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)

þ **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

o **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	**88-0488686**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11588 Sorrento Valley Road, Suite 17 San Diego, CA	**92121**
(Address of principal executive offices)	(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 þ No o

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 o Accelerated Filer þ Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

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

	September 30, 2006	December 31, 2005
ASSETS		
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
LIABILITIES AND STOCKHOLDERS EQUITY		
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

	Three Months Ended		Nine Months Ended	
	2006	2005	2006	2005
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

	2006	2005
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.

In Thousands (except per share data)	Three Months Ended September 30,2005	Nine Months Ended September 30,2005
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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4. Inventory

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:

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

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

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

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, Halozyme 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
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.

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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 operat