HALOZYME THERAPEUTICS INC
Form 10QSB
November 14, 2005

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

(Mark One)

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

For the quarterly period ended September 30, 2005

OR

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

For the transition period from_____to_____

Commission file number 000-49616

HALOZYME THERAPEUTICS, INC.

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

Nevada	**88-0488686**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

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

(Address of principal executive offices)

(858) 794-8889

(Issuer s telephone number)

Not Applicable

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

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No 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

APPLICABLE ONLY TO CORPORATE ISSUERS

The number of shares of the registrant s outstanding common stock as of October 31, 2005 was 50,045,757.

Transitional Small Business Disclosure Format (Check one):

Yes o No þ

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HALOZYME THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEET UNAUDITED
AS OF SEPTEMBER 30, 2005

ASSETS	
CURRENT ASSETS:	
Cash and cash equivalents	$ 6,635,623
Accounts receivable, net	41,274
Inventory	45,354
Prepaid expenses	215,002
Total current assets	6,937,253
PROPERTY AND EQUIPMENT, net	425,140
OTHER ASSETS	22,835
Total Assets	$ 7,385,228
LIABILITIES AND STOCKHOLDERS EQUITY	
CURRENT LIABILITIES:	
Accounts payable	$ 1,441,144
Accrued expenses	370,366
Total current liabilities	1,811,510
COMMITMENTS AND CONTINGENCIES	
STOCKHOLDERS EQUITY:	
Common stock, $0.001 par value; 100,000,000 shares authorized; 50,045,757 shares issued and outstanding	50,045
Additional paid-in-capital	28,357,440
Accumulated deficit	(22,833,767)
Total Stockholders Equity	5,573,718
Total Liabilities and Stockholders Equity	$ 7,385,228

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

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HALOZYME THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS UNAUDITED
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

	Three Months Ended		Nine Months Ended	
	2005	2004	2005	2004
REVENUES:				
Product Sales	$ 25,644	$	$ 71,347	$
EXPENSES:				
Cost of sales	10,091		31,115	
Research and development	3,173,261	2,598,335	7,808,500	4,816,492
Selling, general and administrative	608,090	664,896	2,214,098	1,743,417
Total Expenses	3,791,442	3,263,231	10,053,713	6,559,909
LOSS FROM OPERATIONS	(3,765,798)	(3,263,231)	(9,982,366)	(6,559,909)
Other income (expense), net	65,322	10,086	220,480	(52,355)
LOSS BEFORE INCOME TAXES	(3,700,476)	(3,253,145)	(9,761,886)	(6,612,264)
Income Tax Expense				
NET LOSS	$ (3,700,476)	$ (3,253,145)	$ (9,761,886)	$ (6,612,264)
Net loss per share, basic and diluted	$ (0.07)	$ (0.08)	$ (0.20)	$ (0.21)
Shares used in computing net loss per share, basic and diluted	49,978,696	39,573,312	49,834,695	31,512,015

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

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HALOZYME THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS UNAUDITED
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2005 AND 2004

	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,761,886)	$ (6,612,264)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	155,070	84,002
Gain on disposal of equipment	(1,200)	
Issuance of common stock and stock options for goods and services	146,802	33,000
Changes in operating assets and liabilities:		
Accounts receivable	(19,114)	
Inventory	6,468	
Prepaid expenses and other assets	(151,366)	(132,733)
Accounts payable and accrued expenses	232,096	1,717,991
Net cash used in operating activities	(9,393,130)	(4,910,004)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(343,505)	(112,420)
Net cash used in investing activities	(343,505)	(112,420)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options net	176,422	
Proceeds from exercise of warrants net	188,122	128,999
Contributed capital net		7,870,146
Net cash provided by financing activities	364,544	7,999,145
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(9,372,091)	2,976,721
CASH AND CASH EQUIVALENTS, beginning of period	16,007,714	503,580
CASH AND CASH EQUIVALENTS, end of period	$ 6,635,623	$ 3,480,301
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Non cash investing and financing activities:		

Conversion of contributed capital to common stock	$	$ 7,870,146

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 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 infertility, ophthalmology, drug delivery, and oncology 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 product and for a limited number of product candidates. In June 2005, the Company launched its first product, Cumulase , a product used in in-vitro fertilization, and transitioned from a development-stage organization to a commercial entity.

DeliaTroph Pharmaceuticals, Inc. (DeliaTroph), the predecessor company to Halozyme, was founded on February 26, 1998. On March 11, 2004, DeliaTroph merged with a publicly traded corporation, Global Yacht Services, Inc. (Global), to form Halozyme. Although Global (which changed its name to Halozyme Therapeutics, Inc. in connection with the Merger) acquired DeliaTroph as a result of the merger, the former shareholders of DeliaTroph held a majority of the voting interest in the combined enterprise immediately after the Merger. Additionally, the Merger resulted in DeliaTroph s management and Board of Directors assuming operational control of Halozyme Therapeutics, Inc. Accordingly, the Merger has been treated as a re-capitalization of DeliaTroph and the financial information presented here and elsewhere in this report reflects the historical activity of DeliaTroph, unless otherwise indicated. Global conducted limited operations prior to the merger in a line of business wholly unrelated to biopharmaceutical operations, and the results of Global s operations are not reflected in the financial information of Halozyme.

Basis of Presentation

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

Operating results for the three and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2005 or for any future period. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2004 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 11, 2005 and other regulatory reports and filings made with the Securities and Exchange Commission.

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosures of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Certain amounts in the prior year financial statements have been reclassified to conform to the current year presentation.

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Stock-Based Compensation

In December 2002, Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123* was issued. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation from the intrinsic value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. The Company adopted the disclosure requirements of SFAS No. 148 effective December 31, 2002. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting prescribed in APB No. 25 and, accordingly, does not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the fair value of the stock at the date of grant. Deferred compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, over the vesting period of the related options.

Had compensation cost for the Company s outstanding employee stock options been determined based on the fair value at the grant dates for those options consistent with SFAS No. 123, the Company s net loss and basic and diluted net loss per share, would have been changed to the following pro forma amounts:

	Three Months Ended September 30,		Nine Months Ended September 30,	
In Thousands (except per share data)	2005	2004	2005	2004
Net loss, as reported	$(3,700)	$(3,253)	$ (9,762)	$(6,612)
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of tax	(288)	(599)	(936)	(1,395)
Pro forma net loss	$(3,988)	$(3,852)	$(10,698)	$(8,007)
Net loss per share, basic and diluted, as reported	$ (0.07)	$ (0.08)	$ (0.20)	$ (0.21)
Pro forma net loss per share, basic and diluted	$ (0.08)	$ (0.10)	$ (0.21)	$ (0.25)

SFAS No. 123 pro forma information regarding net loss is required by SFAS No. 123, and has been determined as if the Company had accounted for its stock-based employee compensation under the fair value method prescribed in SFAS No. 123. The fair value of the options was estimated at the date of grant using the Black-Scholes pricing model with the following assumptions for the three months ended September 30, 2005 and 2004: weighted-average risk-free interest rate of 4.1% and 3.0%; a dividend yield of 0%; a stock price volatility of 76% and 100%; and a weighted-average life of the option of 48 months.

The effects of applying SFAS No. 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed over their respective vesting periods.

The Company accounts for options issued to nonemployees under SFAS No. 123 and Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services*. As such, the value of such options is periodically remeasured and income or expense is recognized during their vesting terms.

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2. Accounts Receivable

Accounts receivable consists of the following:

	September 30, 2005	December 31, 2004
Interest receivable	$ 18,600	$ 22,160
Trade receivables	22,674	
Less allowance for doubtful accounts		
Accounts receivable, net	$ 41,274	$ 22,160

3. Inventory

Inventory is stated at the lower of cost or market and consists of raw materials of $9,489 and work in process of $35,865 used in the manufacture of the Company s Cumulase product. Inventories are valued using a standard cost approach that approximates the first-in, first-out method. The inventory of raw materials and work in process represents those units the Company expects to sell in the European Union and the United States.

4. Property and Equipment

	September 30, 2005	December 31, 2004
Research equipment	$ 614,050	$ 333,403
Computer and office equipment	143,940	102,775
Leasehold improvements	148,486	131,567
	906,476	567,745
Less accumulated depreciation and amortization	(481,336)	(332,240)
	$ 425,140	$ 235,505

Depreciation and amortization expense totaled $44,000 and $33,000 for the three months ended September 30, 2005 and 2004 and $155,000 and $84,000 for the nine months ended September 30, 2005 and 2004.

5. Net Loss Per Common Share

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Numerator Net loss	$ (3,700,476)	$ (3,253,145)	$ (9,761,886)	$ (6,612,264)
Denominator Weighted average shares outstanding	49,978,696	39,573,312	49,834,695	31,512,015
Net loss per share	$ (0.07)	$ (0.08)	$ (0.20)	$ (0.21)
Incremental common shares (not included because of their anti-dilutive nature)				
Stock options	8,647,521	7,013,397	8,647,521	7,013,397
Stock warrants	11,622,048	11,459,885	11,622,048	11,459,885
Potential common equivalents	20,269,569	18,473,282	20,269,569	18,473,282

6. Commitments and Contingencies

Material Agreement On March 24, 2005, Halozyme Therapeutics, Inc. (the Company) entered into a Development and Supply Agreement (the Supply Agreement) and a First Amendment to the existing Exclusive Distribution Agreement, dated August 13, 2004 (the Distribution Agreement) with Baxter Healthcare Corporation (Baxter). The following descriptions of the agreements are a summary of the material terms of the agreements. The Company will supply Baxter the active pharmaceutical ingredient, and Baxter will fill and finish the Hylenex (formerly referred to as Enhanze SC) product and hold it for subsequent distribution, pending regulatory approval. The Supply Agreement provides for additional product development opportunities that the parties may mutually decide to pursue. In addition, Baxter has a right of first refusal on certain product line extensions and select new products. The First Amendment provides for specific and consistent definitions among the Supply Agreement and Distribution Agreement, modifies various covenants of Baxter relating to the definition of marketing and incremental sales costs, including a cap on the annualized amount of marketing and incremental sales costs to be paid by Baxter. In the event that both parties agree in advance to combine marketing and incremental sales costs in excess of the cap, such excess marketing and incremental sales costs shall be shared equally.

Difficulties in our relationship with Baxter or delays or interruptions in their fill and finish operations could limit or stop our ability to provide sufficient quantities of our products, on a timely basis, and if our products are approved, could limit or stop commercial sales, which would have a material adverse effect on our business and financial condition.

7. Segment Information

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

8. Recent Accounting Pronouncements

On December 16, 2004, the FASB issued SFAS No. 123R, Share-Based Payment, which is an amendment to SFAS No. 123, Accounting for Stock-Based Compensation. This new standard eliminates the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and generally requires such transactions be accounted for using a fair-value-based method and the resulting cost recognized in our financial statements. This new standard is effective for awards that are

granted, modified or settled in cash in interim and annual periods beginning after June 15, 2005,

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December 15, 2005 for small business issuers. In addition, this statement will apply to unvested options granted prior to the effective date. The Company will adopt this new standard effective for the first fiscal quarter of 2006. While we are currently evaluating the impact on our consolidated financial statements of the adoption of SFAS No. 123R, we anticipate that our adoption of SFAS No. 123R will have a significant impact on our results of operations for 2006 and future periods, although our overall financial position will not be affected.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs: an amendment of ARB No. 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe the provisions of SFAS No. 151, when applied, will have a material impact on our financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections which 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 No. 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 No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS No. 154 to have a material impact on our financial position 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

DeliaTroph Pharmaceuticals, Inc. (DeliaTroph), the predecessor company to Halozyme, was founded on February 26, 1998. On March 11, 2004, DeliaTroph merged with a publicly traded corporation, Global Yacht Services, Inc. (Global), to form Halozyme. Although Global (which changed its name to Halozyme Therapeutics, Inc. in connection with the Merger) acquired DeliaTroph as a result of the merger, the former shareholders of DeliaTroph held a majority of the voting interest in the combined enterprise immediately after the Merger. Additionally, the Merger resulted in DeliaTroph s management and Board of Directors assuming operational control of Halozyme Therapeutics, Inc. Accordingly, the Merger has been treated as a re-capitalization of DeliaTroph and the financial information presented here and elsewhere in this report reflects the historical activity of DeliaTroph, unless otherwise indicated. Global conducted limited operations prior to the merger in a line of business wholly unrelated to biopharmaceutical operations, and the results of Global s operations are not reflected in the financial information of Halozyme.

We are a biopharmaceutical company dedicated to the development and planned commercialization of recombinant human enzymes for the infertility, ophthalmology, drug delivery, and oncology communities. Our existing product 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. Currently, we have limited revenue from product sales of Cumulase and all of our potential products, with the exception of Cumulase, are either in the discovery, pre-clinical, clinical, or pre-NDA approval stage. It may be years, if ever, before we are able to obtain the necessary regulatory approvals necessary to generate meaningful revenue from the sale of these potential products. In addition, we have 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 $22,833,767 as of September 30, 2005.

Our technology is based on recombinant human PH20 (rHuPH20), a human synthetic version of hyaluronidase that degrades hyaluronic acid, a space-filling, gel"-like substance that is a major component of tissues throughout the body, such as the skin and eyes. The PH20 enzyme is a naturally occurring enzyme that digests hyaluronic acid to temporarily break down the gel, thereby facilitating the penetration and dispersion of other drugs that are injected in the skin or in the muscle.

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Bovine and ovine-derived hyaluronidases have been used in multiple therapeutic areas, including in vitro fertilization and ophthalmology, where an FDA-approved bovine version was used as a drug delivery agent to enhance dispersion of local anesthesia for cataract surgery for over 50 years. Despite the multiple potential therapeutic applications for hyaluronidase, there are problems with existing and potential animal-derived product offerings, including:

Impurity: Most such commercial enzyme preparations are crude extracts from cattle testes and are typically less than 1-5% pure.

Prion disease: Cattle testes are an organ with the highest concentration of hyaluronidase, but also with the highest levels of a protein implicated in the development of neurodegenerative disorders associated with prion disease, such as Mad Cow Disease.

Immunogenicity: Hyaluronidases can also be found in bacteria, leeches, certain venoms, and marine organisms. Very few companies are pursuing clinical development of any of these enzymes. Regardless, all such preparations are non-human, and are therefore likely to elicit potent immune reactions, possess endotoxin, or have some of the same defects as slaughterhouse derivations.

There have been successes in replacing animal-derived drugs with human recombinant biologics, as in the case of insulin, Pulmozyme® and human growth hormone. Our objective is to execute this recombinant human enzyme replacement strategy by applying our products under development to key markets in multiple therapeutic areas, beginning with in vitro fertilization, ophthalmology, and drug delivery.

Current Product and Product Candidates

We currently have one product, Cumulase. We also have two product candidates, Hylenex and Chemophase , which are currently engaged in the regulatory approval process. 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 of 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 Vitrase®, and Amphastar Pharmaceuticals, Inc., with Amphadase . The FDA determined that Vitrase and Amphadase were each new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, however, the FDA confirmed to us that Hylenex would be designated a new chemical entity and we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Hylenex. In September 2005, during discussions with the FDA regarding the Hylenex NDA, we were informed by the FDA that it would be unable to meet its Prescription Drug User Fee Act action date for Hylenex. The FDA is still reviewing the Hylenex NDA and the FDA has not indicated when it will respond to our application.

During June 2005, we submitted an investigational new drug application (IND) in order to begin clinical testing of our Chemophase product candidate. We received authorization to initiate clinical testing of Chemophase in August 2005, and we commenced our initial clinical protocol under this IND in October 2005.

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 third-party manufacturing costs, fill and finish costs, and freight associated with the sales of Cumulase and the write-off related to short dating of certain Cumulase inventory.

Research and Development. Our research and development expenses consist primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our Chemophase and Hylenex (formerly referred to as Enhanze SC) product candidates which are both based on our recombinant human PH20 (rHuPH20) enzyme, a human synthetic version of hyaluronidase. We are also developing Chemophase, which is also based on our rHuPH20 enzyme, and we initiated a phase I clinical trial for Chemophase in October 2005.

Since our inception through September 30, 2005, we have incurred research and development costs of $16.7 million. From January 1, 2002 through September 30, 2005, approximately 73% of our research and development costs were associated with the research and development of our recombinant human PH20 enzyme used in our Cumulase and Hylenex product candidates. In addition, for the nine months ended September 30, 2005, approximately 33% 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 and Chemophase product candidates for commercialization. However, we expect our research and development costs to increase substantially if we are able to advance our product candidates into later stages of clinical development.

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

Product candidate completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals, and the subsequent compliance with applicable regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. While we filed an NDA for our Hylenex product candidate in March 2005 and we submitted an IND for our Chemophase product candidate in June 2005, we cannot be certain when or if these product candidates will receive regulatory approval or whether any net cash inflow from these product candidates, or any of our other 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, legal fees, other professional services expenses, and marketing expenses.

Other Income and Expense, Net. Other income and expense, net consists primarily of interest income earned on our cash and cash equivalents. For the prior year, other income and expense, net, also includes the liabilities assumed as a result of the Merger.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management s best knowledge of current events and circumstances that may impact the Company in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management.

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Revenue Recognition and Accounts Receivable

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 products that have reached their expiration date. Thus, no allowance for product returns has been established.

Recognition of Expenses in Outsourced Contracts

We have several contracts that extend across multiple reporting periods, including our largest contract representing a $1 million research study. 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 5% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by $50,000.

Inventory and Property and Equipment

Our critical accounting policies also include estimating the useful lives of fixed assets and the resulting depreciation expense and the amount and valuation of inventory.

Results of Operations Comparison of Three Months Ended September 30, 2005 and 2004

Revenues Product sales were $26,000 for the three months ended September 30, 2005 and consisted of sales of Cumulase, which we launched in June 2005.

Cost of Sales Cost of sales were $10,000 for the three months ended September 30, 2005 and consisted primarily of third-party manufacturing costs, fill and finish costs, and freight associated with the sales of Cumulase.

Research and Development Research and development expenses were $3,173,000 for the three months ended September 30, 2005 compared to $2,598,000 for the three months ended September 30, 2004. Our research and development expenses consisted primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization and depreciation. Research and development expenses increased by $575,000 due primarily to the initiation of toxicology studies for our Chemophase product candidate, the hiring of additional research and development personnel, and contract manufacturing costs for development and production of our rHuPH20 enzyme for research, clinical and commercial use. We expect research and development costs to continue to increase in future periods as we increase our research efforts and continue to develop and manufacture our product candidates.

Selling, General and Administrative Selling, general and administrative expenses were $608,000 for the three months ended September 30, 2005 compared to $665,000 for the three months ended September 30, 2004. Selling, general and administrative expenses decreased by $57,000 primarily due to decreases in legal fees. We anticipate that compliance with provisions of the Sarbanes-Oxley Act of 2002, particularly Section 404 relating to audits of our internal controls, will increase our general and administrative costs in future periods as the compliance deadlines for certain of these provisions approach.

Other Income and Expense Other income was $65,000 for the three months ended September 30, 2005 compared to $10,000 in other income for the three months ended September 30, 2004. The increase in other income was due to an increase in interest income relating to our higher cash and cash equivalents.

Net Loss Net loss for the three months ended September 30, 2005 was $3,700,000 or $0.07 per common share, compared to $3,253,000, or $0.08 per common share for the three months ended September 30, 2004. The increase in net loss was due to an increase in operating expenses, reflecting our increased research and development efforts and additional personnel.

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Results of Operations Comparison of Nine Months Ended September 30, 2005 and 2004

Revenues Product sales were $71,000 for the nine months ended September 30, 2005 and consisted of sales of Cumulase, which we launched in June 2005. There was no product sales during the nine months ended September 30, 2004.

Cost of Sales Cost of sales were $31,000 for the nine months ended September 30, 2005 and consisted primarily of third-party manufacturing costs, fill and finish costs, and freight associated with the sales of Cumulase and the write-off related to short dating of certain Cumulase inventory.

Research and Development Research and development expenses were $7,809,000 for the nine months ended September 30, 2005 compared to $4,816,000 for the nine months ended September 30, 2004. Our research and development expenses consisted primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, facility costs, amortization and depreciation. Research and development expenses increased by $2,993,000 due primarily to the completion of Cumulase 510(k) requirements, the completion of Hylenex NDA requirements, the completion of the Chemophase IND, the initiation of toxicology studies for Chemophase, the hiring of additional research and development personnel, and contract manufacturing costs for development and production of our rHuPH20 enzyme for research, clinical and potential commercial use. We expect research and development costs to continue to increase in future periods as we increase our research efforts and continue to develop and manufacture our first two product candidates.

Selling, General and Administrative Selling, general and administrative expenses were $2,214,000 for the nine months ended September 30, 2005 compared to $1,743,000 for the nine months ended September 30, 2004. Selling, general and administrative expenses increased by $471,000 due to the hiring of additional general and administrative personnel, the increased legal and accounting fees associated with becoming a public reporting entity and increased marketing costs associated with the launch of Cumulase. We anticipate that compliance with provisions of the Sarbanes-Oxley Act of 2002, particularly Section 404 relating to audits of our internal controls, will increase our general and administrative costs in future periods as the compliance deadlines for certain of these provisions approach.

Other Income and Expense Other income was $220,000 for the nine months ended September 30, 2005 compared to $52,000 in other expense for the nine months ended September 30, 2004. The increase in other income was due to an increase in interest income relating to our higher cash and cash equivalents. The other expense during 2004 was due to the assumption of Global s liabilities as a result of the Merger partially offset by interest income during the period.

Net Loss Net loss for the nine months ended September 30, 2005 was $9,762,000 or $0.20 per common share, compared to $6,612,000 or $0.21 per common share for the nine months ended September 30, 2004. The increase in net loss was due to an increase in operating expenses, reflecting our increased research and development efforts and additional personnel.

Liquidity and Capital Resources As of September 30, 2005, cash and cash equivalents were $6,636,000 versus $16,008,000 as of December 31, 2004, a decrease of $9,372,000. This decrease resulted primarily from net cash used in operations and for the purchase of property and equipment.

Net cash used in operations was $9,393,000 during the nine months ended September 30, 2005 compared to $4,910,000 of cash used in operations during the nine months ended September 30, 2004. This increased use of cash was due to an increase in our research and development efforts and additional personnel.

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Net cash used in investing activities was $344,000 during the nine months ended September 30, 2005 compared to $112,000 during the nine months ended September 30, 2004. This was due to the increased purchase of property and equipment and leasehold improvements during 2005.

Net cash provided by financing activities was $365,000 during the nine months ended September 30, 2005 versus approximately $7,999,000 during the nine months ended September 30, 2004. 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. In January 2004, we sold common stock and warrants to purchase common stock for approximately $8,057,000, or $7,670,000 net of issuance costs.

We expect our cash requirements to increase significantly 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 into the first quarter of 2006. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds from our 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. 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 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, 2005, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

RISK FACTORS

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

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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, 2005, we have incurred aggregate net losses of $22,834,000.

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 obtain FDA or other regulatory approval for certain products 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 11.6 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 5.9 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 1,971,000 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, 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.

During March 2005, we filed a new drug application (NDA) for the spreading agent Hylenex (formerly referred to as Enhanze SC), the first product in our Enhanze Technology platform. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an ovine (ram) derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) derived hyaluronidase, Amphadase . The FDA determined that each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. The approval of Hylenex depends on a variety of factors, some of which are beyond our control, including, among others, the timing, content and outcome of actions and decisions by the FDA regarding Hylenex and other third-party products and the impact and scope of the market exclusivity previously afforded to these third-party products. On March 3, 2005, the FDA confirmed to us that Hylenex would be designated a new chemical entity. Therefore, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Hylenex; but if the FDA later changes its determination

and decides that either or both apply to Hylenex, then such a decision could have a material adverse impact on our operations. In September 2005, during discussions with the FDA regarding the Hylenex NDA, we were informed by the FDA that it would be unable to meet its Prescription Drug User Fee Act action date for Hylenex. The FDA is still reviewing the Hylenex NDA and the FDA has not indicated when it will respond to our application.

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During June 2005, we submitted an investigational new drug application (IND) in order to begin clinical testing of our Chemophase product candidate. We received authorization to initiate clinical testing of Chemophase in August 2005, and we commenced our initial clinical protocol under this IND in October 2005.

The processes for obtaining FDA approval are extensive, time-consuming and costly, and there is no guarantee that the FDA will approve our NDA application for Hylenex or any NDAs that we intend to file with respect to any of our other 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 to merit an approval;
- FDA officials may not find that the data from pre-clinical testing and clinical trials justify approval, or they may require additional studies that would make it commercially unattractive to continue pursuit of approval;
- the FDA may not approve our manufacturing processes or facilities, or the processes or facilities of our contract manufacturers or raw material suppliers;
- the FDA may change its formal or informal approval policies, act contrary to previous guidance, or adopt new regulations;
- the FDA may determine that the exclusive rights granted to previously approved hyaluronidase products apply to our products, including Hylenex, thus significantly delaying the approval of these products, and;
- the FDA may approve a product candidate for indications that are narrow or under conditions that place the product at a competitive disadvantage, which may limit our sales and marketing activities or otherwise 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.

As discussed above in the Risk Factor titled *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,* the Hylenex NDA is subject to FDA review and we have initiated clinical testing for Chemophase. We may not receive regulatory approval of these, or any other, products in a timely manner, or at all.

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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.

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 be successful.

We have entered into non-exclusive distribution agreements with MediCult AS, a Denmark-based distributor, MidAtlantic Diagnostics, Inc., a New Jersey-based distributor, and Cook Ob/Gyn Incorporated, an Indiana-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, pending FDA approval. Baxter will also market and sell Hylenex on an exclusive basis in the European Union, pending applicable regulatory approvals and the finalization of the specific terms of that arrangement between us and Baxter.

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We depend upon the efforts of these third parties to promote and sell our Cumulase product and, pending applicable regulatory approvals, our Hylenex product candidate but there can be no assurance that the efforts of these third parties will result in product sales.

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

We have signed a commercial supply agreement with Avid Bioservices, Inc. (Avid), a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. Avid will produce the active pharmaceutical ingredient used in both Cumulase and Hylenex under current Good Manufacturing Practices for commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. The FDA has already conducted a pre-approval inspection (PAI) of Avid and has recommended that Avid be approved to manufacture Hylenex. Avid does not expect, however, to receive final approval until the Hylenex NDA is approved by the FDA. If Avid does not receive final approval from the FDA, for any reason, the commercialization of Hylenex 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 Cumulase and Hylenex 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, package and fill and finish our product candidates for distribution, our product development and commercialization efforts for these candidates could be delayed or stopped.

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, package and fill and finish the products prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are economically acceptable to us, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a third-party to fill and finish Cumulase. In addition, we currently utilize Baxter Healthcare Corporation (Baxter) to fill and finish Hylenex under a development and supply agreement.

We may be unable to execute our strategic plan, which could have a material adverse impact on our business and financial condition.

Our ability to execute our strategic plan is dependent upon our ability to gain additional regulatory approvals for our current product candidates in a timely manner, achieve market acceptance for our approved products and develop additional product candidates. If we are unable to execute our strategic plan on a timely basis for any reason, our ability to generate revenues would be substantially impaired, which would materially harm 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 also rely on the expertise and guidance of independent directors to develop business strategies and to guide our execution of these strategies. Due to changes in the regulatory environment for public companies over the past few years, the demand for independent directors has increased and it may be difficult for us, due to competition from both like-sized and larger companies, to recruit qualified independent directors.

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

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

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, including sales of shares issued in our most recent financings, 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, 8.2 million shares of common stock remain issuable upon exercise of these warrants. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise. We filed a registration statement on Form S-3 (Registration No. 333-114776), which was declared effective on April 1, 2005, covering 23,902,482 of the shares issued in the January 2004 private financing transaction and issuable upon exercise of the warrants issued in that transaction.

As a result of our October 2004 financing transaction, we issued 7,925,715 shares of common stock to certain institutional and accredited investors for $13.9 million in gross proceeds. In connection with this transaction, we also issued warrants for the purchase of 2,609,542 shares of common stock. We filed a registration statement on Form S-3 (Registration No. 333-120448), which was declared effective on November 26, 2004, covering the 10,535,257 shares issued to the private investors and issuable upon exercise of the warrants.

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. Sales of substantial amounts of shares of our common stock, or even the potential for such sales through the exercise of warrants, could lower the market price of our common stock and impair the Company s ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into Halozyme common stock.

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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 closing high and low stock prices during the twelve months ended October 31, 2005 were $3.10 and $1.50, 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;

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 FDA may determine that the exclusive rights granted to previously approved hyaluronidase products apply to our products, including Hylenex, thus significantly delaying the approval of these products;

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 contract manufacturer;

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 October 31, 2005, our average daily trading volume was approximately 55,000 shares. If limited trading in our stock continues, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

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

As discussed above in the Risk Factor titled *We will need to raise funds in the next twelve months, and there can be no assurance that such funds will be available,* we may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 5.9 million shares of common stock. The redemption price for these warrants is $0.01 per share, but the warrant holders have the opportunity to exercise their warrants prior to redemption at the price of $1.75 per share. If we decide to redeem any portion of our outstanding warrants in the future, some selling security holders may choose to sell outstanding shares of common stock in order to finance the exercise of the warrants prior to their redemption. This pattern of selling may result in a reduction of our common stock s market price.

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Risks Related To Our Industry

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

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including Halozyme, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and to a lesser extent by the U.S. Drug Enforcement Administration (DEA), and foreign and state government agencies. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other domestic and foreign statutes and regulations govern or influence the testing, manufacturing, packaging, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, 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. We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping our products. Consequently, there is always a risk that the FDA or other applicable governmental authorities will not approve our products, or will take post-approval action limiting or revoking our ability to sell our products, or that the rate, timing and cost of such approvals will adversely affect our product introduction plans or results of operations.

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

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

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

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

- our patents and pending patent applications cover products and/or technology that we invented first;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate our technologies;
- any of our pending patent applications will result in issued patents; and

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

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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 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;

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

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

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

If third-party reimbursement is not available, our products may not be accepted in the market.

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

Third-party payers are increasingly attempting to limit both the coverage and the level of reimbursement of new drug products to contain costs. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. 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.

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), and Amphastar Pharmaceuticals, Inc., among others. These competitors may develop technologies and products that are more effective or less costly than our current or future product candidates or that could render our technologies and product candidates obsolete or noncompetitive. Many of these competitors have substantially more resources and product development, manufacturing and marketing experience and capabilities than we do. In addition, many of our competitors have significantly greater experience than we do in undertaking pre-clinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare. Other manufacturers have FDA approved products for use as spreading agents, including ISTA Pharmaceuticals, Inc. (ISTA), with an ovine-derived hyaluronidase (Vitrase®) and Amphastar Pharmaceuticals, Inc., with a bovine (bull) hyaluronidase, Amphadase . The FDA determined that

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each of these products were new chemical entities and hence afforded market exclusivity, precluding identical products from being marketed for a period of five years. On March 3, 2005, the FDA confirmed to us that Hylenex would be designated a new chemical entity and, based on this confirmation, we believe that it is unlikely that the Vitrase or Amphadase marketing exclusivity will apply to Hylenex. If, however, the FDA later changes its determination and decides that either or both market exclusivities apply to Hylenex, then such a decision would have a material adverse impact on our operations.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to furnish a report of management s assessment of the effectiveness of our internal controls over financial reporting as part of our Annual Report 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.

Provisions in our charter documents and Nevada law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock, and could entrench management.

Our charter and bylaws contain provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions include:

a classified board of directors;

advance notice requirements for nominations for election to the board of directors; and

special voting requirements for the amendment of our charter and bylaws.

We are also subject to anti-takeover provisions under Nevada law, each of which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our common stock.

Item 3. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

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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, 2005, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, Halozyme may be involved in litigation relating to claims arising out of its operations in the normal course of business. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Halozyme currently is not a party to any legal proceedings, the adverse outcome of which, in management s opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position.

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

During August 2005, an existing shareholder exercised warrants to purchase 53,798 common shares for gross proceeds of $41,247. The shares and underlying warrants were purchased for investment in a private placement exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.

Item 3. Defaults Upon Senior Securities.

None.

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

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Title
2.1	Agreement of Merger between DeliaTroph Pharmaceuticals, Inc. and Registrant, dated January 28, 2004 (1)
3.1	Amended and Restated Articles of Incorporation (1)
3.2	Bylaws as Amended (2)
10.1	License Agreement between University of Connecticut and Registrant, dated November 15, 2002 (3)
10.2*	Agreement for Services between Avid Bioservices, Inc. and Registrant, dated November 19, 2003 (3)
10.3*	Distribution Agreement between MidAtlantic Diagnostics, Inc. and Registrant, dated January 30, 2004 (3)
10.4*	Distribution Agreement between MediCult AS and Registrant, dated February 9, 2004 (3)
10.5*	Distribution Agreement between Cook Ob/Gyn Incorporated and Registrant, dated April 13, 2004 (3)
10.6	2004 Stock Plan and Form of Option Agreement thereunder (4)
10.7	Form of Indemnity Agreement for Directors and Executive Officers (4)
10.8*	Exclusive Distribution Agreement between Baxter Healthcare and Registrant, dated August 13, 2004 (5)

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Exhibit	Title
10.9	Form of Callable Stock Purchase Warrant (4)
10.10	Securities Purchase Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004 (6)
10.11	Form of Common Stock Purchase Warrant (6)
10.12	Registration Rights Agreement between Registrant and the other signatories thereto, dated as of October 12, 2004 (6)
10.13	DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder (7)
10.14	Nonstatutory Stock Option Agreement With Andrew Kim (7)
10.15*	Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (8)
10.16*	Development and Supply Agreement with Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
10.17*	First Amendment to the Exclusive Distribution Agreement between Baxter Healthcare Corporation and Registrant, dated March 24, 2005 (9)
10.18	Halozyme Therapeutics, Inc. 2005 Outside Directors Stock Plan (10)
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 Information Statement on Schedule 14C filed on February 17, 2004.

(2) Incorporated by reference to the Registrant s Current Report

on Form 8-K, filed December 14, 2004, 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.

* Confidential treatment has been requested for certain portions of this exhibit. These portions have been omitted from this agreement and have been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned in the City of San Diego, on November 11, 2005.

Halozyme Therapeutics, Inc.,
a Nevada corporation

Date: November 11, 2005

By: /s/ Jonathan E. Lim

Jonathan E. Lim, MD

Its: President, Chief Executive Officer,
Chairman of the Board
(Principal Executive Officer)

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Date: November 11, 2005

By: /s/ David A. Ramsay

David A. Ramsay

Its: Secretary, Chief Financial Officer
(Principal Financial and Accounting Officer)