
Accounts payable and accrued expenses	585,444	232,096
Deferred revenue	(131,773)	
Net cash used in operating activities	(9,076,490)	(9,393,130)
Cash flows from investing activities:		
Purchase of property and equipment	(255,456)	(343,505)
Net cash used in investing activities	(255,456)	(343,505)
Cash flows from financing activities:		
Proceeds from exercise of stock options	137,258	176,422
Proceeds from exercise of warrants    net	6,163,405	188,122
Net cash provided by financing activities	6,300,663	364,544
Net decrease in cash and cash equivalents	(3,031,283)	(9,372,091)
Cash and cash equivalents, beginning of period	19,132,194	16,007,714
Cash and cash equivalents, end of period	\$ 16,100,911	\$ 6,635,623

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

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**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 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.

The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for its existing products and for a limited number of product candidates. In June 2005, the Company launched its first product, Cumulase®, 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 and nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2006 or for any future period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2005 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 24, 2006 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. Certain amounts in the prior year financial statements have been reclassified to conform to the current year presentation. 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. Significant Accounting Policies**

***Change in Accounting Method for Share-Based Compensation***

In December 2004, the Financial Accounting Standards Board ( FASB ) revised Statement of Financial Accounting Standards No. 123 ( SFAS 123(R) ), Share-Based Payment. On April 14, 2005, the U.S. Securities and Exchange Commission adopted a new rule amending the effective dates for SFAS 123(R). In accordance with the new rule, the accounting provisions of SFAS 123(R) became effective for us beginning in the quarter ended March 31, 2006.

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We adopted the provisions of SFAS 123(R) on January 1, 2006. Accordingly, compensation costs for all share-based awards to employees are measured based on the grant date fair value of those awards and recognized over the period during which the employee is required to perform service in exchange for the award (generally over the vesting period of the award). We have no awards with market or performance conditions. Excess tax benefits, as defined by SFAS 123(R), will be recognized as an addition to additional paid-in-capital. Effective January 1, 2006 and for all periods subsequent to that date, SFAS 123(R) supersedes our previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ). In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ( SAB 107 ) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* ( FAS 123(R)-3 ). The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool ( APIC pool ) related to the tax effects of employee share-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee share-based compensation awards that are outstanding upon adoption of SFAS 123(R). An entity may make a one-time election to adopt the transition method described in this guidance. An entity may take up to one year from the later of its initial adoption of SFAS 123(R) or the effective date of this guidance, which was November 11, 2005. We are in the process of determining whether to adopt the alternative transition method provided in FAS 123(R)-3 for calculating the tax effects of share-based compensation pursuant to SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, 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 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 FASB Statement No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ). Our condensed consolidated financial statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our condensed consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of SFAS 123(R).

Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Share-based compensation expense recognized in our condensed consolidated statement of operations for the three and nine months ended September 30, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123(R). For share awards granted during the three and nine months ended September 30, 2006, expenses are amortized under the straight-line method. For share awards granted prior to 2006, expenses are amortized under the straight-line method prescribed by SFAS 123. As share-based compensation expense recognized in the condensed consolidated statement of operations for the third quarter of fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. 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. Pre-vesting forfeitures were estimated to be approximately 10% for employees in the third quarter of 2006 based on our historical experience and those of our peer group. In our pro forma information required under SFAS 123 for the periods prior to 2006, we accounted for forfeitures as they occurred.

The adoption of SFAS 123R resulted in incremental share-based compensation expense of \$334,000 and \$912,000 in the three and nine months ended September 30, 2006, respectively. The incremental share-based compensation caused our net loss to increase by the same amounts and basic and diluted loss per share to increase by \$0.01 per share and \$0.01 per share in the three and nine months ended September 30, 2006, respectively. Total compensation expense related to all of our share-based awards, recognized under SFAS 123R, for the three and nine months ended September 30, 2006 was comprised of the following:



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	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	\$ 107,379	\$ 310,588
Selling, general and administrative	226,454	601,227
Share-based compensation expense before taxes	333,833	911,815
Related income tax benefits		
Share-based compensation expense	\$ 333,833	\$ 911,815
Net share-based compensation expense per basic and diluted share	\$ 0.01	\$ 0.01
Share-based compensation expense from:		
Stock options	278,047	826,286
Restricted stock awards	55,786	85,529
Total	\$ 333,833	\$ 911,815

Since we have a net operating loss carryforward as of September 30, 2006, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statement of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in the nine months ended September 30, 2006 which would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities. Share-based compensation expense was not recognized during the three and nine months ended September 30, 2005.

Through 2005, we accounted for share-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations and provided the required pro forma disclosures of SFAS 123. Under the intrinsic value method, no share-based compensation expense had been recognized in our condensed consolidated statement of operations for share-based awards to employees, because the exercise price of our stock options granted to employees equaled the fair market value of the underlying stock at the date of grant.

The following table summarizes the pro forma effect on our net loss and per share data if we had applied the fair value recognition provisions of SFAS 123 to share-based employee compensation for the three and nine months ended September 30, 2005.

	Three Months Ended September 30,2005	Nine Months Ended September 30,2005
In Thousands (except per share data)		
Net loss, as reported	\$ (3,700)	\$ (9,762)
Add: Share-based employee compensation expense		
Deduct: Total share-based employee compensation expense determined under fair value based method for all awards	(288)	(936)
Pro forma net loss	\$ (3,988)	\$ (10,698)

Net loss per share, basic and diluted, as reported	\$	(0.07)	\$	(0.20)
Pro forma net loss per share, basic and diluted	\$	(0.08)	\$	(0.21)

For employee stock options granted during the three months ended September 30, 2005, we determined pro forma compensation expense under the provisions of SFAS 123 using the Black-Scholes model and the following assumptions: (1) an expected volatility of 76%, (2) an expected term of 4.0 years, (3) a risk-free interest rate of 4.1% and (4) an expected dividend yield of 0%. The weighted average fair value of options granted during the nine months ended September 30, 2005 was \$1.16 per share.

We account for stock options granted to non-employees in accordance with Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, ( EITF 96-18 ). Under EITF 96-18, we determine the fair value of the stock options granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

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As of September 30, 2006, we had four equity incentive plans (the Plans): the 2001 Stock Plan, the 2004 Stock Plan, the 2005 Outside Directors Stock Plan, and the 2006 Stock Plan. All of the Plans were approved by the shareholders. Under the Plans we had an aggregate of 2,447,443 shares of our common stock reserved for issuance as of September 30, 2006. Options are subject to terms and conditions established by the Compensation Committee of our Board of Directors. Options have a term of ten years and generally vest over three to four years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans). At the present time, we intend to issue new common shares upon the exercise of stock options. A summary of stock options outstanding and changes under the Plans during the nine months ended September 30, 2006 are presented below.

	Shares underlying stock options	Weighted average exercise price per share	Weighted average remaining contractual term (yrs)
Outstanding at December 31, 2005	8,535,751	\$ 1.01	
Granted	409,432	\$ 2.62	
Exercised	(186,323)	\$ 0.74	
Cancelled	(240,592)	\$ 0.84	
Outstanding at September 30, 2006	8,518,268	\$ 1.10	7.00
Exercisable at September 30, 2006	6,059,654	\$ 0.86	6.70

The aggregate intrinsic value was \$13.8 million on outstanding options and \$11.2 million on exercisable options at September 30, 2006. The weighted average grant-date fair values of options granted during the nine months ended September 30, 2006 and 2005 were \$1.56 per share and \$1.16 per share, respectively. Cash received from stock option exercises for the nine months ended September 30, 2006 and 2005 was \$137,258 and \$176,422, respectively. The intrinsic value of options exercised during the nine months ended September 30, 2006 and 2005 was \$331,997 and \$721,076, respectively. As of September 30, 2006, \$2.3 million of total unrecognized compensation costs related to non-vested stock option awards is expected to be recognized over a weighted average period of 1.9 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 the assumptions noted in the following table. 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 for a period consistent with the expected term of the option in effect at the time of the grant. Assumptions used in the Black-Scholes model were as follows:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Expected volatility	75.0%	75.0%
Average expected term in years	4.0	4.0
Risk-free interest rate	5.1%	4.6-5.1%
Expected dividend yield	0%	0%

*Restricted stock awards.* Restricted stock awards are grants that entitle the holder to acquire shares of restricted common stock at a fixed price, which is typically nominal. The shares of restricted stock cannot be sold, pledged, or

otherwise disposed of until the award vests and any unvested shares may be reacquired by us for the original purchase price following the awardee's termination of service. During May 2006, we issued 75,000 restricted stock awards under our Outside Directors' Stock Plan. During July 2006, we issued 15,000 restricted stock awards under our Outside Directors' Stock Plan. Annual grants of restricted stock under the Outside Directors' Stock Plan typically vest in full the first day the awardee may trade Company stock in compliance with the Company's insider trading policy following the date immediately preceding the first annual meeting of stockholders following the grant date. As of September 30, 2006, these 90,000 outstanding restricted stock awards were nonvested.

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The grant-date fair value of restricted stock awards granted during the nine months ended September 30, 2006 was \$244,950. No restricted stock awards were granted in the nine months ended September 30, 2005. As of September 30, 2006, the total unrecognized compensation cost related to unvested shares was \$159,421, which is expected to be recognized over a weighted-average period of 0.7 year.

***Revenue Recognition***

We recognize revenue from product sales in accordance with Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists*, when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product sales net of estimated allowances for product returns, managed care rebates, reimbursements relating to Medicare, patient coupons, chargebacks from distributors, wholesaler fees and prompt payment and other discounts. Such estimates require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, coupons, chargebacks and discounts exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted.

Cumulase 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 from customers the return of any Cumulase product 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 and Baxter will fill and finish Hylenex and hold it for subsequent distribution. During the fourth quarter of 2005, and the first nine months of 2006, the Company transferred \$254,000 and \$137,000, respectively, of the active pharmaceutical ingredient for Hylenex to Baxter for filling and finishing. Because of our continued involvement in the development and production process of Hylenex under the terms of the Development and Supply Agreement (the Supply Agreement), the earnings process is not considered to be complete. Accordingly, the Company defers revenue and the related product costs resulting from transfers of the active pharmaceutical ingredient for Hylenex to Baxter until the product is ultimately sold to customers, or otherwise disposed.

***Research and Development Costs***

Costs and expenses that can be clearly identified as research and development are charged to expense as incurred in accordance with 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. 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. As a result of our agreement with Baxter, both parties have agreed to share equally the cost of any Hylenex post-approval clinical trials and related clinical organization costs.

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

Inventories consist of the following:

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
Raw materials	\$ 131,554	\$ 259,452
Work in process	55,049	19,506
Finish goods	47,164	
	<b>\$ 233,767</b>	<b>\$ 278,958</b>

Inventory includes \$254,000 of costs associated with the transfer of the active pharmaceutical ingredient ( API ) for Hylenex to Baxter in the fourth quarter of 2005 and \$137,000 of API during the first nine months of 2006 under the Supply Agreement. During the third quarter of 2006, the Company recognized \$319,000 in revenue and cost of goods sold related to the sale of the API for Hylenex to Baxter. The Supply Agreement provides for Baxter to purchase the API and fill and finish the product for subsequent distribution to customers. The transfer of the API to Baxter is recorded as a deferred charge and is included in raw materials, work in process inventory, and finished goods at September 30, 2006. Inventories are valued using an actual cost approach that approximates the first-in, first-out method.

**5. Property and Equipment**

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
Research equipment	\$ 737,144	\$ 615,455
Computer and office equipment	203,041	149,320
Leasehold improvements	155,285	148,486
	<b>1,095,470</b>	<b>913,261</b>
Less accumulated depreciation and amortization	<b>(634,636)</b>	<b>(532,013)</b>
	<b>\$ 460,834</b>	<b>\$ 381,248</b>

Depreciation and amortization expense totaled \$63,062 and \$43,933, for the three months ended September 30, 2006 and 2005 and \$172,702 and \$155,070 for the nine months ended September 30, 2006 and 2005, respectively.

**6. Deferred Revenue**

During August 2004, the Company signed an Exclusive Distribution Agreement (the Distribution Agreement ) with Baxter Healthcare Corporation ( Baxter ) to market, distribute and sell Hylenex in the United States and Puerto Rico. During March 2005, the Company entered into a Development and Supply Agreement (the Supply Agreement ) and a First Amendment to the existing Distribution Agreement with Baxter. Under the terms of the agreements, Halozyyme will supply Baxter the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. In December 2005, Hylenex received FDA approval for use in the United States.

During the fourth quarter of 2005 and the first nine months of 2006, the Company transferred \$254,000 and \$137,000, respectively, of the active pharmaceutical ingredient for Hylenex to Baxter for filling and finishing. Because of



Halozyme's continued involvement in the development and production process of Hylenex under the

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terms of the Supply Agreement, the earnings process is not considered to be complete. Accordingly, the Company defers revenue and the related product costs resulting from transfers of the active pharmaceutical ingredient for Hylenex to Baxter until the product is ultimately sold to customers, or otherwise disposed. During the third quarter of 2006, the Company recognized \$319,000 in revenue related to the sale of the API for Hylenex to Baxter.

In addition, the company deferred \$50,000 related to a research agreement entered into in September 2006, for which revenue has not yet been recognized. The revenue will be recognized over the service period which is expected to be less than one year.

**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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Numerator Net loss	\$ (3,651,037)	\$ (3,700,476)	\$ (10,374,023)	\$ (9,761,886)
Denominator Weighted average shares outstanding	62,731,254	49,978,696	61,669,201	49,834,695
Net loss per share	\$ (0.06)	\$ (0.07)	\$ (0.17)	\$ (0.20)
Incremental common shares (not included because of their anti-dilutive nature)				
Stock options and awards	8,608,268	8,647,521	8,608,268	8,647,521
Stock warrants	7,607,114	11,622,048	7,607,114	11,622,048
Potential common equivalents	16,215,382	20,269,569	16,215,382	20,269,569

**8. Stockholders Equity**

During February and March 2006, holders of the Company's various outstanding warrants exercised rights to purchase 1,101,601 common shares for gross proceeds of approximately \$1,279,302. During April and May 2006, holders of the Company's various outstanding warrants exercised rights to purchase 588,500 common shares for gross proceeds of approximately \$1,029,875. During July, August and September 2006, holders of the Company's various outstanding warrants exercised rights to purchase 2,236,034 common shares for gross proceeds of approximately \$3,893,829. Warrants to purchase approximately 7.6 million shares of our common stock are outstanding as of September 30, 2006.

**Table of Contents****9. Commitments and Contingencies**

**Operating Leases** On May 20, 2003, the Company signed a two-year lease for 5,728 square feet of office and lab space in a building located at 11588 Sorrento Valley Road, San Diego, California, commencing on June 1, 2003. On October 28, 2004, the Company signed an 18-month lease for an additional 5,060 square feet of office and lab space in the same building, commencing on January 1, 2005. During August 2006, these leases were subsequently extended to December 31, 2007 and the Company leased an additional 5,060 square feet of office space in the same building, commencing on August 1, 2006 and expiring on December 31, 2007. Additionally the Company leases certain office equipment under operating leases. Rent expense totaled \$82,000 and \$62,000 for the three months ended September 30, 2006 and 2005 and \$207,000 and \$176,000 for the nine months ended September 30, 2006 and 2005.

**Material Agreements** During August 2004, we signed an Exclusive Distribution Agreement (the Distribution Agreement ) with Baxter Healthcare Corporation ( Baxter ) to market, distribute and sell Hylenex in the United States and Puerto Rico. During March 2005, we entered into a Development and Supply Agreement (the Supply Agreement ) and a First Amendment to the existing Distribution Agreement with Baxter. Under the terms of the agreements we will supply Baxter the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. The Supply Agreement provides for additional product development opportunities that the parties may mutually decide to pursue. In addition, Baxter has a right of first refusal on certain product line extensions and select new products. The First Amendment provides for specific and consistent definitions among the Supply Agreement and Distribution Agreement and modifies various covenants of Baxter relating to the definition of marketing and incremental sales costs, including a \$3 million annual cap on the amount of marketing and incremental sales costs to be paid by Baxter. In the event that both parties agree in advance to combined marketing and incremental sales costs in excess of the cap, such excess marketing and incremental sales costs shall be shared equally. Currently, the parties anticipate that combined marketing and incremental sales costs for 2006 will be in excess of the cap. As such, it is likely that aggregate revenues from sales of Hylenex will be less than our portion of these shared additional marketing and incremental sales costs.

Effective December 30, 2005, the Company 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. The first two payments of \$25,000 and \$250,000 were paid in accordance with the original Agreement in March and May 2005, respectively. The first \$250,000 annual technology fee installment was paid in February 2006 in accordance with the First Amendment. Other terms of the amendment include a termination clause which allows the Company 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. Beginning in 2006, the annual technology fee payments will be 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.

**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.

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**11. New Accounting Pronouncements**

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*. SFAS 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS 154 did not have a material impact on our financial condition or results of operations.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This statement amends the guidance in ARB No. 43 Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). The provision of this statement will be effective for inventory costs during the fiscal years beginning after June 15, 2005. As a result of our manufacturing process being outsourced, the adoption of SFAS 151 did not have a material impact on our financial condition or results of operations.

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

*In addition to historical information, the following discussion contains forward-looking statements that are subject to risks and uncertainties. Actual results may differ substantially from those referred to herein due to a number of factors, including but not limited to risks described in the section entitled Risks Related to Our Business and elsewhere in this Quarterly Report.*

**Overview**

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 and the sale of the API for Hylenex. 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 \$36,721,277 as of September 30, 2006.

Additionally, in December 2005, we issued 10,000,000 shares of common stock to certain institutional and accredited investors for \$17.5 million in gross proceeds, or \$1.75 per share. These shares were sold under our universal shelf registration statement in a registered direct offering. We currently have \$32.5 million remaining under our 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, 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 issue additional options, warrants or other derivative securities convertible into Halozyyme common stock to fund the continued development of our product candidates and general corporate purposes.

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***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<sup>®</sup>, 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<sup>®</sup> 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.

***Baxter Agreement***

During August 2004, we signed an Exclusive Distribution Agreement (the Distribution Agreement ) with Baxter Healthcare Corporation ( Baxter ) to market, distribute and sell Hylenex in the United States and Puerto Rico.

During March 2005, we entered into a Development and Supply Agreement (the Supply Agreement ) and a First Amendment to the existing Distribution Agreement with Baxter. Under the terms of the agreements, we will supply Baxter with the active pharmaceutical ingredient, and Baxter will fill and finish Hylenex and hold it for subsequent distribution. The Supply Agreement provides for additional product development opportunities that the parties may mutually decide to pursue. In addition, Baxter has a right of first refusal on certain product line extensions and select new products. The First Amendment provides for specific and consistent definitions among the Supply Agreement and Distribution Agreement, modifies various covenants of Baxter relating to the definition of marketing and incremental sales costs, including a \$3 million annual cap on the amount of marketing and incremental sales costs to be paid by Baxter. In the event that both parties agree in advance to combined marketing and incremental sales costs in excess of the cap, such excess marketing and incremental sales costs shall be shared equally. Currently, the parties anticipate that combined marketing and incremental sales costs for 2006 will be in excess of the cap. As such, it is likely that aggregate revenues from sales of Hylenex will be less than our portion of these shared additional marketing and incremental sales costs.

***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.

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***Costs and Expenses***

*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.

*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, amortization and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our 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 September 30, 2006, we have incurred research and development costs of \$25.6 million. From January 1, 2002 through September 30, 2006, 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. In addition, for the nine months ended September 30, 2006, approximately 12% 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 research and development activities continue to expand.

*Other Income, Net.* Other income, net consists primarily of interest income earned on 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 from product sales in accordance with Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists*, when there is persuasive evidence that an arrangement exists, when title has passed, the price is fixed or determinable, and we are reasonably assured of collecting the resulting receivable. We recognize product sales net of estimated allowances for product returns, managed care rebates, reimbursements relating to Medicare, patient coupons, chargebacks from distributors, wholesaler fees and prompt payment and other discounts. Such estimates require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for returns, rebates, coupons, chargebacks and discounts exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted.

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 and Baxter will fill and finish Hylenex and hold it for subsequent distribution. During the fourth quarter of 2005, we transferred \$254,000 of the active pharmaceutical ingredient for Hylenex to Baxter for filling and finishing. During the first nine months of 2006, we transferred another \$137,000 of the active pharmaceutical ingredient for Hylenex to Baxter for filling and finishing. Because of our continued involvement in the development and production process of Hylenex under the terms of the Supply Agreement, the earnings process is not considered to be complete. Accordingly, the Company defers revenue and the related product costs resulting from transfers of the active pharmaceutical ingredient for Hylenex to Baxter until the product is ultimately sold to customers, or otherwise disposed.

***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) 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 in the three and nine months ended September 30, 2006 was \$334,000 and \$912,000. Selling, general and administrative expense and research and development expense in the third quarter of 2006 included share-based compensation of \$227,000 and \$107,000, respectively. As of September 30, 2006, \$2.4 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period 1.9 years.

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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). Because changes in the subjective input assumptions can materially affect our estimates of fair values of our share-based compensation, in our opinion, existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, early termination or forfeiture of those share-based payments in the future. 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.

The guidance in SFAS 123(R) and SAB 107 is relatively new, and best practices are not well established. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Theoretical valuation models and market-based methods are evolving and may result in lower or higher fair value estimates for share-based compensation. The timing, readiness, adoption, general acceptance, reliability and testing of these methods is uncertain. Sophisticated mathematical models may require voluminous historical information, modeling expertise, financial analyses, correlation analyses, integrated software and databases, consulting fees, customization and testing for adequacy of internal controls. Market-based methods are emerging that, if employed by us, may dilute our earnings per share and involve significant transaction fees and ongoing administrative expenses. The uncertainties and costs of these extensive valuation efforts may outweigh the benefits to investors.

*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



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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 \$218,000 clinical trial. 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. A 10% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by \$21,800.

*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.

*Income Taxes*

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We have considered future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. In the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amounts, an adjustment to the deferred tax assets would increase our income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to income in the period such determination was made.

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-KSB for the year ended December 31, 2005, which contain accounting policies and other disclosures required by U.S. GAAP.

**Results of Operations – Comparison of Three Months Ended September 30, 2006 and 2005**

**Revenues** Product sales were \$362,000 for the quarter ended September 30, 2006 compared to \$26,000 for the quarter ended September 30, 2005. Cumulase product sales were \$43,000 and \$26,000 and sales of the API for Hylenex were \$319,000 and \$0 for the three months ended September 30, 2006 and 2005, respectively.

**Cost of Sales** Cost of sales were \$356,000 for the quarter ended September 30, 2006 compared to \$10,000 for the quarter ended September 30, 2005 and consisted of third-party manufacturing costs, fill and finish costs and freight costs. Cumulase cost of sales was \$22,000 which includes a \$16,000 expense for approximately half the costs related to a Cumulase batch which failed to meet product release specifications. Cost of sales related to the sale of API for Hylenex was \$334,000 which includes \$319,000 related to transfers of API to Baxter and \$15,000 for labels that did not meet specifications for the three months ended September 30, 2006. Cost of sales for the three months ended September 30, 2005 is comprised of \$10,000 related to the Cumulase product.

**Research and Development** Research and development expenses were \$2,429,000 for the quarter ended September 30, 2006 compared to \$3,107,000 for the quarter ended September 30, 2005. Our research and development expenses consisted primarily of costs associated with the development and manufacturing of our

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product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization and depreciation. Research and development expenses decreased by \$678,000 due primarily to decreased contract manufacturing, analytical, and stability costs related to the development and production of our rHuPH20 enzyme of approximately \$644,000 and decreased Chemophase toxicology study costs of \$719,000, partially offset by higher clinical trial costs of approximately \$551,000 and share-based compensation costs of approximately \$107,000. 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 \$1,403,000 for the quarter ended September 30, 2006 compared to \$674,000 for the quarter ended September 30, 2005. General and administrative expenses increased by \$729,000 due to increased share-based compensation expenses of approximately \$227,000, general and administrative personnel costs of approximately \$218,000, recruiting fees of approximately \$163,000, and legal and accounting fees of approximately \$159,000. We anticipate that compliance with provisions of the Sarbanes-Oxley Act of 2002, including Section 404 relating to audits of our internal controls, will increase our general and administrative costs in future periods.

**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 in the third quarter of 2006 was \$334,000. Selling, general and administrative expense and research and development expense in the third quarter of 2006 include share-based compensation of \$227,000 and \$107,000, respectively. As of September 30, 2006, \$2.4 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 1.9 years. See Note 3, Significant Accounting Policies Change in Accounting Method for Share-Based Compensation in the Notes to Condensed Consolidated Financial Statements (unaudited) for further discussion.

**Other Income and Expense** Other income was \$175,000 for the quarter ended September 30, 2006 compared to \$65,000 for the quarter ended September 30, 2005. The increase in other income was due to higher interest income as a result of maintaining higher average cash balances during 2006 and higher interest rates.

**Net Loss** Net loss for the quarter ended September 30, 2006 was \$3,651,000, or \$0.06 per common share, compared to \$3,700,000, or \$0.07 per common share for the quarter ended September 30, 2005.

**Results of Operations Comparison of Nine Months Ended September 30, 2006 and 2005**

**Revenues** Product sales were \$555,000 for the nine months ended September 30, 2006 compared to \$71,000 for the nine months ended September 30, 2005. Cumulase product sales were \$236,000 and \$71,000 and sales of the API for Hylenex were \$319,000 and \$0 for the nine months ended September 30, 2006 and 2005, respectively.

**Cost of Sales** Cost of sales were \$396,000 for the nine months ended September 30, 2006 compared to \$31,000 for the nine months ended September 30, 2005 and consisted of third-party manufacturing costs, fill and finish costs and freight costs. Cumulase cost of sales was \$62,000 which includes \$28,000 in expense for approximately half the costs related to two Cumulase batches which failed to meet product release specifications. Cost of sales related to the sale of API for Hylenex was \$334,000 which includes \$319,000 related to transfers of API to Baxter and \$15,000 for labels that did not meet specifications for the nine months ended September 30, 2006. Cost of sales for the nine months ended September 30, 2005 is comprised of \$31,000 related to the Cumulase product.

**Research and Development** Research and development expenses were \$6,536,000 for the nine months ended September 30, 2006 compared to \$7,579,000 for the nine months ended September 30, 2005. 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

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materials, costs for consultants and related contract research, facility costs, amortization and depreciation. Research and development expenses decreased by \$1,043,000 due primarily to lower contract manufacturing, analytical, and stability costs related to the development and production of our rHuPH20 enzyme of approximately \$1,282,000, decreased Chemophase toxicology and other research study costs of approximately \$1,335,000, partially offset by higher clinical trial costs relating primarily to our Hylenex and Chemophase trials of approximately \$786,000, higher consulting and compensation costs of approximately \$614,000 and higher share-based compensation costs of approximately \$311,000. 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 \$4,538,000 for the nine months ended September 30, 2006 compared to \$2,443,000 for the nine months ended September 30, 2005. General and administrative expenses increased by \$2,095,000 due to increased share-based compensation expense of approximately \$601,000, legal and accounting fees of approximately \$589,000, general and administrative personnel costs of approximately \$399,000, recruiting fees of approximately \$255,000, and strategic consulting fees of approximately \$124,000. We anticipate that compliance with provisions of the Sarbanes-Oxley Act of 2002, including Section 404 relating to audits of our internal controls, will increase our general and administrative costs in future periods.

**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 in the nine months ended September 30, 2006 was \$912,000. Selling, general and administrative expense and research and development expense in the nine months ended September 30, 2006 include share-based compensation of \$601,000 and \$311,000, respectively. As of September 30, 2006, \$2.4 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 1.9 years. See Note 3, Significant Accounting Policies Change in Accounting Method for Share-Based Compensation in the Notes to Condensed Consolidated Financial Statements (unaudited) for further discussion.

**Other Income and Expense** Other income was \$540,000 for the nine months ended September 30, 2006 compared to \$220,000 for the nine months ended September 30, 2005. The increase in other income was due to higher interest income as a result of maintaining higher average cash balances during 2006 and higher interest rates.

**Net Loss** Net loss for the nine months ended September 30, 2006 was \$10,374,000, or \$0.17 per common share, compared to \$9,762,000, or \$0.20 per common share for the nine months ended September 30, 2005. The increase in net loss was due to an increase in operating expenses, primarily in share based compensation, professional services and additional personnel costs.

**Liquidity and Capital Resources** As of September 30, 2006, cash and cash equivalents were \$16,101,000 versus \$19,132,000 as of December 31, 2005, a decrease of \$3,031,000. This decrease resulted primarily from net cash used in operations for the nine months ended September 30, 2006 partially offset by the exercise of common stock warrants totaling \$6,163,000.

Net cash used in operations was \$9,076,000 during the nine months ended September 30, 2006 compared to \$9,393,000 of cash used in operations during the nine months ended September 30, 2005. This was due primarily to the increase in accounts payable and accrued expenses in 2006.

Net cash used in investing activities was \$255,000 during the nine months ended September 30, 2006 compared to \$344,000 during the nine months ended September 30, 2005. This change was due to fewer purchases of property and equipment during 2006.

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Net cash provided by financing activities was \$6,301,000 during the nine months ended September 30, 2006 versus \$365,000 during the nine months ended September 30, 2005. During the first nine months of 2006, we raised \$137,000 through the exercise of stock options and \$6,163,000 through the exercise of warrants. During the first nine months of 2005, we raised \$176,000 through the exercise of stock options and \$188,000 through the exercise of warrants.

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.

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 most recent private financing. We may finance future cash needs through the sale of other equity securities, the exercise of our callable warrants, strategic collaboration agreements, debt financing, or any combination of the foregoing. There are 2.6 million callable warrants outstanding as of September 30, 2006. 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 will permit us, from time to time, to offer and sell up to \$50 million of equity or debt securities. We currently have the ability to issue debt and equity securities for an aggregate of \$32.5 million under our shelf registration statement. We cannot be certain that our existing cash and cash equivalents will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs or delay the launch of our product candidates. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

**Off-Balance Sheet Arrangements** As of September 30, 2006, 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-KSB filed with the Securities and Exchange Commission on March 24, 2006.*

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**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, we expect to incur significant operating losses over the next several years. We have never been profitable, and we may never become profitable. Through September 30, 2006, we have incurred aggregate net losses of \$36,721,277.

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

Currently, warrants to purchase approximately 7.6 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 2.6 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, when we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If we are successful in raising additional capital, a substantial number of additional shares will be outstanding and would dilute the ownership interest of our investors.

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

With the exception of the December 2004 receipt of a CE (European Conformity) Mark and April 2005 FDA clearance for Cumulase, 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

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

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

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

the FDA may 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.

In addition, we intend to market certain of our products, and perhaps have certain of our products manufactured, in foreign countries. The process of obtaining 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.

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

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

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

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

our ability to fund our sales and marketing efforts;

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

the effectiveness of our sales and marketing efforts; and

the introduction of generic competitors.

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

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

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

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

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

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

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

We have signed a commercial supply agreement with Avid Bioservices, Inc. ( Avid ), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. Avid will produce the active pharmaceutical ingredient used in each of Cumulase, Hylenex and Chemophase under current Good Manufacturing Practices 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. If Avid does not maintain its status as an FDA-approved manufacturing facility, 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 is experiencing technical challenges integrating our product into their proprietary manufacturing process. If our third party manufacturer is unable to successfully manufacture Cumulase, or if our distributor is unable to resolve their technical issues, we may be unable to supply enough Cumulase product to meet demand. In addition, we currently utilize a subsidiary of Baxter Healthcare Corporation ( Baxter ) to prepare, fill, finish, and package Hylenex under a development and supply agreement. Baxter has only limited experience manufacturing Hylenex batches and we rely on its ability to successfully manufacture Hylenex batches according to product specifications. Any delays or interruptions in Baxter's ability to manufacture Hylenex batches could have a material adverse impact on our business and financial condition.

**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

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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.

**If actual future payments for allowances, discounts, returns and rebates exceed the estimates we made at the time of the sale of our products, our financial position, results of operations and cash flows may be negatively impacted.**

We recognize product revenue net of estimated allowances for discounts, returns and rebates. Such estimates are inherently difficult because we have limited experience selling our products and any judgments that we make relating to discounts, returns and rebates are subjective. We will accept the return of our product that is damaged in accordance with our return goods policy and procedures. We may also give credits for expired product. Actual results may differ significantly from our estimated allowances for discounts, returns and rebates. Any changes in estimates and assumptions based upon actual results may have an impact on our results of operations and/or financial condition. In addition, our financial position, results of operations and cash flows may be negatively impacted if actual future payments for discounts, returns and rebates exceed the estimates we made at the time of the sale of our products.

**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 4.3 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.

As a result of our December 2005 financing transaction, we issued 10,000,000 shares of common stock to certain institutional and accredited investors for \$17.5 million in gross proceeds, or \$1.75 per share. These shares were sold under our universal shelf registration statement in a registered direct offering. 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 this universal shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair the Company's ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into Halozyme common stock.

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

We participate in a highly dynamic industry, which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low stock prices during the twelve months ended September 30, 2006 were \$3.71 and \$1.70, 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, any of the following factors may lead to a significant drop in our stock price:

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;

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

During the ninety-day period ending September 30, 2006, our average daily trading volume was approximately 61,000 shares. If limited trading in our stock continues, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

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

We may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 2.6 million shares of common stock. The redemption price for these warrants is \$0.01 per share, but the warrant holders have the opportunity to exercise their warrants prior to redemption at the price of \$1.75 per share. If we decide to redeem any portion of our outstanding warrants in the future, some selling security holders may choose to sell outstanding shares of common stock in order to finance the exercise of the warrants prior to their redemption. This pattern of selling may result in a reduction of our common stock's market price.

**Risks Related To Our Industry**

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

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

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



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

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

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

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

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

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

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

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

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

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

We currently own or license several U.S. patents and also have pending patent applications. There can be no assurance that our existing patents, or any patents issued to us as a result of such applications, will provide a basis for commercially viable products, will provide us with any competitive advantages, or will not face third-party challenges or be the subject of further proceedings limiting their scope or enforceability.

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

In addition to protecting our own intellectual property rights, third parties may assert patent, trademark or copyright infringement or other intellectual property claims against us based on what they believe are their own intellectual property rights. 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

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that our products infringe a third-party's intellectual property rights. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. Further, we may be stopped from developing, manufacturing or selling our products until we obtain a license from the owner of the relevant technology or other intellectual property rights. If such a license is available at all, it may require us to pay substantial royalties or other fees.

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

**We face intense competition and rapid technological change that could result in the development of products by others that are superior to the products we are developing.**

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

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

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



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

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

**Item 3. 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 Controls Over Financial Reporting**

There have been no significant changes in our internal controls over financial reporting that occurred during the quarter ended September 30, 2006, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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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 2005 Annual Report on Form 10-KSB and is incorporated herein by reference. There are no material changes to the risk factors described in our Form 10-KSB.

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

During April and May 2006, holders of the Company's various outstanding warrants exercised rights to purchase 588,500 common shares for gross proceeds of approximately \$1,029,875. During July, August, and September, holders of the Company's various outstanding warrants exercised rights to purchase 2,236,034 common shares for gross proceeds of approximately \$3,893,829. 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)
10.4*	Distribution Agreement between MediCult AS and Registrant, dated February 9, 2004 (3)



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<b>Exhibit</b>	<b>Title</b>
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*	Exclusive Distribution Agreement between Baxter Healthcare and Registrant, dated August 13, 2004 (5)
10.8	Form of Callable Stock Purchase Warrant (4)
10.9	Securities Purchase Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004 (6)
10.10	Form of Common Stock Purchase Warrant (6)
10.11	Registration Rights Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004 (6)
10.12	DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder (7)
10.13	Nonstatutory Stock Option Agreement With Andrew Kim (7)
10.14*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (8)
10.15*	Development and Supply Agreement with Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
10.16*	First Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
10.17	Halozyme Therapeutics, Inc. 2005 Outside Directors Stock Plan (10)
10.18*	Second Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation and Registrant, dated December 8, 2005 (11)
10.19	Placement Agent Agreement, dated as of December 12, 2005 between Halozyme, SG Cowen & Co., LLC, Rodman & Renshaw, LLC and Roth Capital Partners, LLC (12)
10.20	Placement Agent Agreement, dated as of December 13, 2005 between Halozyme, SG Cowen & Co., LLC, Rodman & Renshaw, LLC and Roth Capital Partners, LLC (13)
10.21	First Amendment to the License Agreement between University of Connecticut and Registrant, dated January 9, 2006 (14)
10.22	Halozyme Therapeutics, Inc. 2006 Stock Plan (16)
10.23	First Amendment to Standard Industrial Net Lease between Registrant and Sorrento Square, dated as of July 1, 2006 (17)

- 10.24 Second Amendment to Standard Industrial Net Lease between Registrant and Sorrento Square, dated as of July 1, 2006 (17)
- 10.25 Form of Stock Option Agreement (2005 Outside Directors Stock Plan) (18)
- 10.26 Form of Restricted Stock Agreement (2005 Outside Directors Stock Plan) (18)
- 10.27 Form of Stock Option Agreement (2006 Stock Plan) (18)
- 10.28 Form of Restricted Stock Agreement (2006 Stock Plan) (18)
- 21.1 Subsidiaries of Registrant (15)
- 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 Quarterly Report on Form 10-QSB, filed November 12, 2004.
- (6) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed October 15, 2004.
- (7) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the Commission on October 26, 2004.
- (8) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed

February 22,  
2005.

- (9) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 30, 2005.
  - (10) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed July 6, 2005.
  - (11) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB, filed March 24, 2006.
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- (12) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 13, 2005.
- (13) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 14, 2005.
- (14) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed January 12, 2006.
- (15) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.
- (16) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.
- (17) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed August 8, 2006.



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

\* 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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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on November 9, 2006.

Halozyme Therapeutics, Inc.,  
a Nevada corporation

Date: November 9, 2006

By: /s/ Jonathan E. Lim

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

Date: November 9, 2006

By: /s/ David A. Ramsay

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