HALOZYME THERAPEUTICS INC
Form 10QSB
November 14, 2005

Table of Contents

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

TABLE OF CONTENTS

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

	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,

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.