

HALOZYME THERAPEUTICS INC

Form 10-Q

August 08, 2008

**Table of Contents**

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

(Mark One)

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

**For the quarterly period ended June 30, 2008**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

**Commission File Number 001-32335**

**HALOZYME THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**88-0488686**

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

**11388 Sorrento Valley Road, San Diego, CA**

(Address of principal executive offices)

**92121**

(Zip Code)

**(858) 794-8889**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

|                                                     |                                                       |                                                                                                    |                                                       |
|-----------------------------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Large accelerated<br>filer <input type="checkbox"/> | Accelerated filer <input checked="" type="checkbox"/> | Non-accelerated filer <input type="checkbox"/><br>(Do not check if a smaller reporting<br>company) | Smaller reporting<br>company <input type="checkbox"/> |
|-----------------------------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------|-------------------------------------------------------|

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 80,387,219 as of August 1, 2008.

**HALOZYME THERAPEUTICS, INC.  
INDEX**

|                     |                                                                                                            | <b>Page</b> |
|---------------------|------------------------------------------------------------------------------------------------------------|-------------|
|                     | <b><u>PART I FINANCIAL INFORMATION</u></b>                                                                 |             |
| <u>Item 1.</u>      | <u>Financial Statements</u>                                                                                |             |
|                     | <u>Condensed Consolidated Balance Sheets - June 30, 2008 and December 31, 2007</u>                         | 3           |
|                     | <u>Condensed Consolidated Statements of Operations - Three and Six Months Ended June 30, 2008 and 2007</u> | 4           |
|                     | <u>Condensed Consolidated Statements of Cash Flows - Six Months Ended June 30, 2008 and 2007</u>           | 5           |
|                     | <u>Notes to Condensed Consolidated Financial Statements</u>                                                | 6           |
|                     | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>               | 13          |
| <u>Item 2.</u>      | <u>Quantitative and Qualitative Disclosures About Market Risk</u>                                          | 33          |
| <u>Item 3.</u>      | <u>Controls and Procedures</u>                                                                             | 34          |
|                     | <b><u>PART II OTHER INFORMATION</u></b>                                                                    |             |
| <u>Item 1.</u>      | <u>Legal Proceedings</u>                                                                                   | 34          |
| <u>Item 1A.</u>     | <u>Risk Factors</u>                                                                                        | 34          |
| <u>Item 2.</u>      | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>                                         | 35          |
| <u>Item 3.</u>      | <u>Defaults Upon Senior Securities</u>                                                                     | 35          |
| <u>Item 4.</u>      | <u>Submission of Matters to a Vote of Security Holders</u>                                                 | 35          |
| <u>Item 5.</u>      | <u>Other Information</u>                                                                                   | 36          |
| <u>Item 6.</u>      | <u>Exhibits</u>                                                                                            | 36          |
|                     | <u>SIGNATURES</u>                                                                                          | 38          |
| <u>EXHIBIT 31.1</u> |                                                                                                            |             |
| <u>EXHIBIT 31.2</u> |                                                                                                            |             |
| <u>EXHIBIT 32</u>   |                                                                                                            |             |

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****HALOZYME THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

|                                                                                                                                                                             | <b>June 30,<br/>2008<br/>(Unaudited)</b> | <b>December 31,<br/>2007</b> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------------------|
| <b>Assets</b>                                                                                                                                                               |                                          |                              |
| Current Assets:                                                                                                                                                             |                                          |                              |
| Cash and cash equivalents                                                                                                                                                   | \$ 82,410,139                            | \$ 97,679,085                |
| Accounts receivable                                                                                                                                                         | 1,160,990                                | 779,825                      |
| Inventory                                                                                                                                                                   | 649,254                                  | 703,468                      |
| Prepaid expenses and other assets                                                                                                                                           | 1,895,820                                | 2,014,680                    |
| Total current assets                                                                                                                                                        | 86,116,203                               | 101,177,058                  |
| Property and equipment, net                                                                                                                                                 | 2,439,765                                | 2,283,316                    |
| Total assets                                                                                                                                                                | \$ 88,555,968                            | \$ 103,460,374               |
| <b>Liabilities and Stockholders' Equity</b>                                                                                                                                 |                                          |                              |
| Current Liabilities:                                                                                                                                                        |                                          |                              |
| Accounts payable                                                                                                                                                            | \$ 2,814,512                             | \$ 3,055,637                 |
| Accrued expenses                                                                                                                                                            | 3,338,896                                | 2,502,259                    |
| Deferred revenue                                                                                                                                                            | 3,255,461                                | 3,306,225                    |
| Total current liabilities                                                                                                                                                   | 9,408,869                                | 8,864,121                    |
| Deferred revenue, net of current portion                                                                                                                                    | 38,376,170                               | 35,963,266                   |
| Deferred rent, net of current portion                                                                                                                                       | 1,116,892                                | 865,063                      |
| Commitments and contingencies (Note 10)                                                                                                                                     |                                          |                              |
| Stockholders' equity:                                                                                                                                                       |                                          |                              |
| Preferred stock \$0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding                                                                           |                                          |                              |
| Common stock \$0.001 par value; 150,000,000 shares authorized; 80,098,622 and 77,903,944 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively | 80,099                                   | 77,904                       |
| Additional paid-in capital                                                                                                                                                  | 125,525,748                              | 122,685,443                  |
| Accumulated deficit                                                                                                                                                         | (85,951,810)                             | (64,995,423)                 |
| Total stockholders' equity                                                                                                                                                  | 39,654,037                               | 57,767,924                   |
| Total liabilities and stockholders' equity                                                                                                                                  | \$ 88,555,968                            | \$ 103,460,374               |

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**

|                                                               | <b>Three Months Ended<br/>June 30,</b> |                | <b>Six Months Ended<br/>June 30,</b> |                |
|---------------------------------------------------------------|----------------------------------------|----------------|--------------------------------------|----------------|
|                                                               | <b>2008</b>                            | <b>2007</b>    | <b>2008</b>                          | <b>2007</b>    |
| Revenues:                                                     |                                        |                |                                      |                |
| Revenues under collaborative agreements                       | \$ 1,351,492                           | \$ 539,434     | \$ 3,015,572                         | \$ 1,162,563   |
| Product sales                                                 | 82,727                                 | 169,082        | 224,165                              | 356,168        |
| Total revenues                                                | 1,434,219                              | 708,516        | 3,239,737                            | 1,518,731      |
| Operating expenses:                                           |                                        |                |                                      |                |
| Cost of product sales                                         | 37,126                                 | 75,518         | 74,316                               | 151,746        |
| Research and development                                      | 8,925,488                              | 4,083,885      | 17,369,679                           | 6,913,249      |
| Selling, general and administrative                           | 3,846,175                              | 2,381,827      | 8,003,778                            | 4,366,861      |
| Total operating expenses                                      | 12,808,789                             | 6,541,230      | 25,447,773                           | 11,431,856     |
| Operating loss                                                | (11,374,570)                           | (5,832,714)    | (22,208,036)                         | (9,913,125)    |
| Interest income                                               | 372,180                                | 1,031,007      | 1,251,649                            | 1,754,114      |
| Net loss                                                      | \$ (11,002,390)                        | \$ (4,801,707) | \$ (20,956,387)                      | \$ (8,159,011) |
| Basic and diluted net loss per share                          | \$ (0.14)                              | \$ (0.07)      | \$ (0.27)                            | \$ (0.11)      |
| Shares used in computing basic and diluted net loss per share | 79,454,496                             | 73,217,967     | 78,923,520                           | 71,610,380     |

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

**HALOZYME THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

|                                                                                           | <b>Six Months Ended<br/>June 30,</b> |                |
|-------------------------------------------------------------------------------------------|--------------------------------------|----------------|
|                                                                                           | <b>2008</b>                          | <b>2007</b>    |
| <b>Operating activities:</b>                                                              |                                      |                |
| Net loss                                                                                  | \$ (20,956,387)                      | \$ (8,159,011) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: |                                      |                |
| Share-based compensation                                                                  | 1,929,793                            | 1,056,464      |
| Depreciation and amortization                                                             | 476,585                              | 209,766        |
| Loss on disposal of equipment                                                             | 9,029                                | 731            |
| Changes in operating assets and liabilities:                                              |                                      |                |
| Accounts receivable                                                                       | (381,165)                            | (31,864)       |
| Inventory                                                                                 | 54,214                               | (177,768)      |
| Prepaid expenses and other assets                                                         | 118,860                              | (735,188)      |
| Accounts payable and accrued expenses                                                     | 366,311                              | (25,659)       |
| Deferred rent                                                                             | 310,990                              |                |
| Deferred revenue                                                                          | 2,362,140                            | 10,387,153     |
| Net cash (used in) provided by operating activities                                       | (15,709,630)                         | 2,524,624      |
| <b>Investing activities:</b>                                                              |                                      |                |
| Purchases of property and equipment                                                       | (472,023)                            | (895,388)      |
| Net cash used in investing activities                                                     | (472,023)                            | (895,388)      |
| <b>Financing activities:</b>                                                              |                                      |                |
| Proceeds from exercise of stock options, net                                              | 665,225                              | 1,460,895      |
| Proceeds from exercise of warrants, net                                                   | 247,482                              | 1,326,121      |
| Proceeds from issuance of common stock, net                                               |                                      | 51,989,488     |
| Net cash provided by financing activities                                                 | 912,707                              | 54,776,504     |
| Net (decrease) increase in cash and cash equivalents                                      | (15,268,946)                         | 56,405,740     |
| Cash and cash equivalents at beginning of period                                          | 97,679,085                           | 44,189,403     |
| Cash and cash equivalents at end of period                                                | \$ 82,410,139                        | \$ 100,595,143 |
| <b>Supplemental disclosure of non-cash investing and financing activities:</b>            |                                      |                |
| Accounts payable for purchases of property and equipment                                  | \$ 170,040                           | \$             |
| See accompanying notes to condensed consolidated financial statements.                    |                                      |                |



**Table of Contents**

**HALOZYME THERAPEUTICS, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)**

**1. Organization and Business**

Halozyme Therapeutics, Inc. ( Halozyme or the Company ) is a biopharmaceutical company developing and commercializing products targeting the extracellular matrix for the drug delivery, metabolism, oncology and dermatology markets.

The Company's operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing its technology and undertaking product development for its existing products and a limited number of product candidates. The Company has two products: Cumulase®, a product used for in vitro fertilization, and HYLENEX, a registered trademark of Baxter International, Inc., a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids. The Company has only limited revenues from the sales of these products. In addition, the Company receives revenues from collaborative agreements with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (collectively Roche ) and Baxter Healthcare Corporation and Baxter Healthcare S.A. (collectively Baxter ). The Company currently has multiple product candidates targeting several indications in various stages of development.

**2. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ( U.S. GAAP ) and with the rules and regulations of the U.S. Securities and Exchange Commission ( SEC ) related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for a complete set of financial statements. These interim condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007. The unaudited consolidated financial information for the interim periods presented herein reflects 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, with such adjustments consisting only of normal recurring adjustments. Operating results for interim periods are not necessarily indicative of the operating results for an entire fiscal year.

The condensed consolidated financial statements include the accounts of Halozyme and its wholly owned subsidiary, Halozyme, Inc. All intercompany accounts and transactions have been eliminated in the condensed consolidated financial statements.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts, as well as disclosures of commitments and contingencies in the financial statements and accompanying notes. Actual results could differ from those estimates.

**3. Adoption of New Accounting Standards**

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. SFAS 157 prioritizes the inputs used in measuring fair value into the following hierarchy:

- Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3 Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

## **Table of Contents**

In February 2008, the Financial Accounting Standards Board ( FASB ) issued FASB Staff Position ( FSP ) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, the Company has adopted the provisions of SFAS 157 with respect to our financial assets and liabilities only. Cash and cash equivalents are carried at fair value based on quoted market prices for identical securities (Level 1 inputs). The adoption of SFAS 157 had no effect on the Company's consolidated financial position or results of operations.

Effective January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ). SFAS 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting SFAS 159, the Company did not elect the fair value option for any of its financial assets or financial liabilities.

Effective January 1, 2008, the Company adopted Emerging Issues Task Force ( EITF ) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed or such time when the entity does not expect the goods to be delivered or services to be performed. The adoption of EITF 07-3 did not have a material impact on the Company's consolidated financial position or results of operations.

## **4. Summary of Significant Accounting Policies**

### ***Revenue Recognition***

The Company generates revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and/or royalties on sales of products resulting from collaborative agreements.

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

***Product Sales*** Revenues from the sales of Cumulase are recognized when the transfer of ownership occurs, which is upon shipment to the distributors. The Company is obligated to accept returns for product that does not meet product specifications. Historically, the Company has not had any product returns due to not meeting product specifications.

In accordance with the Amended and Restated Development and Supply Agreement (the Development and Supply Agreement ) with Baxter, the Company supplies Baxter with the active pharmaceutical ingredient ( API ) for HYLENEX at its fully burdened cost plus a margin. Baxter fills and finishes HYLENEX and holds it for subsequent distribution, at which time the Company ensures it meets product specifications and releases it as available for sale. Because of the Company's continued involvement in the development and production process of HYLENEX, the earnings process is not considered to be complete. Accordingly, the Company defers the revenue and related product costs on the API for HYLENEX until the product is filled, finished, packaged and released. Baxter may only return the API for HYLENEX to the Company if it does not conform to the specified criteria set forth in the Development and Supply Agreement or upon termination of such agreement. The Company has historically demonstrated that the API shipped to Baxter has consistently met the specified criteria. Therefore, no allowance for product returns has been established. In addition, the Company receives product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the agreement with Baxter. Product sales revenues are recognized as the Company earns such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts can be reasonably estimated.



## **Table of Contents**

***Collaborative Agreements*** The Company analyzes each element of its collaborative agreements to determine the appropriate revenue recognition. The Company recognizes revenue on nonrefundable upfront payments in which it has an ongoing involvement or performance obligation over the period of significant involvement under the related agreements. The Company recognizes milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees are nonrefundable and (3) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Reimbursements of research and development services are recognized as revenue during the period in which the services are performed. Royalties to be received based on sales of licensed products by the Company's collaborators incorporating the Company's products will be recognized as earned.

### ***Costs and Expenses***

The Company's costs and expenses include the following:

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

***Research and Development Expenses.*** Research and development expenses consist primarily of costs associated with the development and manufacturing of the Company's product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, clinical trials, facility costs, and depreciation. The Company charges all research and development expenses to operations as they are incurred, in accordance with SFAS No. 2, *Accounting for Research and Development Costs*. The Company's research and development activities are primarily focused on the development of its product candidates based on the Company's proprietary recombinant human PH20 enzyme ( rHuPH20 ).

The Company's expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions, clinical research organizations, and other vendors that conduct and manage clinical trials on its behalf.

***Selling, General and Administrative.*** Selling, general and administrative expenses consist primarily of compensation and other expenses related to the Company's corporate operations and administrative employees, accounting and legal fees, other professional services expenses, marketing expenses, as well as other expenses associated with operating as a publicly traded company.

### ***Share-Based Compensation***

The Company accounts for share-based awards exchanged for employee services in accordance with SFAS No. 123(R), *Share-Based Payment* ( SFAS 123R ). Under SFAS 123R, share-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense, net of estimated forfeitures, over the employee's requisite service period.

**Table of Contents**

Total share-based compensation expense related to all of the Company's share-based awards for the three and six months ended June 30, 2008 and 2007 was allocated as follows:

|                                                                  | <b>Three Months Ended June<br/>30,</b> |             | <b>Six Months Ended June<br/>30,</b> |              |
|------------------------------------------------------------------|----------------------------------------|-------------|--------------------------------------|--------------|
|                                                                  | <b>2008</b>                            | <b>2007</b> | <b>2008</b>                          | <b>2007</b>  |
| Research and development                                         | \$ 347,123                             | \$ 157,564  | \$ 610,769                           | \$ 302,886   |
| Selling, general and administrative                              | 719,154                                | 483,420     | 1,319,024                            | 753,578      |
| Share-based compensation expense before tax                      | 1,066,277                              | 640,984     | 1,929,793                            | 1,056,464    |
| Related income tax benefit                                       |                                        |             |                                      |              |
| Share-based compensation expense, net of tax                     | \$ 1,066,277                           | \$ 640,984  | \$ 1,929,793                         | \$ 1,056,464 |
| Net share-based compensation expense per basic and diluted share | \$ 0.01                                | \$ 0.01     | \$ 0.02                              | \$ 0.01      |
| Share-based compensation expense from:                           |                                        |             |                                      |              |
| Stock options                                                    | \$ 725,615                             | \$ 465,608  | \$ 1,345,478                         | \$ 826,088   |
| Restricted stock awards                                          | 340,662                                | 175,376     | 584,315                              | 230,376      |
|                                                                  | \$ 1,066,277                           | \$ 640,984  | \$ 1,929,793                         | \$ 1,056,464 |

Since the Company has a net operating loss carryforward as of June 30, 2008, no excess tax benefits for the tax deductions related to share-based awards were recognized in the interim condensed consolidated statement of operations. For the three months ended June 30, 2008 and 2007, employees exercised stock options to purchase 75,379 and 554,140 shares of common stock, respectively, for aggregate proceeds of approximately \$71,000 and \$1.0 million, respectively. For the six months ended June 30, 2008 and 2007, employees exercised stock options to purchase 1,708,032 and 837,400 shares of common stock, respectively, for aggregate proceeds of approximately \$665,000 and \$1.5 million, respectively.

As of June 30, 2008, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock awards granted prior to that date was approximately \$5.4 million and \$787,000, respectively, which is expected to be recognized over a weighted-average period of 2.5 years and 1.0 year, respectively.

**Stock Options** During the three months ended June 30, 2008 and 2007, the Company granted 179,500 and 155,500 stock options, respectively, with an estimated weighted-average grant-date fair value of \$2.92 and \$6.38 per share, respectively. During the six months ended June 30, 2008 and 2007, the Company granted 776,150 and 451,881 stock options, respectively, with an estimated weighted-average grant-date fair value of \$3.15 and \$5.25 per share, respectively.

**Restricted Stock Awards ( RSAs )** During the three and six months ended June 30, 2008, the Company granted 192,500 RSAs with an estimated weighted-average grant-date fair value of \$4.94 per share. During the three and six months ended June 30, 2007, the Company granted 105,000 RSAs with an estimated weighted-average grant-date fair value of \$10.37 per share.

**5. Inventory**

Inventory consisted of the following:

**June 30,**

|                 |                   | <b>December<br/>31,<br/>2007</b> |
|-----------------|-------------------|----------------------------------|
|                 | <b>2008</b>       |                                  |
| Raw materials   | \$ 573,858        | \$ 578,397                       |
| Finished goods  | 65,517            | 78,677                           |
| Work in process | 9,879             | 46,394                           |
|                 | <b>\$ 649,254</b> | <b>\$ 703,468</b>                |

Inventory is stated at the lower of cost or market.

**Table of Contents****6. Property and Equipment**

Property and equipment, net consisted of the following:

|                                           | <b>June 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|-------------------------------------------|--------------------------|------------------------------|
| Research equipment                        | \$ 2,330,100             | \$ 1,892,658                 |
| Computer and office equipment             | 877,056                  | 789,851                      |
| Leasehold improvements                    | 705,254                  | 633,996                      |
|                                           | 3,912,410                | 3,316,505                    |
| Accumulated depreciation and amortization | (1,472,645)              | (1,033,189)                  |
|                                           | \$ 2,439,765             | \$ 2,283,316                 |

Depreciation and amortization expense totaled approximately \$248,000 and \$477,000 for the three and six months ended June 30, 2008, respectively, and \$123,000 and \$210,000 for the three and six months ended June 30, 2007, respectively.

**7. Deferred Revenue**

Deferred revenue consisted of the following:

|                                          | <b>June 30,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|------------------------------------------|--------------------------|------------------------------|
| Collaborative agreements                 | \$ 41,316,919            | \$ 39,079,524                |
| Product sales                            | 314,712                  | 189,967                      |
| Total deferred revenue                   | 41,631,631               | 39,269,491                   |
| Less current portion                     | (3,255,461)              | (3,306,225)                  |
| Deferred revenue, net of current portion | \$ 38,376,170            | \$ 35,963,266                |

**Roche Agreement** In December 2006, the Company entered into a license and collaboration agreement with Roche for Enhance Technology (the Roche Agreement). Under the terms of the Roche Agreement, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, the Company's proprietary recombinant human hyaluronidase, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid \$20.0 million to the Company in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets.

Due to the Company's continuing involvement obligations, revenue from the \$20.0 million upfront payment was deferred and is being recognized over the term of the Roche Agreement. The Company recognized revenue from the Roche upfront payment in the amounts of approximately \$290,000 and \$580,000 for the three and six months ended June 30, 2008, respectively, and \$290,000 and \$580,000 for the three and six months ended June 30, 2007, respectively.

**Baxter Agreements** In September 2007, the Company and Baxter entered into an Enhance Technology License and Collaboration Agreement (the Gammagard License). Under the terms of the Gammagard License, Baxter paid the Company a nonrefundable upfront payment of \$10.0 million. Due to the Company's continuing involvement obligations, the \$10.0 million upfront payment was deferred and is being recognized over the term of the Gammagard License. The Company recognized approximately \$152,000 and \$303,000 in revenue from the upfront payment under the Gammagard License for the three and six months ended June 30, 2008, respectively.

In February 2007, the Company amended certain agreements with Baxter for HYLENEX and entered into a new agreement for kits and co-formulations with rHuPH20 (the Baxter Agreements). Under the terms of the Baxter

Agreements, Baxter paid the Company a nonrefundable upfront payment of \$10.0 million. Due to the Company's continuing involvement obligations, the \$10.0 million upfront payment was deferred and is being recognized over the term of the Baxter Agreements. The Company recognized revenue from the upfront payment under the Baxter Agreements in the amounts of \$147,000 and \$293,000 for the three and six months ended June 30, 2008, respectively, and \$147,000 and \$223,000 for the three and six months ended June 30, 2007, respectively.

**Table of Contents**

In addition, Baxter will make payments to the Company based on sales of the products covered under the Baxter Agreements. As of June 30, 2008, Baxter prepaid a total of \$4.5 million of such product-based payments. Baxter is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. The prepaid product-based payments are deferred and are being recognized as product sales revenues as the Company earns such revenues from the sales of HYLENEX by Baxter.

**8. Net Loss Per Share**

The Company calculates basic and diluted 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, without consideration for common stock equivalents. Stock options, unvested stock awards and warrants are considered to be common equivalents and are only included in the calculation of diluted earnings per common share when their effect is dilutive. Because of the Company's net loss, all of stock options, unvested stock awards and warrants were excluded from the calculation. The Company has excluded the following stock options, unvested stock awards and warrants from the calculation of diluted net loss per common share as of June 30, 2008 and 2007 because their effect is anti-dilutive:

|                          | <b>2008</b>       | <b>2007</b>       |
|--------------------------|-------------------|-------------------|
| Stock options and awards | 6,875,569         | 8,291,975         |
| Warrants                 | 4,536,242         | 5,575,881         |
|                          | <b>11,411,811</b> | <b>13,867,856</b> |

**9. Stockholders' Equity**

During the six months ended June 30, 2008 and 2007, holders of the Company's outstanding options exercised rights to purchase 1,708,032 and 837,400 common shares, respectively, for net proceeds of approximately \$665,000 and \$1.5 million, respectively. Options to purchase approximately 6.7 million and 7.8 million shares of the Company's common stock were outstanding as of June 30, 2008 and December 31, 2007, respectively.

During the six months ended June 30, 2008 and 2007, holders of the Company's outstanding warrants exercised rights to purchase 322,788 and 1,138,522 common shares, respectively, for the net proceeds of approximately \$247,000 and \$1.3 million, respectively. Warrants to purchase approximately 4.5 million and 4.9 million shares of the Company's common stock were outstanding as of June 30, 2008 and December 31, 2007, respectively.

**10. Commitments and Contingencies**

From time to time the Company is involved in legal actions arising in the normal course of its business. The Company is not presently subject to any material litigation nor, to management's knowledge, is any litigation threatened against the Company that collectively is expected to have a material adverse effect on the Company's consolidated cash flows, financial condition or results of operations.

**11. New Accounting Pronouncements**

In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, which establishes how the participants in a collaborative arrangement shall report costs incurred and revenue generated from transactions with third parties in each entity's respective statement of operations. The Company will be required to adopt EITF Issue No. 07-1 in the first quarter of 2009 and it is not expected to have a material impact on the Company's consolidated financial position or results of operations.

In May 2008, the FASB issued SFAS No. 162, *Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). This statement is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement will be effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendment to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS 162 to have a material impact on its consolidated financial position or results of operations.



**Table of Contents**

In June 2008, the FASB issued FSP EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP EITF 03-6-1 ). FSP EITF 03-6-1 clarified that all outstanding unvested share-based payment awards that contain rights to nonforfeitable dividends participate in undistributed earnings with common shareholders. Awards of this nature are considered participating securities and the two-class method of computing basic and diluted earnings per share must be applied. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of FSP EITF 03-6-1 to have a material impact on its consolidated financial position or results of operations.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock* ( EITF 07-5 ). EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of EITF 07-5 to have a material impact on its consolidated financial position or results of operations.

## **Table of Contents**

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

*As used in this report, unless the context suggests otherwise, the terms we, our, ours, and us refer to Halozyme Therapeutics, Inc., and its wholly owned subsidiary, Halozyme, Inc., which are sometimes collectively referred to herein as the Company.*

*The following information should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2007 filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2008. Past financial or operating performance is not necessarily a reliable indicator of future performance, and our historical performance should not be used to anticipate results or future period trends.*

*Except for the historical information contained herein, this report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements reflect management's current forecast of certain aspects of our future. You can identify most forward-looking statements by forward-looking words such as believe, think, may, could, will, estimate, continue, anticipate, intend, seek, plan, expect, should, would, potential, likely, opportunity and similar expressions in this report. Such statements are based on currently available operating, financial and competitive information and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially from those anticipated or implied in our forward-looking statements due to a number of factors including, but not limited to, those set forth below under the section entitled Risks Factors and elsewhere in this Quarterly Report on Form 10-Q.*

#### **Overview**

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

Our operations to date have been limited to organizing and staffing the Company, acquiring, developing and securing our technology and undertaking product development for our existing products and a limited number of product candidates. Over the last year, we have expanded investments in our proprietary product candidates as we increased our focus on our proprietary product pipeline. We have two marketed products: Cumulase®, a product used for IVF, and HYLENEX, a registered trademark of Baxter International, Inc., a product used as an adjuvant to increase the absorption and dispersion of other injected drugs and fluids. Currently, we have only limited revenue from the sales of Cumulase and HYLENEX, in addition to revenues from collaborative agreements with Baxter Healthcare Corporation, or Baxter, and F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or collectively Roche. Revenues from product sales depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our product candidates. All of our product candidates are in the research, pre-clinical, or clinical stage. It may be years, if ever, before we are able to obtain the regulatory approvals necessary to generate meaningful revenue from the sale of these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately \$86.0 million as of June 30, 2008.

**Table of Contents**

We currently have an effective universal shelf registration statement which will permit us, from time to time, to offer and sell up to \$32.5 million of additional equity or debt securities. Sales of a substantial number of shares of our common stock pursuant to this registration statement or in connection with other transactions, or even the potential for such sales through the exercise of currently outstanding warrants, could lower the market price of our common stock and impair our 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 our common stock to fund the continued development of our product candidates and for other general corporate purposes.

**Current Products and Product Candidates**

We have two marketed products and multiple product candidates targeting several indications in various stages of development. The following table summarizes our products and product candidates:

| <b>Product</b>          | <b>Indication (Brief Description)</b>        | <b>Development Status</b> |
|-------------------------|----------------------------------------------|---------------------------|
| Cumulase                | In vitro fertilization                       | Marketed                  |
| HYLENEX                 | Adjuvant for drug and fluid infusion         | Marketed                  |
| Chemophase®             | Chemoadjuvant for superficial bladder cancer | Phase I/IIa               |
| Enhance Technology      | Adjuvant for enhanced drug delivery          | Phase I                   |
| Proprietary rHuPH20     | Oncology, metabolism                         | Phase I                   |
| Proprietary Non-rHuPH20 | Oncology, dermatology                        | Pre-Clinical              |

Cumulase is an *ex vivo* (used outside the body) formulation of rHuPH20 to replace the bovine enzyme currently used for the preparation of oocytes prior to IVF during the process of intracytoplasmic sperm injection, in which the enzyme is an essential component. We launched Cumulase in the European Union and the United States in June 2005.

HYLENEX is a human recombinant formulation for rHuPH20 to facilitate the absorption and dispersion of other injected drugs or fluids. When injected under the skin or in the muscle, hyaluronidase can digest the hyaluronic acid gel, allowing for temporarily enhanced penetration and dispersion of other injected drugs or fluids. We received approval from the Food and Drug Administration, or FDA, for HYLENEX in December 2005. In February 2007, we entered into an expanded collaboration agreement with Baxter under which Baxter fills and finishes HYLENEX and holds it for subsequent distribution.

Chemophase, our lead oncology product candidate, is an investigative chemoadjuvant designed to enhance the transport of chemotherapeutic agents to tumor tissue, potentially increasing diffusion in tissues without affecting vascular permeability. Chemophase is being developed for potential use in the treatment of patients with superficial bladder cancer. In September 2007, we completed enrollment in our Phase I/IIa clinical trial. In June 2008, we announced the results of the Phase I/IIa clinical trial. The Chemophase combination treatment of mitomycin plus rHuPH20 enzyme was well tolerated and appears safe. The study reported no dose-limiting toxicities and no observed side effects attributable to the enzyme, and established the dose for subsequent clinical trials, therefore achieving the pre-defined primary objective of the study. In addition, there were no neutralizing antibodies to rHuPH20 detected and the plasma concentration of mitomycin was either non-measurable or negligible and well below the threshold that may be predictive for myelosuppression (a decrease in bone marrow activity, resulting in fewer red blood cells, white blood cells, and platelets).

Enhance Technology, a proprietary drug enhancement system using rHuPH20, is our broader technology opportunity that can potentially lead to partnerships with other pharmaceutical companies. We are currently seeking partnerships with pharmaceutical companies that market or develop drugs requiring or benefiting from injection via the subcutaneous or intramuscular routes that could benefit from this technology. In December 2006, we signed our first Enhance Technology partnership with Roche. In September 2007, we signed our second Enhance Technology partnership with Baxter.

**Table of Contents**

One of our proprietary rHuPH20 programs focuses on co-formulation of rHuPH20 and insulin for the treatment of diabetes mellitus. Combining rHuPH20 with insulin may facilitate faster insulin spreading from the subcutaneous space into the vascular compartment leading to faster insulin response and improved glycemic control potentially resulting in fewer hypoglycemic episodes. Diabetes mellitus is an increasingly prevalent, costly condition associated with substantial morbidity and mortality. Attaining and maintaining normal blood sugar levels to minimize the long term clinical risks is a key treatment goal for diabetic patients. In June 2008, we announced data from our Phase I clinical trial showing that combining rHuPH20 with Humulin R® (regular insulin human) or Humalog® (insulin lispro) yielded pharmacokinetics and glucodynamics that better mimicked physiologic prandial (mealtime) insulin release and activity than either Humulin R or Humalog alone. By making mealtime insulin faster, i.e., shifting insulin exposure and glucose lowering activity to earlier times and away from late postprandial times, combination with rHuPH20 yielded a profile of insulin kinetics and activity more like that of natural, endogenous prandial insulin release.

**Collaborative Agreements*****Roche Agreement***

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

***Baxter Agreements***

In September 2007, we entered into an Enhance Technology License and Collaboration Agreement, or the Gammagard License, with Baxter. Under the terms of the Gammagard License, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with a current Baxter product, Gammagard Liquid. Under the terms of the agreement, Baxter made an initial upfront payment of \$10 million to us. Pending successful completion of a series of regulatory and sales milestones, Baxter may make further milestone payments totaling \$37 million to us. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard License is applicable to both kit and co-formulation combinations. Baxter will assume all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard License, while we will be responsible for the supply of the rHuPH20 enzyme. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard License.

In February 2007, we amended certain agreements with Baxter for HYLENEX and entered into a new agreement, collectively the Baxter Agreements, for kits and co-formulations with rHuPH20. Under the terms of the Baxter Agreements, Baxter paid us a nonrefundable upfront payment of \$10 million and, pending the successful completion of a series of regulatory and sales events, Baxter will make milestone payments to us which could potentially reach a value of up to \$25 million. In addition, Baxter will make payments to us based on the sales of products covered under the Baxter Agreements. In February 2007, Baxter prepaid \$1.0 million of such product-based payments in connection with the execution of the Baxter Agreements. In January 2008, Baxter prepaid another \$3.5 million of such product-based payments and is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009. Baxter will also now assume development, manufacturing, clinical, regulatory, sales and marketing

costs of the products covered by the Baxter Agreements. We will continue to supply Baxter with the API for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. In addition, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with Baxter hydration fluids and generic small molecule drugs, with the exception of combinations with (i) bisphosphonates, as well as (ii) cytostatic and cytotoxic chemotherapeutic agents, the rights to which have been retained by us. In addition, in February 2007, an affiliate of Baxter purchased 2,070,394 shares of our common stock for approximately \$20 million.

## **Table of Contents**

### ***Revenues***

Revenues from product sales depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our products and product candidates.

Revenues from license and collaboration agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before earned. Nonrefundable upfront fees, where we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. Milestone payments are generally recognized as revenue upon the achievement of the milestones as specified in the underlying agreement, assuming we meet certain criteria. Royalty revenues from the sale of licensed products will be recognized upon the sale of such products.

During 2006 and 2007, we entered into the Roche Agreement, the Baxter Agreements and the Gammagard License, which consist of nonrefundable upfront license fees, reimbursements of research and development services, various clinical, regulatory or sales milestones and future product-based or royalty payments, as applicable. Due to our ongoing involvement obligations under the agreements, we recorded the nonrefundable upfront license fees as deferred revenues. Such revenues are being recognized over the terms of the underlying agreements.

### ***Costs and Expenses***

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

*Research and Development.* Our research and development expenses consist primarily of costs associated with the development and manufacturing of our product candidates, compensation and other expenses for research and development personnel, supplies and materials, costs for consultants and related contract research, clinical trials, facility costs, and depreciation. We charge all research and development expenses to operations as they are incurred. Our research and development activities are primarily focused on the development of our various product candidates.

Since our inception in 1998 through June 30, 2008, we have incurred research and development expenses of \$66.3 million. From 2005 through June 30, 2008, approximately 21% of our research and development expenses were associated with the research and development of our rHuPH20 enzyme used in our Cumulase and HYLENEX products, and approximately 13% of our research and development expenses 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 Chemophase product candidate for commercialization. However, we expect our research and development expenses to increase substantially if we are able to advance our Chemophase product candidate and our other 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 both our proprietary rHuPH20 and proprietary non-rHuPH20 programs, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific and clinical progress of each product candidate and other market and regulatory developments.

Product candidate completion dates and costs vary significantly for each product candidate and are difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations. We cannot be certain when, or if, our Chemophase product candidate, or any of our other product candidates, will receive regulatory approval or whether any net cash inflow from our Chemophase product candidate, or any of our other product candidates, or development projects, will commence.

## **Table of Contents**

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

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial position and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### ***Revenue Recognition***

We generate revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and/or royalties on sales of products resulting from collaborative arrangements.

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

### ***Product Sales***

Revenues from the sale of Cumulase are recognized when the transfer of ownership occurs, which is upon shipment to the distributors. We are obligated to accept returns for product that does not meet product specifications. Historically, we have not had any product returns.

Under the terms of the Baxter Agreements, we supply Baxter the API for HYLENEX at our fully burdened cost plus a margin. Baxter fills and finishes HYLENEX and holds it for subsequent distribution, at which time we ensure it meets product specifications and release it as available for sale. Because of our continued involvement in the development and production process of HYLENEX, the earnings process is not considered to be complete. Accordingly, we defer the revenue and related product costs on the API for HYLENEX until the product is filled, finished, packaged and released. Baxter may only return the API for HYLENEX to us if it does not conform to the specified criteria set forth in the Development and Supply Agreement or upon termination of such agreement. We have historically demonstrated that the API shipped to Baxter has consistently met the specified criteria. Therefore, no allowance for product returns has been established. In addition, we receive product-based payments upon the sale of HYLENEX by Baxter, in accordance with the terms of the Baxter Agreements. Product sales revenues are recognized as we earn such revenues based on Baxter's shipments of HYLENEX to its distributors when such amounts can be reasonably estimated. Through June 30, 2008, Baxter has prepaid a total of \$4.5 million of such product-based payments which was deferred and is being recognized as earned. Baxter is obligated to prepay \$5.5 million of additional product-based payments on or prior to January 1, 2009.

## **Table of Contents**

### ***Revenues under Collaborative Agreements***

Revenues from collaborative and licensing agreements are recognized based on the performance requirements of the underlying agreements. Revenue is deferred for fees received before earned. Nonrefundable upfront payments, in which we have an ongoing involvement or performance obligation, are recorded as deferred revenue and recognized as revenue over the contract or development period. We recognize milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement, (2) the fees are nonrefundable and (3) our performance obligations after the milestone achievement will continue to be funded by our collaborator at a level comparable to the level before the milestone achievement. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue. Reimbursements of research and development services are recognized as revenue during the period in which the services are performed. Royalties to be received based on sales of licensed products by our collaborators incorporating our products will be recognized as earned in accordance with the terms of the underlying agreements.

### ***Share-Based Compensation***

We account for share-based awards exchanged for employee services in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, or SFAS 123R, which we adopted effective January 1, 2006, including the provisions of the SEC's Staff Accounting Bulletin No. 107, or SAB 107. We use the fair value method to account for share-based payments with a modified prospective application which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of SFAS 123R apply to new awards and awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods were not revised for comparative purposes.

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

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

### ***Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities, including salaries and benefits, facilities and other overhead expenses, clinical trials, research-related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will

be recognized as an expense as the related goods are delivered or the related services are performed. If the goods will not be delivered, or services will not be rendered, then the capitalized advance payment is charged to expense.

## **Table of Contents**

Milestone payments that we make in connection with in-licensed technology or product candidates are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology or product candidates. We consider the future economic benefits from the licensed technology or product candidates to be uncertain until such licensed technology or product candidates are approved for marketing by the FDA or when other significant risk factors are abated. For expense accounting purposes, management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain.

Payments in connection with our clinical trials are often made under contracts with multiple contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price or on a time-and-material basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones. Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies, and clinical trials progress. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trials contracts, we are unable to quantify an estimate of the reasonably likely effect of any such changes on our consolidated results of operations or financial position. Historically, we have had no material changes in our clinical trial expense accruals that would have had a material impact on our consolidated results of operations or financial position.

### ***Inventory***

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

### ***Fair Value***

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. SFAS 157 prioritizes the inputs used in measuring fair value into the following hierarchy:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable;  
and

Level 3 Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

In February 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we have adopted the provisions of SFAS 157 with respect to our financial assets and liabilities only. Cash and cash equivalents are carried at fair value based on quoted market prices for identical securities (Level 1 inputs). The adoption of SFAS 157 had no effect on our consolidated financial position or results of operations.

**Table of Contents**

Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159. SFAS 159 allows an entity the irrevocable option to elect to measure specified financial assets and liabilities in their entirety at fair value on a contract-by-contract basis. If an entity elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting date. In adopting SFAS 159, we did not elect the fair value option for any of our financial assets or financial liabilities.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. Refer to our audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2007, which contain accounting policies and other disclosures required by U.S. GAAP.

**Results of Operations*****Three Months Ended June 30, 2008 Compared to Three Months Ended June 30, 2007***

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements were \$1.4 million for the three months ended June 30, 2008 compared to \$539,000 for the three months ended June 30, 2007. Revenues under collaborative agreements consisted of the amortization of upfront fees received from Baxter and Roche of \$588,000 and \$436,000 for the three months ended June 30, 2008 and 2007, respectively. Revenues under collaborative agreements also consisted of reimbursements for research and development services from Baxter of \$554,000 and \$98,000 and Roche of \$210,000 and \$5,000 for the three months ended June 30, 2008 and 2007, respectively. Such reimbursements are for research and development services rendered by us at the request of Baxter and Roche. Therefore, the amount of future revenues related to reimbursable research and development services is uncertain.

**Product Sales** Product sales were \$83,000 for the three months ended June 30, 2008 compared to \$169,000 for the three months ended June 30, 2007. The decrease of \$86,000 was primarily due to the decrease in sales of Cumulase as one of our distributors is shifting to a new Cumulase product formulation.

**Cost of Product Sales** Cost of product sales were \$37,000 for the three months ended June 30, 2008 compared to \$76,000 for the three months ended June 30, 2007. The decrease of \$39,000 was primarily due to decreases in the sales of Cumulase and API for HYLENEX.

**Research and Development** Research and development expenses were \$8.9 million for the three months ended June 30, 2008 compared to \$4.1 million for the three months ended June 30, 2007. The increase of \$4.8 million was primarily due to the increase in outsourced research and development costs of \$1.9 million due to our various pre-clinical programs and the manufacturing scale-up of our rHuPH20 enzyme. In addition, compensation costs increased by \$1.4 million primarily due to the increase in our research and development headcount. At June 30, 2008, our headcount for research and development functions totaled 83 employees, compared with 37 employees at June 30, 2007. Additionally, our facilities expenses increased by \$589,000 resulting from leasing larger facilities effective July 2007 to accommodate the increase in headcount, research supplies expenses increased by \$379,000 and clinical trial expenses increased by \$343,000 for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. We expect research and development costs to continue to increase in future periods as we increase our research efforts and headcount, expand our clinical trials, and continue to develop and manufacture our product candidates.

**Selling, General and Administrative** SG&A expenses were \$3.8 million for the three months ended June 30, 2008 compared to \$2.4 million for the three months ended June 30, 2007. The increase of approximately \$1.4 million was primarily due to the increase in compensation costs of \$660,000, of which \$236,000 related to share-based compensation. At June 30, 2008, our headcount for SG&A functions totaled 30 employees, compared with 19 employees at June 30, 2007. In addition, legal expenses related to patent applications increased by \$371,000, facilities expense increased by \$126,000 and market research expenses increased by \$123,000. We expect SG&A expenses to increase in future periods as we continue to expand our operations.

## **Table of Contents**

**Interest Income** Interest income was \$372,000 for the three months ended June 30, 2008 compared to \$1.0 million for the three months ended June 30, 2007. The decrease in interest income was primarily due to lower interest rates during the three months ended June 30, 2008 as compared to the same period in 2007.

**Net Loss** Net loss for the three months ended June 30, 2008 was \$11.0 million, or \$0.14 per common share, compared to \$4.8 million, or \$0.07 per common share, for the three months ended June 30, 2007. The increase in net loss was primarily due to an increase in operating expenses, partially offset by increases in revenues.

### ***Six Months Ended June 30, 2008 Compared to Six Months Ended June 30, 2007***

**Revenues Under Collaborative Agreements** Revenues under collaborative agreements were \$3.0 million for the six months ended June 30, 2008 compared to \$1.2 million for the six months ended June 30, 2007. Revenues under collaborative agreements consisted of the amortization of upfront fees received from Baxter and Roche of \$1.2 million and \$803,000 for the six months ended June 30, 2008 and 2007, respectively. Revenues under collaborative agreements also consisted of reimbursements for research and development services from Baxter of \$1.0 million and \$166,000 and Roche of \$834,000 and \$193,000 for the six months ended June 30, 2008 and 2007, respectively. Such reimbursements are for research and development services rendered by us at the request of Baxter and Roche. Therefore, the amount of future revenues related to reimbursable research and development services is uncertain.

**Product Sales** Product sales were \$224,000 for the six months ended June 30, 2008 compared to \$356,000 for the six months ended June 30, 2007. The decrease of \$132,000 was primarily due to the decrease in sales of Cumulase as one of our distributors is shifting to a new Cumulase product formulation.

**Cost of Product Sales** Cost of product sales were \$74,000 for the six months ended June 30, 2008 compared to \$152,000 for the six months ended June 30, 2007. The decrease of \$78,000 was primarily due to decreases in the sales of Cumulase and API for HYLENEX.

**Research and Development** Research and development expenses were \$17.4 million for the six months ended June 30, 2008 compared to \$6.9 million for the six months ended June 30, 2007. The increase of \$10.5 million was primarily due to the increase in outsourced research and development costs of \$4.4 million due to our various pre-clinical programs and the manufacturing scale-up of our rHuPH20 enzyme. In addition, compensation costs increased by \$2.8 million primarily due to the increase in our research and development headcount. At June 30, 2008, our headcount for research and development functions totaled 83 employees, compared with 37 employees at June 30, 2007. Additionally, our facilities expenses increased by \$1.1 million resulting from leasing larger facilities effective July 2007 to accommodate the increase in headcount, clinical trial expenses increased by \$945,000 and research supplies expenses increased by \$788,000 for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. We expect research and development costs to continue to increase in future periods as we increase our research efforts and headcount, expand our clinical trials and continue to develop and manufacture our product candidates.

**Selling, General and Administrative** SG&A expenses were \$8.0 million for the six months ended June 30, 2008 compared to \$4.4 million for the six months ended June 30, 2007. The increase of approximately \$3.6 million was primarily due to the increase in compensation costs of \$1.7 million, of which \$565,000 related to share-based compensation. At June 30, 2008, our headcount for SG&A functions totaled 30 employees, compared with 19 employees at June 30, 2007. In addition, legal expenses increased by \$1.3 million of which \$635,000 related to the settlement of an arbitration matter and \$527,000 related to patent applications. We expect SG&A expenses to increase in future periods as we continue to expand our operations.

**Interest Income** Interest income was \$1.3 million for the six months ended June 30, 2008 compared to \$1.8 million for the six months ended June 30, 2007. The decrease in interest income was primarily due to lower interest rates during the six months ended June 30, 2008 as compared to the same period in 2007.

## **Table of Contents**

**Net Loss** Net loss for the six months ended June 30, 2008 was \$21.0 million, or \$0.27 per common share, compared to \$8.2 million, or \$0.11 per common share, for the six months ended June 30, 2007. The increase in net loss was primarily due to an increase in operating expenses, partially offset by increases in revenues.

## **Liquidity and Capital Resources**

### ***Overview***

Our principal sources of liquidity are our existing cash and cash equivalents. As of June 30, 2008, we had cash and cash equivalents of approximately \$82.4 million. We expect our cash requirements to increase significantly as we continue to increase our research and development for, seek regulatory approvals of, and develop and manufacture our current product candidates. As we expand our research and development efforts and pursue additional product opportunities, we anticipate significant cash requirements for hiring of personnel, capital expenditures and investment in additional internal systems and infrastructure. The amount and timing of cash requirements will depend on the research, development, manufacture, regulatory and market acceptance of our product candidates, if any, and the resources we devote to researching, developing, manufacturing, commercializing and supporting our product candidates.

We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months. Currently, we anticipate cash expenses of approximately \$45.0 million to \$55.0 million for the year ending December 31, 2008, depending on the progress of various pre-clinical and clinical programs and the timing of our manufacturing scale up. 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 of the Roche and Baxter collaborations and the sale of our common stock to New River Management V, LP, or New River. 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.

In June 2005, we filed a shelf registration statement on Form S-3 (Registration No. 333-125731) which initially allowed us, from time to time, to offer and sell up to \$50.0 million of equity or debt securities. We have sold common stock under this registration statement for an aggregate of approximately \$17.5 million, so we currently have the ability to issue debt and equity securities for an aggregate of \$32.5 million. We cannot be certain that our existing cash and cash equivalents will be adequate for our anticipated needs or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs or delay the launch of our product candidates. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders could result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

### ***Cash Flows***

Net cash used by operations was \$15.7 million for the six months ended June 30, 2008 compared to \$2.5 million provided by operations for the six months ended June 30, 2007. This change was primarily due to the increase in operating expenses as well as the \$11.0 million initial upfront payments received from Baxter in the six months ended June 30, 2007, as compared to the \$3.5 million product-based payment received from Baxter in the six months ended June 30, 2008.

Net cash used in investing activities was \$472,000 for the six months ended June 30, 2008 compared to \$895,000 for the six months ended June 30, 2007. This decrease was due to the decrease in purchases of property and equipment during the six months ended June 30, 2008 as compared to the same period in 2007.

Net cash provided by financing activities was \$913,000 for the six months ended June 30, 2008 compared to \$54.8 million for the six months ended June 30, 2007. Net cash provided by financing activities for the six months ended June 30, 2008 primarily consisted of proceeds from stock options and warrants exercised. During the six months ended June 30, 2007, we sold common stock for proceeds of approximately \$52.0 million, net of issuance costs. Additionally, we received approximately \$2.8 million in proceeds from warrant and stock option exercises during the six months ended June 30, 2007.



## **Table of Contents**

### ***Off-Balance Sheet Arrangements***

As of June 30, 2008, 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 did 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.

### ***Recent Accounting Pronouncements***

See Note 3, *Adoption of New Accounting Standards*, and Note 11, *New Accounting Pronouncements*, in the Notes to Condensed Consolidated Financial Statements for discussions of new accounting pronouncements and their effect, if any on us.

### **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 on Form 10-Q and those we may make from time to time. For a more detailed discussion of the factors that could cause actual results to differ, see the Risk Factors section in our Annual Report on Form 10-K filed with the SEC on March 14, 2008. In addition to the risk factors discussed below, we are also subject to additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of these known or unknown risks or uncertainties actually occurs, our business, financial position and results of operations could be materially and adversely affected and the value of our securities could decline significantly.*

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

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

We have generated only minimal revenue from product sales to date and may never generate significant revenues from future product sales. Even if we do achieve significant revenues from product sales, licensing revenues and milestone payments, we expect to incur significant operating losses over the next several years. We have never been profitable, and we may never become profitable. Through June 30, 2008, we have incurred aggregate net losses of approximately \$86.0 million.

**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, the April 2005 FDA clearance for Cumulase and the December 2005 FDA approval for our spreading agent, HYLENEX, none of our product candidates has 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.

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

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

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



**Table of Contents**

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

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

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

restrictions on our products or manufacturing processes;

warning letters;

withdrawal of the products from the market;

voluntary or mandatory recall;

fines;

suspension or withdrawal of regulatory approvals;

suspension or termination of any of our ongoing clinical trials;

refusal to permit the import or export of our products;

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

product seizure; or

injunctions or the imposition of civil or criminal penalties.

**If any party to a key collaboration agreement, including us, fails to perform material obligations under such agreement, or if a key collaboration agreement is terminated for any reason, our business would significantly suffer.**

We have entered into key collaboration agreements under which we may receive significant future payments in the form of maintenance fees, milestone payments and royalties. In the event that a party fails to perform under a key collaboration agreement, or if a key collaboration agreement is terminated, the reduction in anticipated revenues could delay or suspend our product development activities for some of our product candidates as well as our commercialization efforts for some or all of our products. In addition, the termination of a key collaboration agreement by one of our partners could materially impact our ability to enter into additional collaboration agreements with new partners on favorable terms, if at all. In certain circumstances, the termination of a key collaboration agreement would require us to revise our corporate strategy going forward and reevaluate the applications and value of our technology.



**Table of Contents**

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

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

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

We depend upon the efforts of these third parties, such as Baxter, to promote and sell our current products, but there can be no assurance that the efforts of these third parties will meet our expectations or result in any significant product sales. While these third parties are largely responsible for the speed and scope of sales and marketing efforts, they may not dedicate the resources necessary to maximize product opportunities and our ability to cause these third parties to increase the speed and scope of their efforts may be limited. In addition, sales and marketing efforts could be negatively impacted by the delay or failure to obtain additional supportive clinical trial data for our products. Our third party partners are responsible for conducting these additional clinical trials and our ability to increase the efforts and resources allocated to these trials may be limited.

**If our sole contract manufacturer is unable to manufacture significant amounts of the active pharmaceutical ingredient used in our products, our product development and commercialization efforts could be delayed or stopped.**

We have signed a commercial supply agreement with Avid Bioservices, Inc., or Avid, a contract manufacturing organization, to produce bulk recombinant human hyaluronidase for clinical trials and commercial use. Avid will produce the active pharmaceutical ingredient used in each of Cumulase, HYLENEX, Chemophase, and Enhance Technology under cGMP for clinical or commercial scale production and will provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. Avid has only limited experience manufacturing our active pharmaceutical ingredient batches, and we rely on its ability to successfully manufacture these batches according to product specifications. In addition, as a result of our contractual obligations to Roche, we will be required to significantly scale up our active pharmaceutical ingredient production during the next few years. We do not currently have a significant inventory of the active pharmaceutical ingredient used in our products and product candidates, so if Avid does not maintain its status as an FDA-approved manufacturing facility, is unable to successfully scale up our active pharmaceutical ingredient production, or is unable to manufacture the active pharmaceutical ingredient used in our products and product candidates according to product specifications for any other reason, the commercialization of our products and the development of our product candidates will be delayed and our business will be adversely affected. We have entered into discussions to establish arrangements with an additional manufacturer for these ingredients. We have not yet established, and may not be able to establish, favorable arrangements with additional manufacturers for these ingredients or products should the existing supplies become unavailable or in the event that our sole contract manufacturer is unable to adequately perform its responsibilities. Any delays or interruptions in the supply of materials by Avid could cause the delay of clinical trials and could delay or prevent the commercialization of product candidates that may receive regulatory approval. Such delays or

interruptions would have a material adverse effect on our business and financial condition.

**Table of Contents**

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

In the event that any of our product candidates are used in clinical trials or receive the necessary regulatory approval for commercialization, we rely on third parties to prepare, fill, finish, and package the products prior to their distribution. If we are unable to locate third parties to perform these functions on terms that are economically acceptable to us, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. We currently utilize a third-party to prepare, fill, finish, and package Cumulase. This third party has only limited experience manufacturing Cumulase batches and, to date, has not demonstrated a consistent ability to manufacture Cumulase according to product specifications. We have entered into an agreement with another third party to prepare, fill, finish and package Cumulase. We are currently in the technology transfer stage with this third party and expect to initiate commercial manufacturing in 2009. If our third party manufacturers are unable to successfully manufacture Cumulase, we may be unable to supply enough Cumulase product to meet demand. In addition, we currently utilize a subsidiary of Baxter to prepare, fill, finish, and package HYLENEX under a development and supply agreement. Baxter has only limited experience manufacturing HYLENEX batches, and we rely on its ability to successfully manufacture HYLENEX batches according to product specifications. Any delays or interruptions in Baxter's ability to manufacture HYLENEX batches in amounts necessary to meet product demand could have a material adverse impact on our business and financial condition.

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

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

Currently, warrants to purchase approximately 4.3 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 1.5 million of our outstanding warrants contain a call feature that, potentially, may allow us to raise funds from the holders of these warrants. We have the ability, at our sole discretion, to call warrants exercisable for up to approximately 1.5 million shares of common stock and, upon such a call, the holders of these warrants have thirty days to decide whether to 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.

Considering our stage of development and the nature of our capital structure, if we are required to raise additional capital in the future, the additional financing may not be available on favorable terms, or at all. If we are successful in raising additional capital, a substantial number of additional shares may be issued and these shares will dilute the ownership interest of our current investors.

**If 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;

**Table of Contents**

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.

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

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

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

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. If we are unable to retain existing personnel or identify or hire additional personnel, we may not be able to research, develop, commercialize or market our product candidates as expected or on a timely basis and, as a result, our business may be harmed. In addition, we rely on the expertise and guidance of independent directors to develop business strategies and to guide our execution of these strategies. Due to changes in the regulatory environment for public companies over the past few years, the demand for independent directors has increased and it may be difficult for us, due to competition from both like-size and larger companies, to recruit qualified independent directors.

Furthermore, if we were to lose key management personnel, particularly Jonathan Lim, M.D., our president and chief executive officer, or Gregory Frost, Ph.D., our vice president and 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 us, other than standard agreements relating to the vesting of stock options that every optionee of the Company 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.

**Table of Contents**

***Risks Related To Ownership of Our Common Stock***

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

As a result of our January 2004 private financing transaction, we issued warrants to private investors for the purchase of approximately 10.5 million shares of common stock at purchase prices ranging from \$0.77 to \$1.75 per share. Currently, approximately 2.2 million shares of common stock remain issuable upon the exercise of these warrants. As a result of our October 2004 financing transaction, we issued warrants for the purchase of approximately 2.7 million shares of common stock at a purchase price of \$2.25 per share. Currently, approximately 2.0 million shares of common stock remain issuable upon the exercise of these warrants. The exercise of these warrants could result in significant dilution to stockholders at the time of exercise which could negatively affect our stock price.

We currently have the ability, from time to time, to offer and sell up to \$32.5 million of additional equity or debt securities under a currently effective universal shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair our 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 our common stock.

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

We participate in a highly dynamic industry which often results in significant volatility in the market price of common stock irrespective of company performance. As a result, our high and low sales prices of our common stock during the twelve months ended June 30, 2008 were \$10.50 and \$4.19, 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 Annual Report on Form 10-K and all other risks and uncertainties that are either not known to us at this time or which we deem to be immaterial, any of the following factors may lead to a significant drop in our stock price:

our failure, or the failure of one of our third party partners, to comply with the terms of our collaboration agreements;

the termination, for any reason, of any of our collaboration agreements;

the sale of common stock by any significant shareholder, including, but not limited to, direct or indirect sales by members of our Board of Directors;

general negative conditions in the healthcare industry;

general negative conditions in the financial markets;

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

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

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

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

the suspension of our Chemophase clinical trial due to market and/or competitive conditions;

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

**Table of Contents**

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

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

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

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

the departure of key personnel.

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

Our stock has historically traded at a low daily trading volume. If recent trading volumes decrease, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

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

We may have the ability to redeem certain outstanding warrants, under certain conditions, that may be exercised for approximately 1.5 million shares of common stock. The redemption price for these warrants is \$0.01 per share, but the warrant holders have the opportunity to exercise their warrants prior to redemption at the price of \$1.75 per share. If we decide to redeem any portion of our outstanding warrants in the future, some selling security holders may choose to sell outstanding shares of common stock in order to finance the exercise of the warrants prior to their redemption. This pattern of selling may result in a reduction of our common stock's market price.

***Risks Related To Our Industry***

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

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including ours, are subject to extensive, complex, costly and evolving regulation by the federal government, principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, or 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, recordkeeping, safety, approval, advertising, promotion, sale and distribution of our products. Under certain of these regulations, we and our contract suppliers and manufacturers are subject to periodic inspection of our 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 we and our contract suppliers and manufacturers are in compliance with all applicable regulations. The FDA also conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems, or our contract suppliers' and manufacturers' processes, are in compliance with cGMP and other FDA regulations. If we, or our contract supplier, fail these inspections, we may not be able to commercialize our product in a timely manner without incurring significant additional costs, or at all.

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

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

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

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

available at all, it may require us to pay substantial royalties or other fees.

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

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

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

Third-party payors 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 payors may not establish adequate levels of reimbursement for the products that we commercialize, which could limit their market acceptance and result in a material adverse effect on our financial condition.

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

## **Table of Contents**

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

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

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds and government and non-government debt securities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate. As of June 30, 2008, we did not have any holdings of derivative financial or commodity instruments, or any foreign currency denominated transactions, and all of our cash and cash equivalents were in money market mutual funds and other highly liquid investments.



## **Table of Contents**

### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decision regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible 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. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

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

There have been no significant changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2008, 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, we may be involved in litigation relating to claims arising out of operations in the normal course of our 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 consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We currently are 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 consolidated results of operations or financial position.

#### **Item 1A. Risk Factors**

A description of the risk factors associated with our business is included under "Risk Factors" in "Management's Discussion and Analysis of Financial Condition and Results of Operations", contained in Item 2 of Part I of this report. This description includes any changes to and supersedes the description of the risk factors associated with our business previously disclosed in Item 1A of Part I, "Risk Factors," of our Annual Report on Form 10-K for the year ended December 31, 2007. There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2007.

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

During the three months ended June 30, 2008, a holder of our various outstanding warrants exercised rights to purchase 322,788 common shares for gross proceeds of approximately \$247,000. The shares and underlying warrants were purchased for investment in a private placement exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

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

Our Annual Meeting of Stockholders was held on May 8, 2008. At the Annual Meeting, our stockholders voted on the following four proposals:

**Proposal No. 1:**

To elect three Class I directors to hold office for a three-year term and until their respective successors are elected and qualified. The voting results were as follows:

| <b>Nominees</b>       | <b>Votes For</b> | <b>Votes Against</b> |
|-----------------------|------------------|----------------------|
| Kathryn E. Falberg    | 59,551,234       | 396,158              |
| Kenneth J. Kelley     | 59,385,864       | 561,528              |
| Jonathan E. Lim, M.D. | 59,531,184       | 416,208              |

We also have: (i) three Class II directors, Randal J. Kirk, John S. Patton, Ph.D. and Steven T. Thornton, whose terms do not expire until our Annual Meeting of Stockholders in 2009; and (ii) three Class III directors, Robert L. Engler, M.D., Gregory I. Frost, Ph.D. and Connie L. Matsui, whose terms do not expire until our Annual Meeting of Stockholders in 2010. All three nominees were elected to the board of directors.

**Proposal No. 2:**

To approve our 2008 Outside Directors Stock Plan and to reserve an aggregate of 600,000 shares of our common stock for issuance under this plan. The voting results were as follows:

For: 36,186,291                      Against: 1,614,169                      Abstained: 49,188

The foregoing proposal was approved.

**Proposal No. 3:**

To approve our 2008 Stock Plan and to reserve an aggregate of 5,000,000 shares of our common stock for issuance under this plan. The voting results were as follows:

For: 36,186,917                      Against: 1,580,843                      Abstained: 81,888

The foregoing proposal was approved.

**Proposal No. 4:**

To ratify the selection of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008. The voting results were as follows:

For: 59,884,670                      Against: 50,671                      Abstained: 12,051

The foregoing proposal was approved.

**Table of Contents**

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

| <b>Exhibit</b> | <b>Title</b>                                                                                                                                                      |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1            | Agreement and Plan of Merger, dated November 14, 2007, by and between the Registrant and the Registrant's predecessor Nevada corporation (1)                      |
| 3.1            | Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on October 7, 2007 (2)                                           |
| 3.2            | Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock (1)                                                               |
| 3.3            | Bylaws (2)                                                                                                                                                        |
| 4.1            | Amended Rights Agreement between Corporate Stock Transfer, as rights agent, and Registrant, dated November 12, 2007 (20)                                          |
| 10.1           | License Agreement between University of Connecticut and Registrant, dated November 15, 2002 (3)                                                                   |
| 10.2           | First Amendment to the License Agreement between University of Connecticut and Registrant, dated January 9, 2006 (9)                                              |
| 10.3*          | Commercial Supply Agreement with Avid Bioservices, Inc. and Registrant, dated February 16, 2005 (7)                                                               |
| 10.4*          | First Amendment to the Commercial Supply Agreement between Avid Bioservices, Inc. and Registrant, dated December 15, 2006 (14)                                    |
| 10.5           | Form of Callable Stock Purchase Warrant (4)                                                                                                                       |
| 10.6           | Form of Common Stock Purchase Warrant (5)                                                                                                                         |
| 10.7#          | DeliaTroph Pharmaceuticals, Inc. 2001 Amended and Restated Stock Plan and form of Stock Option Agreements for options assumed thereunder (6)                      |
| 10.8           | Nonstatutory Stock Option Agreement With Andrew Kim (6)                                                                                                           |
| 10.9#          | 2004 Stock Plan and Form of Option Agreement thereunder (4)                                                                                                       |
| 10.10#         | Halozyme Therapeutics, Inc. 2005 Outside Directors' Stock Plan (8)                                                                                                |
| 10.11#         | Form of Stock Option Agreement (2005 Outside Directors' Stock Plan) (12)                                                                                          |
| 10.12#         | Form of Restricted Stock Agreement (2005 Outside Directors' Stock Plan) (12)                                                                                      |
| 10.13#         | Halozyme Therapeutics, Inc. 2006 Stock Plan (11)                                                                                                                  |
| 10.14#         | Form of Stock Option Agreement (2006 Stock Plan) (12)                                                                                                             |
| 10.15#         | Form of Restricted Stock Agreement (2006 Stock Plan) (12)                                                                                                         |
| 10.16#         | Halozyme Therapeutics, Inc. 2008 Stock Plan (21)                                                                                                                  |
| 10.17#         | Halozyme Therapeutics, Inc. 2008 Outside Directors' Stock Plan (21)                                                                                               |
| 10.18#         | Form of Indemnity Agreement for Directors and Executive Officers (19)                                                                                             |
| 10.19#         | Outside Director Compensation Plan (23)                                                                                                                           |
| 10.20#         | 2007 Senior Executive Incentive Plan (23)                                                                                                                         |
| 10.21#         | 2008 Senior Executive Incentive Structure (22)                                                                                                                    |
| 10.22#         | Change in Control Policy (22)                                                                                                                                     |
| 10.23#         | Severance Policy (23)                                                                                                                                             |
| 10.24*         | Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)  |
| 10.25*         | Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)  |
| 10.26*         | License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)                    |
| 10.27*         | Enhance Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007 (18) |
| 10.28*         |                                                                                                                                                                   |

Edgar Filing: HALOZYME THERAPEUTICS INC - Form 10-Q

License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006 (13)

10.29 Stock Purchase Agreement between Roche Finance Ltd and Registrant, dated December 5, 2006 (13)

10.30 Stock Purchase Agreement between Baxter International, Inc. and Registrant, dated February 14, 2007 (15)

**Table of Contents**

| <b>Exhibit</b> | <b>Title</b>                                                                                                                                                          |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.31          | Stock Purchase Agreement between New River Management V, LP and Registrant, dated April 23, 2007(16)                                                                  |
| 10.32          | Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007 (17)                                                                                    |
| 10.33          | Sublease Agreement (11388 Sorrento Valley Road), effective as of July 2, 2007 (17)                                                                                    |
| 10.34          | Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007 (17)                                                                        |
| 21.1           | Subsidiaries of Registrant (10)                                                                                                                                       |
| 31.1           | Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended                                  |
| 31.2           | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended                                  |
| 32             | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| (1)            | Incorporated by reference to the Registrant's Current Report on Form 8-K, filed November 20, 2007.                                                                    |
| (2)            | Incorporated by reference to the Registrant's definitive proxy statement filed with the SEC on Form DEF14A on October 11, 2007.                                       |
| (3)            | Incorporated by reference to the Registrant's Registration Statement on Form SB-2 filed with the Commission on April 23, 2004.                                        |
| (4)            | Incorporated by reference to the Registrant's amendment number two to                                                                                                 |

the Registration  
Statement on  
Form SB-2 filed  
with the  
Commission on  
July 23, 2004.

- (5) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed  
October 15,  
2004.
- (6) Incorporated by  
reference to the  
Registrant's  
Registration  
Statement on  
Form S-8 filed  
with the  
Commission on  
October 26,  
2004.
- (7) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed  
February 22,  
2005.
- (8) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed July 6,  
2005.
- (9) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed January 12,  
2006.

- (10) Incorporated by reference to the Registrant's Annual Report on Form 10-KSB/A, filed March 29, 2005.
- (11) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed March 24, 2006.
- (12) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed August 8, 2006.
- (13) Incorporated by reference to the Registrant's Current Report on Form 8-K/A, filed December 15, 2006.
- (14) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed December 21, 2006.
- (15) Incorporated by reference to the Registrant's Current Report on Form 8-K/A, filed February 20, 2007.

(16)

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

(17) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed July 31,  
2007.

(18) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed  
September 12,  
2007.

(19) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed  
December 20,  
2007.

(20) Incorporated by  
reference to the  
Registrant's  
Annual Report  
on Form 10-K,  
filed March 14,  
2008.

(21) Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed March 19,  
2008.

(22)

Incorporated by  
reference to the  
Registrant's  
Current Report  
on Form 8-K,  
filed April 21,  
2008.

(23) Incorporated by  
reference to the  
Registrant's  
Quarterly  
Report on Form  
10-Q, filed  
May 9, 2008.

\* 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.

# Indicates  
management  
contract or  
compensatory  
plan or  
arrangement.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Halozyme Therapeutics, Inc.,  
a Delaware corporation

Dated: August 8, 2008

/s/ Jonathan E. Lim  
Jonathan E. Lim, MD  
President and Chief Executive Officer  
(Principal Executive Officer)

Dated: August 8, 2008

/s/ David A. Ramsay  
David A. Ramsay  
Vice President and Chief Financial Officer  
(Principal Financial and Accounting  
Officer)