HALOZYME THERAPEUTICS INC
Form 10-Q
August 07, 2009

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

(Mark One)

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

For the quarterly period ended June 30, 2009

OR

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

For the transition period from _____to_____.

Commission File Number 001-32335

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**88-0488686**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11388 Sorrento Valley Road, San Diego, CA	**92121**
(Address of principal executive offices)	(Zip Code)

(858) 794-8889

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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 filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 89,723,189 as of August 3, 2009.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2009 (Unaudited)	December 31, 2008 (Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 89,240,763	$ 63,715,906
Accounts receivable	893,093	7,264,410
Inventory	803,534	441,323
Prepaid expenses and other assets	2,711,585	2,591,149
Total current assets	93,648,975	74,012,788
Property and equipment, net	2,646,666	2,549,925
Total Assets	$ 96,295,641	$ 76,562,713
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 5,430,644	$ 6,668,791
Accrued expenses	4,721,593	3,995,897
Deferred revenue	5,016,178	3,553,730
Total current liabilities	15,168,415	14,218,418
Deferred revenue, net of current portion	53,667,269	45,894,726
Deferred rent, net of current portion	1,025,399	1,069,573
Commitments and contingencies (Note 11)		
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; 89,656,578 and 81,553,654 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	89,657	81,554
Additional paid-in capital	171,779,912	128,948,064
Accumulated deficit	(145,435,011)	(113,649,622)
Total stockholders equity	26,434,558	15,379,996
Total Liabilities and Stockholders Equity	$ 96,295,641	$ 76,562,713

Note: The balance sheet at December 31, 2008 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by US generally accepted accounting principles for complete financial statements.

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
Revenues under collaboration agreements	$ 1,246,205	$ 1,351,492	$ 3,940,369	$ 3,015,572
Product sales	179,951	82,727	258,158	224,165
Total revenues	1,426,156	1,434,219	4,198,527	3,239,737
Operating expenses:				
Cost of product sales	45,097	37,126	49,301	74,316
Research and development	14,561,137	8,925,488	28,601,224	17,369,679
Selling, general and administrative	3,903,642	3,846,175	7,390,464	8,003,778
Total operating expenses	18,509,876	12,808,789	36,040,989	25,447,773
Operating loss	(17,083,720)	(11,374,570)	(31,842,462)	(22,208,036)
Interest income	23,695	372,180	57,073	1,251,649
Net loss	$ (17,060,025)	$ (11,002,390)	$ (31,785,389)	$ (20,956,387)
Basic and diluted net loss per share	$ (0.21)	$ (0.14)	$ (0.38)	$ (0.27)
Shares used in computing basic and diluted net loss per share	82,990,107	79,454,496	82,807,253	78,923,520

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2009	**2008**
Operating activities:		
Net loss	$ (31,785,389)	$ (20,956,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,870,766	1,929,793
Depreciation and amortization	680,071	476,585
Loss on disposal of equipment	2,685	9,029
Changes in operating assets and liabilities:		
Accounts receivable	6,371,317	(381,165)
Inventory	(362,211)	54,214
Prepaid expenses and other assets	(120,436)	118,860
Accounts payable and accrued expenses	(616,029)	366,311
Deferred rent	26,616	310,990
Deferred revenue	9,234,991	2,362,140
Net cash used in operating activities	(14,697,619)	(15,709,630)
Investing activities:		
Purchases of property and equipment	(746,709)	(472,023)
Net cash used in investing activities	(746,709)	(472,023)
Financing activities:		
Proceeds from issuance of common stock, net	38,174,371	
Proceeds from exercise of warrants, net	2,213,515	247,482
Proceeds from exercise of stock options, net	581,299	665,225
Net cash provided by financing activities	40,969,185	912,707
Net increase (decrease) in cash and cash equivalents	25,524,857	(15,268,946)
Cash and cash equivalents at beginning of period	63,715,906	97,679,085
Cash and cash equivalents at end of period	$ 89,240,763	$ 82,410,139
Supplemental disclosure of non-cash investing and financing activities:		
Accounts payable for purchases of property and equipment	$ 32,788	$ 170,040

See accompanying notes to condensed consolidated financial statements.

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

1. Organization and Business

Halozyme Therapeutics, Inc. (Halozyme or the Company) is a biopharmaceutical company dedicated to the development and commercialization of products targeting the extracellular matrix for the endocrinology, oncology, dermatology and drug delivery markets. The Company s existing products and products under development are primarily based on intellectual property covering the family of human enzymes known as hyaluronidases.

The Company s operations to date have involved 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 currently has four proprietary programs in various stages of research and development, including three programs in clinical development. The Company also has three partnered programs. The Company s key partnerships are with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (Roche) to apply Enhanze$^{\hat{O}}$ Technology to Roche s biological therapeutic compounds for up to 13 targets and with Baxter Healthcare Corporation (Baxter) to apply Enhanze Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUID$^{\hat{O}}$ and to develop and supply active pharmaceutical ingredient (API) for HYLENEX, a registered trademark of Baxter International, Inc. There are two marketed products that utilize the Company s technology: HYLENEX, a product used as an adjuvant to increase the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization. Currently, the Company receives only limited revenue from the sales of HYLENEX and from the sales of bulk materials to the third party that produces Cumulase, in addition to revenues from its partnerships with Baxter and Roche.

2. Basis of Presentation

The accompanying interim 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 unaudited 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, 2008. 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. Further, in connection with the preparation of the interim unaudited condensed financial statements and in accordance with the recently issued Statement of Financial Accounting Standards (SFAS) No. 165, *Subsequent Events*, the Company evaluated subsequent events after the balance sheet date of June 30, 2009 through August 7, 2009.

The 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 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.

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3. Accounting Pronouncements

Adoption of Recent Accounting Pronouncements

Effective April 1, 2009, the Company adopted SFAS No. 165, *Subsequent Events*. SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The adoption of SFAS No. 165 did not have a material impact on the Company s consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted Emerging Issues Task Force (EITF) Issue No. 07-01, *Accounting for Collaboration Arrangements.* Issue No. 07-1 focuses on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the statement of operations and certain related disclosure questions. The adoption of Issue No. 07-01 did not have a material impact on the Company s consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted SFAS No. 141 (revised 2007), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired in connection with business combinations. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. The adoption of SFAS No. 141(R) did not have a material effect on the Company s consolidated financial condition and results of operations.

Effective January 1, 2009 the Company adopted the FASB Staff Position (FSP) No. EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities*. FSP No. 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. The adoption of FSP EITF 03-6-1 did not have a material impact on the Company s consolidated financial position or results of operations.

Effective January 1, 2009, the Company adopted EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity s Own Stock*. EITF Issue No. 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. The adoption of EITF Issue No. 07-5 did not have a material impact on the Company s consolidated financial position or results of operations.

Pending Adoption of Recent Accounting Pronouncement

In June 2009, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) No. 2009-01, which amends the FASB Accounting Standards Codification for the issuance of SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. ASU No. 2009-01 includes SFAS No. 168 in its entirety. SFAS No. 168 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS No. 168 replaces SFAS No. 162, *Hierarchy of Generally Accepted Accounting Principles.* ASU No. 2009-01 will be effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of ASU No. 2009-01 to have a material impact on its consolidated financial position or results of operations.

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4. Summary of Significant Accounting Policies

Fair Value Measurements

The Company determines fair value measurements in accordance with SFAS No. 157, *Fair Value Measurements*, and FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. FSP No. FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active.

SFAS No. 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.

Cash and cash equivalents of approximately $89.2 million at June 30, 2009 are carried at fair value based on quoted market prices for identical securities (Level 1 inputs).

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, license fees, 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 (SAB) 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 Company s distributor. The Company is obligated to accept returns for product that does not meet product specifications. Historically, the Company has not had any product returns as a result of not meeting product specifications.

In accordance with the Amended and Restated Development and Supply Agreement (the HYLENEX Partnership) with Baxter, the Company supplies Baxter with 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 HYLENEX Partnership 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 HYLENEX Partnership. 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.

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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 and license fees 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.

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 include salaries and benefits, facilities and other overhead expenses, external clinical trials, research-related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as incurred when these expenditures relate to the Company s research and development efforts and have no alternative future uses.

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 or such time when the Company does not expect the goods to be delivered or services to be performed.

Milestone payments that the Company makes 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. The Company considers 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 U.S. Food and Drug Administration 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.

Clinical Trial Expenses

Expenses related to clinical trials are accrued based on the Company s 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), the Company modifies its accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Historically, the Company has had no material changes in its clinical trial expense accruals that would have had a material impact on its consolidated results of operations or financial position.

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Share-Based Compensation

The Company accounts for share-based awards exchanged for employee services in accordance with SFAS No. 123(R), *Share-Based Payment*. Under SFAS No. 123(R), 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. Total share-based compensation expense related to all of the Company s share-based awards was allocated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	$ 506,762	$ 347,123	$ 968,008	$ 610,769
Selling, general and administrative	542,048	719,154	902,758	1,319,024
Share-based compensation expense before tax	1,048,810	1,066,277	1,870,766	1,929,793
Related income tax benefit				
Share-based compensation expense, net of tax	$ 1,048,810	$ 1,066,277	$ 1,870,766	$ 1,929,793
Net share-based compensation expense per basic and diluted share	$ 0.01	$ 0.01	$ 0.02	$ 0.02
Share-based compensation expense from:				
Stock options	$ 737,474	$ 725,615	$ 1,418,465	$ 1,345,478
Restricted stock awards	311,336	340,662	452,301	584,315
	$ 1,048,810	$ 1,066,277	$ 1,870,766	$ 1,929,793

Since the Company has a net operating loss carryforward as of June 30, 2009, no excess tax benefits for the tax deductions related to share-based awards were recognized in the interim unaudited condensed consolidated statement of operations. For the three months ended June 30, 2009 and 2008, employees exercised stock options to purchase 320,313 and 75,379 shares of common stock, respectively, for aggregate proceeds of approximately $347,000 and $71,000, respectively. For the six months ended June 30, 2009 and 2008, employees exercised stock options to purchase 448,430 and 1,708,032 shares of common stock, respectively, for aggregate proceeds of approximately $581,000 and $665,000, respectively.

As of June 30, 2009, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock awards granted prior to that date was approximately $7.9 million and $673,000, respectively, which is expected to be recognized over a weighted-average period of 2.9 years and 7 months, respectively.

5. Inventory

Inventory is stated at the lower of cost or market and consists of the following:

	June 30, 2009	December 31, 2008
Raw materials	$ 745,347	$ 435,386
Work in process	48,088	
Finished goods	10,099	5,937

	$ 803,534	$ 441,323

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6. Property and Equipment

Property and equipment, net consists of the following:

	June 30, 2009	December 31, 2008
Research equipment	$ 3,233,925	$ 2,699,706
Computer and office equipment	1,164,414	1,079,034
Leasehold improvements	930,738	814,067
	5,329,077	4,592,807
Accumulated depreciation and amortization	(2,682,411)	(2,042,882)
	$ 2,646,666	$ 2,549,925

Depreciation and amortization expense totaled approximately $351,000 and $248,000 for the three months ended June 30, 2009 and 2008, respectively, and $680,000 and $477,000 for the six months ended June 30, 2009 and 2008, respectively.

7. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2009	December 31, 2008
Accrued compensation and payroll taxes	$ 2,103,110	$ 2,060,866
Accrued research and development expenses	2,057,646	1,543,321
Accrued expenses	560,837	391,710
	$ 4,721,593	$ 3,995,897

8. Deferred Revenue

Deferred revenue consists of the following:

	June 30, 2009	December 31, 2008
Collaborative agreements	$ 48,443,427	$ 44,905,031
Product sales	10,240,020	4,543,425
Total deferred revenue	58,683,447	49,448,456
Less current portion	5,016,178	3,553,730
Deferred revenue, net of current portion	$ 53,667,269	$ 45,894,726

Roche Partnership In December 2006, the Company and Roche entered into a license and collaborative agreement for Enhanze Technology (the Roche Partnership). Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, the Company s proprietary recombinant human hyaluronidase, with 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. In addition, through June 30, 2009 Roche paid an aggregate of approximately $13.5 million in connection with Roche s election of the fourth and fifth exclusive target

and annual designation maintenance fees for the remaining eight Roche targets.

Due to the Company s continuing involvement obligations, revenues from the upfront payment, exclusive designation fees and annual designation maintenance fees were deferred and are being recognized over the term of the Roche Partnership. The Company recognized revenue from the upfront payment, exclusive designation fees and annual maintenance designation fees under the Roche Partnership in the amounts of approximately $458,000 and $290,000 for the three months ended June 30, 2009 and 2008, respectively, and $900,000 and $580,000 for the six months ended June 30, 2009 and 2008, respectively.

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Baxter Partnerships In September 2007, the Company and Baxter entered into an Enhanze Technology License and Collaboration Agreement (the Gammagard Partnership). Under the terms of the Gammagard Partnership, 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 Partnership. The Company recognized revenue from the upfront payment under the Gammagard Partnership in the amount of approximately $152,000 for the three months ended June 30, 2009 and 2008 and $303,000 for the six months ended June 30, 2009 and 2008.

In February 2007, the Company and Baxter amended certain existing agreements for HYLENEX and entered into a new agreement for kits and formulations with rHuPH20 (the HYLENEX Partnership). Under the terms of the HYLENEX Partnership, 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 HYLENEX Partnership. The Company recognized revenue from the upfront payment under the HYLENEX Partnership in the amount of approximately $147,000 for the three months ended June 30, 2009 and 2008 and $293,000 for the six months ended June 30, 2009 and 2008.

In addition, Baxter will make payments to the Company based on sales of the products covered under the HYLENEX Partnership. Baxter has prepaid $10.0 million of such product-based payments. 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.

9. 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 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 outstanding 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 because their effect is anti-dilutive:

	As of June 30,	
	2009	**2008**
Stock options and awards	8,010,845	6,875,569
Warrants	1,756,286	4,536,242
	9,767,131	11,411,811

10. Stockholders Equity

In June 2009, the Company issued 6,150,000 shares of common stock in a public offering at a price of $6.50 per share, generating approximately $38.2 million in net proceeds.

During the six months ended June 30, 2009 and 2008, holders of the Company s outstanding options exercised rights to purchase approximately 448,000 and 1.7 million common shares, respectively, at weighted exercise prices of $1.30 and $0.49 per share, respectively, for net proceeds of approximately $581,000 and $665,000, respectively. Options to purchase approximately 7.8 million and 7.3 million shares of the Company s common stock were outstanding as of June 30, 2009 and December 31, 2008, respectively.

During the six months ended June 30, 2009 and 2008, holders of the Company s outstanding warrants exercised to purchase approximately 1.4 million and 323,000 shares of common stock, respectively, at weighted exercise prices of $1.81 and $0.77 per share, respectively, for net proceeds of approximately $2.2 million and $247,000, respectively. Warrants to purchase approximately 1.8 million and 3.2 million shares of the Company s common stock at weighted exercise prices of $2.25 and $2.05 per share, respectively, were outstanding as of June 30, 2009 and December 31, 2008, respectively.

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11. 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.

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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. 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. Words such as expect, anticipate, intend, plan, believe, seek, estimate, think, may, could, will, would, should, continue, potential, likely, opportunity and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of indentifying forward-looking statements in this report. Additionally, statements concerning future matters such as the development or regulatory approval of new products, enhancements of existing products or technologies, third party performance under key collaboration agreements, revenue and expense levels and other statements regarding matters that are not historical are forward-looking statements. 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 endocrinology, oncology, dermatology and drug delivery markets. Our existing products and our products under development are primarily based on intellectual property covering the family of human enzymes known as hyaluronidases. Hyaluronidases are enzymes (proteins) that break down hyaluronan, or HA, which is a naturally occurring space-filling, gel-like substance that is a major component of tissues throughout the body, such as skin and cartilage. Our primary technology is based on our proprietary recombinant human PH20 enzyme, or rHuPH20, a human synthetic version of hyaluronidase. The rHuPH20 enzyme is a naturally occurring enzyme that digests HA 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. Our proprietary rHuPH20 technology is applicable to multiple therapeutic areas and may be used to both expand existing markets and create new ones for the development of our own proprietary products. The rHuPH20 technology may also be applied to existing and developmental products of third parties through key partnerships.

Our operations to date have involved organizing and staffing our operating subsidiary, Halozyme, Inc., acquiring, developing and securing our technology and undertaking product development for our existing products and a limited number of product candidates. We continue to increase our focus on our proprietary product pipeline and have expanded investments in our proprietary product candidates. We currently have four proprietary programs in various stages of research and development, including three programs in clinical development. We also have three partnered programs. Our key partnerships are with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, to apply Enhanze® Technology to Roche s biological therapeutic compounds for up to 13 targets and with Baxter Healthcare Corporation, or Baxter, to apply Enhanze Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUID® and to develop and supply active pharmaceutical ingredient, or API, for HYLENEX, a registered trademark of Baxter International, Inc. There are two marketed products that utilize our technology: HYLENEX, a product used as an adjuvant to increase the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. Currently, we receive only limited revenue from the sales of HYLENEX and from the sales of bulk materials to the third party that produces Cumulase, in addition to revenues from our partnerships with Baxter and Roche.

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We have product candidates in the research, preclinical and clinical stages, but future revenues from the sales of these product candidates will depend on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates. It may be years, if ever, before we are able to obtain regulatory approvals for these product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately $145.4 million as of June 30, 2009.

In November 2008, we filed a shelf registration statement on Form S-3 (Registration No. 333-155787) which allowed us, from time to time, to offer and sell up to $50.0 million of equity or debt securities. In June 2009, we sold approximately $40.0 million of our common stock in a public offering at a price of $6.50 per share. We may utilize this universal shelf in the future to raise capital to fund the continued development of our product candidates, the commercialization of our products or for other general corporate purposes.

Our 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 proprietary product and product candidates as well as our partnered product and product candidates:

Insulin-PH20

Our lead proprietary program focuses on the formulation of rHuPH20 with insulin for the treatment of diabetes mellitus. 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. Combining rHuPH20 with either regular or analog insulin may facilitate faster insulin dispersion and absorption from the subcutaneous space into the vascular compartment leading to faster insulin response and improved glycemic control, potentially resulting in fewer hypoglycemic episodes. By making mealtime insulin onset faster, i.e., providing earlier insulin to the blood and thus earlier glucose

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lowering activity, a combination of insulin with rHuPH20 may yield a better profile of insulin effect, more like that found in healthy, non-diabetic people.

We have initiated multiple clinical trials in connection with our Insulin-PH20 program and we plan on initiating additional trials. Our strategy is to develop a best in class insulin product with demonstrated clinical benefits for type 1 and 2 diabetes mellitus patients. The status and/or results from some of these trials are summarized below:

- In July 2009, we initiated a Phase 2 clinical study in patients with type 2 diabetes mellitus. This randomized cross-over design study is designed to compare the postprandial glycemic excursions following a standardized test meal for three treatment regimens: insulin lispro (Humalog®, a mealtime insulin analog) with rHuPH20, regular insulin (Humulin® R, a non-analog insulin) with rHuPH20 and lispro alone. This Phase 2 study will also investigate the pharmacokinetics and glucodynamics of each treatment.
- In June 2009, we announced preliminary results from our Phase 2 clinical trial in type 1 diabetic patients comparing Humalog with and without rHuPH20. These results demonstrated faster insulin absorption and increased peak insulin concentrations after co-administration of rHuPH20 with Humalog. Study results also showed a significant reduction in postprandial blood glucose levels following administration of a standardized test meal, with improvements in both peak glycemic response and total hyperglycemic exposure compared to Humalog alone. Mean glucose levels after the meal challenge remained within current treatment targets throughout the eight hour post meal observation period. We presented these results at the American Diabetes Association (ADA) 69th Scientific Sessions in New Orleans.
- In May 2009, we initiated a Phase 2 clinical trial to compare regular insulin with rHuPH20 to lispro alone. After a one-month observation period that includes dose optimization, patients will be randomized to regular insulin with rHuPH20 or lispro and treated for three months. At the end of three months, patients will crossover to the other study treatment for another three months. The study will evaluate safety and efficacy.

PEGPH20

We are investigating PEGylated-rHuPH20, or PEGPH20, a new molecular entity, as a candidate for the systemic treatment of tumors rich in HA. PEGylation refers to the attachment of polyethylene glycol to our rHuPH20 enzyme, which extends its half life in the blood from less than 30 seconds to more than 24 hours. An estimated 20% to 40% of solid tumors including prostate, breast, pancreas and colon may produce significant amounts of HA that forms a halo-like coating over the surface of the tumor cell. The quantity of HA produced by the tumor cells correlates with increased tumor growth and metastasis and has been linked with tumor progression in some studies.

In preclinical studies, PEGPH20 has been shown to remove the HA coating surrounding several tumor cell lines. Treatment of PC3 (a prostate cancer cell line that produces HA) tumor-bearing mice with PEGPH20 as a single agent demonstrated a slowing of tumor growth relative to controls. Repeat dosing with PEGPH20 produced a sustained depletion of HA in the tumor microenvironment. For tumor models that did not produce HA, the presence of PEGPH20 had no effect. Administration of the combination of PEGPH20 with docetaxel or with liposomal doxorubicin in HA producing animal tumor models produced a significant survival advantage for the combination relative to either chemotherapeutic agent alone.

Additional studies have demonstrated that PEGPH20 can significantly reduce tumor interstitial fluid pressure (IFP) in an animal cancer model in a dose dependent fashion, achieving more than 85% reduction in IFP following IV administration. Elevated tumor IFP has been associated with poor patient prognosis and resistance to chemotherapeutic regimens. Therefore, based on these animal studies and other tests conducted by Halozyme, PEGPH20 may represent a potentially innovative treatment approach against tumors that produce HA.

In the first quarter of 2009, we initiated a Phase 1 clinical trial for our PEGPH20 program. This first in human trial with PEGPH20 is a dose-evaluating, multicenter, pharmacokinetic and pharmacodynamic, safety study, in which patients with advanced solid tumors will receive intravenous administration of PEGPH20 as a single agent.

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Based on initial data from this trial, and after consultation with the FDA, we have revised the original trial design to allow for lower doses of PEGPH20 to be administered with the same frequency. We do not expect this revision of the trial design to delay the completion of this trial.

Chemophase

Chemophase is an investigative drug being developed for potential use in the treatment of patients with superficial bladder cancer. Our Chemophase program combines our rHuPH20 enzyme with mitomycin C, a cytotoxic drug, for direct administration into the bladder immediately after transurethral resection of bladder tumors, a standard surgical treatment for the disease. Many bladder tumor cells produce high quantities of HA and thus treatment to remove the HA coating could increase their exposure to mitomycin C. This may lead to a lower recurrence of the cancer and a better prognosis for patients.

During the first quarter of 2009, we decided to reallocate certain resources previously budgeted for Chemophase to other higher priority programs, such as our Insulin-PH20 and PEGPH20 programs. We are currently exploring strategic alternatives that will allow the Chemophase program to continue its clinical development.

Enhanze Technology

Enhanze Technology, a proprietary drug enhancement approach using rHuPH20, is a broad technology that we have licensed to other pharmaceutical companies. When formulated with other injectable drugs, Enhanze Technology can facilitate the subcutaneous dispersion and absorption of these drugs by temporarily opening flow channels under the skin. Molecules as large as 200 nanometers may pass freely through the extracellular matrix, which recovers its normal density within approximately 24 hours, leading to a drug delivery platform which does not permanently alter the architecture of the skin. The principal focus of our Enhanze Technology platform is the use of rHuPH20 to facilitate subcutaneous route of administration for large molecule biological therapeutics. Potential benefits of subcutaneous administration of these biologics include life cycle management, patient convenience and benefits to payors.

We currently have Enhanze Technology partnerships with Roche and Baxter and we are currently pursuing additional partnerships with pharmaceutical companies that market or develop drugs that could benefit from injection via the subcutaneous route of administration.

Roche Partnership

In December 2006, Halozyme and Roche entered into an Enhanze Technology partnership, or the Roche Partnership. Under the terms of the Roche Partnership, Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds resulting from the collaboration. Roche initially had the exclusive right to apply rHuPH20 to only three pre-defined Roche biologic targets with the option to exclusively develop and commercialize rHuPH20 with an additional ten targets. In December 2008, we announced that Roche elected to add a fourth exclusive target to the three original exclusive targets, and in June 2009 we announced that Roche elected to add a fifth exclusive target. We also previously announced the commencement of Phase 1 clinical trials for products directed at two of the exclusive targets. Roche retains the option to exclusively develop and commercialize rHuPH20 with an additional eight targets through the payment of annual license maintenance fees. Pending the successful completion of various clinical, regulatory and sales events, Roche will be obligated to make milestone payments to us as well as royalty payments on the sales of products that result from the partnership.

Baxter Gammagard Partnership

GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, Halozyme and Baxter entered into an Enhanze Technology partnership, or the Gammagard Partnership. Under the terms of this partnership, Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID. Pending the successful completion of various regulatory and sales milestones, Baxter will be obligated to make milestone payments to us as well as royalty payments on the sales of products that result from the partnership. Baxter is responsible for all development, manufacturing, clinical,

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regulatory, sales and marketing costs under the Gammagard Partnership, 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 January of 2009, we announced the commencement of a Phase 3 clinical trial for GAMMAGARD LIQUID with rHuPH20, and in July 2009, we announced the completion of enrollment for this study.

HYLENEX Partnership

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, facilitates the dispersion and absorption of other injected drugs or fluids. In February 2007, Halozyme and Baxter amended certain existing agreements relating to HYLENEX and entered into a new agreement for kits and formulations with rHuPH20, or the HYLENEX Partnership. Pending the successful completion of a series of regulatory and sales events, Baxter will be obligated to make milestone payments to us as well as royalty payments on the sales of products that result from the partnership. Baxter is responsible for development, manufacturing, clinical, regulatory, sales and marketing costs of the products covered by the HYLENEX Partnership. We will continue to supply Baxter with API for HYLENEX, and Baxter will prepare, fill, finish and package HYLENEX and hold it for subsequent distribution. Baxter has indicated that the HYLENEX product launch will occur in the fourth quarter of 2009. In addition, under the HYLENEX Partnership, Baxter has 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 Halozyme.

Cumulase

Cumulase is an *ex vivo* (used outside of the body) formulation of rHuPH20 to replace the bovine (bull) enzyme currently used for the preparation of oocytes (eggs) prior to IVF during the process of intracytoplasmic sperm injection (ICSI), in which the enzyme is an essential component. Cumulase strips away the HA that surrounds the oocyte, allowing the clinician to then perform the ICSI procedure.

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 they are earned. Nonrefundable upfront payment and license 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 are recognized upon the sale of such products.

During 2006 and 2007, we entered into the Roche Partnership, the HYLENEX Partnership and the Gammagard Partnership. Elements of these partnerships include nonrefundable license fees, reimbursements of research and development services, various clinical, development, regulatory or sales milestones and future product-based or royalty payments, as applicable. Due to our ongoing involvement obligations under these partnerships, we recorded the nonrefundable license fees and annual designation maintenance fees as deferred revenues. Such revenues are being recognized over the terms of the underlying agreements that define the terms of the partnerships.

Costs and Expenses

Cost of Sales. Cost of 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,

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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, 2009, we have incurred research and development expenses of $121.7 million. From January 1, 2006 through June 30, 2009, approximately 9% of our research and development expenses were associated with the research and development of our rHuPH20 enzyme used in our HYLENEX product, and approximately 14% and 13% of our research and development expenses were associated with the development of our PEGPH20 and Insulin-PH20 product candidates, respectively. Due to the uncertainty in obtaining the U.S. Food and Drug Administration, or 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 proprietary product candidates for commercialization. However, we expect our research and development expenses to increase substantially if we are able to advance our product candidates into later stages of clinical development.

Clinical development timelines, likelihood of success and total costs vary widely. We anticipate that we will make ongoing 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. We plan on focusing our resources on those proprietary and partnered product candidates that represent the most valuable economic and strategic opportunities.

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 product candidates will receive regulatory approval or whether any net cash inflow from our other product candidates, or development projects, will commence.

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 SG&A 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, license fees, 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 revenue in accordance with SEC Staff Accounting Bulletin, or SAB, 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 our distributor. We are obligated to accept returns for product that does not meet product specifications. Historically, we have not had any product returns as a result of not meeting product specifications.

Under the terms of the HYLENEX Partnership, 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 certain specified criteria set forth in the HYLENEX Partnership 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 HYLENEX Partnership. 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. Baxter has prepaid $10.0 million of product-based payments. The prepaid product-based payments were initially deferred and are being recognized as product sales revenue as the Company earns such revenue from the sales of HYLENEX by Baxter.

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 they are earned. Nonrefundable upfront payments and license fees, 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 are recognized as earned in accordance with the terms of the underlying agreements.

Share-Based Payments

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*, which we adopted effective January 1, 2006, including the provisions of the SAB No. 107 and 110. 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 No. 123(R) 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 volatilities are based on the historical volatility of our common stock and our peer group. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common

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stock in the foreseeable future, we estimated the dividend yield to be 0%. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience and those of our peer group.

If factors change and we employ different assumptions in the application of SFAS No. 123(R) in future periods, the share-based compensation expense that we record under SFAS No. 123(R) may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123(R). 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 No. 123(R) and SAB No. 107 and 110 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 include 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 or such time that the Company does not expect the goods to be delivered or services to be rendered.

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, 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 API for our Cumulase and HYLENEX products. 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

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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 Measurements

We determine fair value measurements in accordance with SFAS No. 157, *Fair Value Measurements*, and FASB Staff Position, or FSP, No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under U.S. GAAP and enhances disclosures about fair value measurements. FSP No. FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active.

SFAS No. 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.

Cash and cash equivalents of approximately $89.2 million at June 30, 2009 are carried at fair value based on quoted market prices for identical securities (Level 1 inputs).

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, 2008, which contain accounting policies and other disclosures required by U.S. GAAP.

Results of Operations

Three Months Ended June 30, 2009 Compared to Three Months Ended June 30, 2008

Revenues Under Collaborative Agreements Revenues under collaborative agreements were approximately $1.2 million for the three months ended June 30, 2009 compared to $1.4 million for the three months ended June 30, 2008. Revenues under collaborative agreements primarily consisted of the amortization of license fees received from Baxter and Roche of approximately $756,000 and $588,000 for the three months ended June 30, 2009 and 2008, respectively. Revenues under collaborative agreements also included reimbursements for research and development services from Baxter of $276,000 and $554,000 and Roche of $214,000 and $210,000 for the three months ended June 30, 2009 and 2008, respectively. Such reimbursements are for research and development services rendered by us at the request of Baxter and Roche and the amount of future revenues related to reimbursable research and development services is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to increase in future periods provided that we meet various clinical and regulatory milestones set forth in such agreements.

Product Sales Product sales were $180,000 for the three months ended June 30, 2009 compared to $83,000 for the three months ended June 30, 2008. The increase of $97,000 was primarily due to the increase in sales of Cumulase and API for HYLENEX. Based upon representations made to us by Baxter regarding the resources to be allocated to the launch of HYLENEX in the fourth quarter of 2009, we expect product sales to increase in future periods due to increased HYLENEX sales.

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Cost of Sales Cost of sales were $45,000 for the three months ended June 30, 2009 compared to $37,000 for the three months ended June 30, 2008.

Research and Development Research and development expenses were $14.6 million for the three months ended June 30, 2009 compared to $8.9 million for the three months ended June 30, 2008. The increase of $5.7 million, or 64%, was primarily due to the increase in clinical trial expenses of $2.0 million, outsourced research and development costs of $1.9 million related to our various preclinical programs and the manufacturing scale-up of our rHuPH20 enzyme, and increased compensation costs of $1.5 million, of which $160,000 related to increased share-based compensation, primarily due to the increase in our research and development headcount. At June 30, 2009, our headcount for research and development functions totaled 98 employees, compared with 83 employees at June 30, 2008. We expect certain research and development costs to increase in future periods as we increase our research efforts, expand our clinical trials and continue to develop and manufacture our product candidates.

Selling, General and Administrative SG&A expenses were $3.9 million for the three months ended June 30, 2009 compared to $3.8 million for the three months ended June 30, 2008. We expect SG&A expenses to increase in future periods as we continue to expand our operations.

Interest Income Interest income was $24,000 for the three months ended June 30, 2009 compared to $372,000 for the three months ended June 30, 2008. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2009 as compared to the same period in 2008.

Net Loss Net loss was $17.1 million, or $0.21 per common share, for the three months ended June 30, 2009 compared to $11.0 million, or $0.14 per common share for the three months ended June 30, 2008. The increase in net loss was primarily due to an increase in operating expenses.

Six Months Ended June 30, 2009 Compared to Six Months Ended June 30, 2008

Revenues Under Collaborative Agreements Revenues under collaborative agreements were approximately $3.9 million for the six months ended June 30, 2009 compared to $3.0 million for the six months ended June 30, 2008. Revenues under collaborative agreements primarily consisted of the amortization of license fees and milestone payments received from Baxter and Roche of approximately $2.5 million and $1.2 million for the six months ended June 30, 2009 and 2008, respectively. Revenues under collaborative agreements also included reimbursements for research and development services from Baxter of $700,000 and $1.0 million and Roche of $744,000 and $834,000 for the six months ended June 30, 2009 and 2008, respectively. Such reimbursements are for research and development services rendered by us at the request of Baxter and Roche and the amount of future revenues related to reimbursable research and development services is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to increase in future periods provided that we meet various clinical and regulatory milestones set forth in such agreements.

Product Sales Product sales were $258,000 for the six months ended June 30, 2009 compared to $224,000 for the six months ended June 30, 2008. The increase of $34,000 was primarily due to an increase in the sales of HYLENEX API. Based upon representations made to us by Baxter regarding the resources to be allocated to the launch of HYLENEX in the fourth quarter of 2009, we expect product sales to increase in future periods due to increased HYLENEX sales.

Cost of Sales Cost of sales were $49,000 for the six months ended June 30, 2009 compared to $74,000 for the six months ended June 30, 2008.

Research and Development Research and development expenses were $28.6 million for the six months ended June 30, 2009 compared to $17.4 million for the six months ended June 30, 2008. The increase of $11.2 million, or 64%, was primarily due to the increase in outsourced research and development costs of $4.5 million related to our various preclinical programs and the manufacturing scale-up of our rHuPH20 enzyme, and increased compensation costs of $3.2 million, of which $357,000 related to increased share-based compensation, primarily due to the increase in our research and development headcount. At June 30, 2009, our headcount for research and development functions totaled 98 employees, compared with 83 employees at June 30, 2008. Additionally, our clinical trial expenses increased by $2.7 million for the six months ended June 30, 2009. We expect certain research and development costs to increase in future periods as we increase our research efforts, expand our clinical trials and continue to develop and manufacture our product candidates.

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Selling, General and Administrative SG&A expenses were $7.4 million for the six months ended June 30, 2009 compared to $8.0 million for the six months ended June 30, 2008. The decrease of approximately $613,000, or 8%, was primarily due to the decrease in corporate legal expenses of $1.2 million. Legal expenses for the six months ended June 30, 2008 included $635,000 related to the settlement of an arbitration matter. The decrease was also due to a $416,000 decrease in share-based compensation. The decrease was partially offset by a $848,000 increase in compensation costs, excluding share-based compensation. We expect SG&A expenses to increase in future periods as we continue to expand our operations.

Interest Income Interest income was $57,000 for the six months ended June 30, 2009 compared to $1.3 million for the six months ended June 30, 2008. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2009 as compared to the same period in 2008.

Net Loss Net loss was $31.8 million, or $0.38 per common share, for the six months ended June 30, 2009 compared to $21.0 million, or $0.27 per common share for the six months ended June 30, 2008. The increase in net loss was primarily due to an increase in operating expenses and a decrease in interest income, 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, 2009, we had cash and cash equivalents of approximately $89.2 million. We expect our cash requirements to increase 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 additional 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 total net cash burn of approximately $30.0 to $35.0 million for the year ending December 31, 2009, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones under our existing collaborative agreements. We do not expect our revenues to be sufficient to fund operations for several years. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing collaborations and cash that we will raise through future transactions. We may finance future cash needs through any one of the following financing vehicles: (i) the public offering of securities; (ii) new collaborative agreements; (iii) expansions or revisions to existing collaborative relationships; (iv) private financings and/or (v) other equity or debt financings.

In November 2008, we filed a shelf registration statement on Form S-3 (Registration No. 333-155787) which allowed us, from time to time, to offer and sell up to $50.0 million of equity or debt securities. In June 2009, we sold approximately $40.0 million of our common stock in a public offering at a price of $6.50 per share. 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 will 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 in operations was $14.7 million for the six months ended June 30, 2009 compared to $15.7 million of net cash used in operations for the six months ended June 30, 2008.

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Net cash used in investing activities was $747,000 for the six months ended June 30, 2009 compared to $472,000 for the six months ended June 30, 2008. This was primarily due to an increase in purchases of property and equipment during 2009.

Net cash provided by financing activities was $41.0 million for the six months ended June 30, 2009 compared to $913,000 for the six months ended June 30, 2008. Net cash provided by financing activities primarily consisted of net proceeds of $38.2 million from the sale of our common stock in June 2009 and $2.8 million from warrant and stock option exercises.

Off-Balance Sheet Arrangements

As of June 30, 2009, 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, *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. 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, licensing fees and milestone payments to date and may never generate significant revenues from future product sales, licensing fees and milestone payments. Even if we do achieve significant revenues from product sales, licensing fees and/or milestone payments, we expect to incur significant operating losses over the next few years. We have never been profitable, and we may never become profitable. Through June 30, 2009, we have incurred aggregate net losses of approximately $145.4 million.

If our contract manufacturers are unable to manufacture significant amounts of the API used in our products and product candidates, our product development and commercialization efforts could be delayed or stopped and our collaborative partnerships could be damaged.

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc., or Avid, and Cook Pharmica LLC, or Cook, to produce bulk API. These manufacturers each produce API under current Good Manufacturing Practices, or cGMP, for clinical uses. In addition, Avid currently produces API for commercialized products. Avid and Cook will also provide support for the chemistry, manufacturing and controls sections for FDA regulatory filings. We rely on their ability to successfully manufacture these batches according to product specifications and Cook has relatively limited experience manufacturing our API. In addition, as a result of our contractual obligations to Roche, we will be required to significantly scale up our commercial API production at Cook during the next few years. If Cook is unable to obtain status as an FDA-approved manufacturing facility, or if either Avid or Cook: (i) are unable to retain status as FDA-approved manufacturing facilities; (ii) are unable to otherwise successfully scale up our API production; or (iii) fail to manufacture the API required by our proprietary and partnered products and product candidates for any other reason, our business will be adversely affected. We

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have not yet established, and may not be able to establish, favorable arrangements with additional API manufacturers and suppliers of the ingredients necessary to manufacture the API should the existing manufacturers and suppliers become unavailable or in the event that our existing manufacturers and suppliers are unable to adequately perform their responsibilities. Any delays, interruptions or other problems regarding the ability of Avid and/or Cook to supply API on a timely basis could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of proprietary or partnered product candidates; and (ii) delay or prevent the effective commercialization of proprietary or partnered products. Such delays would likely damage our relationship with our partners under our key collaboration agreements and they would have a material adverse effect on our business and financial condition.

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.

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 depend upon the efforts of third parties, such as Baxter for HYLENEX, 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. In some cases, 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 we have problems with third parties that prepare, fill, finish and package our products and product candidates for distribution, our product commercialization and development efforts for these products and product candidates could be delayed or stopped.

We rely on third parties to prepare, fill, finish and package our products and product candidates 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 subsidiary of Baxter to prepare, fill, finish and package HYLENEX under a development and supply agreement. Baxter has limited experience

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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.

Most of our current proprietary and partnered products and product candidates rely on the rHuPH20 enzyme.

The rHuPH20 enzyme is a key technological component of Enhanze Technology, our insulin program, HYLENEX and other proprietary and partnered products and product candidates. An adverse development for rHuPH20 (e.g., we are unable to obtain sufficient quantities of rHuPH20, we are unable to obtain or maintain material proprietary rights to rHuPH20, or we discover negative characteristics of rHuPH20) would substantially impact multiple areas of our business, including current and potential partnerships as well as proprietary programs.

If our proprietary and partnered product candidates do not receive and maintain regulatory approvals, they will not be commercialized, and this failure would substantially impair our ability to generate revenues.

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. To date, two of our product candidates have received regulatory approval from the FDA.

The process for obtaining FDA approval is extensive, time-consuming and costly, and there is no guarantee that the FDA will approve any new drug applications, or NDAs, that may be filed with respect to any of our proprietary or partnered product candidates, or that the timing of any such approval will be appropriate for our desired product launch schedule and other business priorities, which are subject to change. There are no proprietary or partnered product candidates currently in the NDA approval process, and we and our partners may not be successful in obtaining such approvals for any potential products.

Our proprietary and partnered product candidates may not receive regulatory approvals 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 preclinical studies or clinical trial results are promising, we or our partners may obtain different results that fail to show the desired levels of safety and efficacy, or we may not, or our partners may not, obtain FDA approval for a variety of other reasons. Clinical trials for any of our proprietary or partnered product candidates could be unsuccessful, which would delay or prohibit regulatory approval and commercialization of the product candidates. FDA approval can be delayed, limited or not granted for many reasons, including, among others:

- FDA review may not find a product candidate safe or effective enough to merit either continued testing or final approval;
- FDA review may not find that the data from preclinical 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 a proprietary or partnered product candidate in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse impact on our business and we will become more dependent on the development of other proprietary or partnered product candidates and/or our ability to successfully acquire other products and technologies. There can be no assurances that any proprietary or partnered product candidate will receive regulatory approval in a timely manner, or at all.

We anticipate that certain proprietary and partnered products will be marketed, and perhaps 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. Foreign regulatory agencies may not provide 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.

If we or our partners fail to comply with regulatory requirements, regulatory agencies may take action against us or them, 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, 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 and our partners 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 or our partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

Regulatory requirements applicable to pharmaceutical products make the substitution of suppliers and manufacturers costly and time consuming. We have minimal 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.

Later discovery of previously unknown problems with our proprietary or partnered 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;

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- 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.

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 continue the development of our product candidates or for other corporate purposes. Our current cash position and expected revenues during the next few years will not constitute the amount of capital necessary for us to continue the development of our proprietary product candidates and to fund general operations. In addition, 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 expect to raise additional capital in the future through one or more financing vehicles that may be available to us. These financing vehicles currently include: (i) the public offering of securities; (ii) new collaborative agreements; (iii) expansions or revisions to existing collaborative relationships; (iv) private financings and/or (v) other equity or debt financings.

Currently, warrants to purchase approximately 1.8 million shares of our common stock at an exercise price of $2.25 per share are outstanding and this amount of outstanding warrants may make us a less desirable candidate for investment for some potential investors. Considering our stage of development, the nature of our capital structure and general market conditions, 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 proprietary or partnered product candidates are approved by the FDA but do not gain market acceptance, our business may suffer and we may not be able to fund future operations.

Assuming that our proprietary or partnered product candidates obtain the necessary regulatory approvals, a number of factors may affect the market acceptance of these existing product candidates or any other products which are developed or acquired in the future, including, among others:

- the price of 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 these products for their prescribed treatments;
- our ability to fund our sales and marketing efforts and the ability and willingness of our partners to fund sales and marketing efforts;
- the degree to which the use of these products is restricted by the product label approved by the FDA;
- the effectiveness of our sales and marketing efforts and the effectiveness of the sales and marketing efforts of our partners; and
- the introduction of generic competitors.

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If these 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 proprietary and partnered product candidates will be restricted to the labels approved by the FDA and these restrictions may limit the marketing and promotion of the ultimate products. If the approved labels are restrictive, the sales and marketing efforts for these products 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 to be 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. In addition, since many of our partnered product candidates include the pharmaceutical products of a third party, we run the risk that problems with the third party pharmaceutical product will give rise to liability claims against us.

Our inability to attract, hire and retain key management and scientific personnel could negatively affect our business.

Our success depends on the performance of key management and scientific employees with biotechnology experience. Given our relatively small staff size relative to the number of programs currently under development, we depend substantially on our ability to hire, train, motivate and retain high quality personnel, especially our scientists and management team. 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 we may not be able to adequately support current and future alliances with strategic partners.

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 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. In 2008, we adopted a severance policy applicable to all employees and a change in control policy applicable to senior executives. We have not adopted any other policies or entered into any other agreements specifically designed to motivate officers or other employees to remain with us.

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

If we or our partners do not achieve projected development goals in the timeframes we publicly announce or otherwise expect, the commercialization of our products and the development of our product candidates may be delayed and, as a result, our stock price may decline.

We publicly articulate the estimated timing for the accomplishment of certain scientific, clinical, regulatory and other product development goals. The accomplishment of any goal is typically based on numerous assumptions and the achievement of a particular goal may be delayed for any number of reasons both within and outside of our control. If scientific, regulatory, strategic or other factors cause us to not meet a goal, regardless of whether that goal has been publicly articulated or not, the commercialization of our products and the development of our proprietary

and partnered product candidates may be delayed. In addition, the consistent failure to meet publicly announced milestones may erode the credibility of our management team with respect to future milestone estimates.

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 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 impact our relationship with existing or potential partners 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 value to justify 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.

Risks Related To Ownership of 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, 2009 were $8.26 and $2.60, 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 Quarterly Report on Form 10-Q 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:

- a dispute regarding our failure, or the failure of one of our third party partners, to comply with the terms of a collaboration agreement;
- the termination, for any reason, of any of our collaboration agreements;

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- the sale of common stock by any significant stockholder, including, but not limited to, direct or indirect sales by members of management or our Board of Directors;
- the resignation, or other departure, of members of management or 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 proprietary or partnered product candidates;
- 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 any clinical trial due to safety or patient tolerability issues;
- the suspension of any 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;
- our failure, or the failure of our third party partners, to generate product revenues anticipated by investors;
- problems with an API contract manufacturer or a fill and finish manufacturer for any product or product candidate; and
- the sale of additional debt and/or equity securities by us.

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 low trading volume continues, it may be difficult for stockholders to sell their shares in the public market at any given time at prevailing prices.

The exercise of outstanding warrants may drive down the market price of our stock.

Outstanding warrants that may be exercised for approximately 1.8 million shares of common stock at an exercise price of $2.25 per share will expire per their terms on October 12, 2009. Some exercising warrant holders may choose to sell outstanding shares of common stock in order to finance the exercise of their warrants, or they may choose to sell the shares that they receive upon exercise of the warrants. This pattern of selling may result in a reduction of our common stock s market price.

Future sales of shares of our common stock pursuant to our universal shelf registration statement may negatively affect our stock price.

We currently have the ability to offer and sell up to $10.0 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.

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Risks Related To Our Industry

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

Extensive industry regulation has had, and will continue to have, a significant impact on our business. All pharmaceutical companies, including 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.

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

- our patents and pending patent applications cover products and/or technology that we invented first;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate our technologies;
- any of our pending patent applications will result in issued patents; and
- any of our issued patents, or patent pending applications that result in issued patents, will be held valid and infringed in the event the patents are asserted against others.

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We currently own or license several U.S. patents and also have pending patent applications applicable to rHuPh20 and other proprietary materials. 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, or result in issued patents with narrow or limited claims, 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 not be acceptable to regulatory agencies. In addition, 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.

Patent protection for protein-based therapeutic products and other biotechnology inventions is subject to a great deal of uncertainty, and if patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize products based on our discoveries.

Patent protection for protein-based therapeutic products is highly uncertain and involves complex legal and factual questions. In recent years, there have been significant changes in patent law, including the legal standards that govern the scope of protein and biotechnology patents. Standards for patentability of full-length and partial genes, and their corresponding proteins, are changing. Recent court decisions have made it more difficult to obtain patents, by making it more difficult to satisfy the requirement of non-obviousness, have decreased the availability of injunctions against infringers, and have increased the likelihood of challenging the validity of a patent through a declaratory judgment action. Taken together, these decisions could make it more difficult and costly for us to obtain, license and enforce our patents. In addition, in recent years, several members of the United States Congress have made numerous proposals to change the patent statute. These proposals include measures that, among other things, would expand the ability of third parties to oppose United States patents, introduce the first to file standard to the United States patent system, and limit damages an infringer is required to pay. If the patent statute is changed, the scope, validity and enforceability of our patents may be significantly decreased.

There also have been, and continue to be, policy discussions concerning the scope of patent protection awarded to biotechnology inventions. Social and political opposition to biotechnology patents may lead to narrower patent protection within the biotechnology industry. Social and political opposition to patents on genes and proteins may lead to narrower patent protection, or narrower claim interpretation, for genes, their corresponding proteins and inventions related to their use, formulation and manufacture. Patent protection relating to biotechnology products is also subject to a great deal of uncertainty outside the United States, and patent laws are evolving and undergoing revision in many countries. Changes in, or different interpretations of, patent laws worldwide may result in our inability to obtain or enforce patents, and may allow others to use our discoveries to develop and commercialize competitive products, which would impair our business.

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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 purchasing 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.

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 the proprietary or partnered 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 our proprietary and partnered products under development.

Our proprietary and partnered products have numerous competitors in the United States and abroad including, among others, major pharmaceutical and specialized biotechnology firms, universities and other research institutions that have developed competing products. For example, for HYLENEX, such competitors include, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc., Amphastar Pharmaceuticals, Inc. and Primapharm, Inc. among others. For our Insulin-PH20 product candidate, such competitors may include Biodel Inc. and Mannkind Corporation. These competitors may develop technologies and products that are more effective, safer, or less costly than our current or future proprietary and partnered 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 preclinical testing and clinical trials of pharmaceutical product candidates and obtaining FDA and other regulatory approvals of products and therapies for use in healthcare.

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

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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, 2009, 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 investments that we believe to be highly liquid.

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, 2009, 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

We have provided updated Risk Factors in the section labeled Risk Factors in Part I, Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations . The Risk Factors

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section provides updated information in certain areas and we added a risk factor that specifically addresses the importance of rHuPH20 for many products and product candidates, but we do not believe those updates have materially changed the type or magnitude of the risks we face in comparison to the disclosure provided in our most recent Annual Report on Form 10-K.

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

During the three months ended June 30, 2009, we issued 119,628 shares of common stock in connection with the cashless exercise of an outstanding warrant. We did not receive any cash proceeds from this cashless exercise. 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 3(a) (9) 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 7, 2009. At the Annual Meeting, our stockholders voted on the following two proposals:

Proposal No. 1:

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

Nominees	Votes For	Votes Against
Randal J. Kirk	58,727,632	241,691
John S. Patton	51,363,127	7,606,196

We also have: (i) 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, and (ii) three Class I directors, Kathryn E. Falberg, Kenneth J. Kelley and Jonathan E. Lim, M.D., whose terms do not expire until our Annual Meeting of Stockholders in 2011. Both nominees were elected to the board of directors.

Proposal No. 2:

To ratify the selection of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009. The voting results were as follows:

For: 58,911,563 Against: 32,703 Abstained: 25,057

The foregoing proposal was approved.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit	Title
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)

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Exhibit	Title
4.1	Amended Rights Agreement between Corporate Stock Transfer, as rights agent, and Registrant, dated November 12, 2007 (19)
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*	Clinical Supply Agreement between Cook Pharmica, LLC and Registrant, dated August 15, 2008 (23)
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 (20)
10.17#	Form of Stock Option Agreement (2008 Stock Plan)
10.18#	Form of Restricted Stock Agreement (2008 Stock Plan)
10.19#	Halozyme Therapeutics, Inc. 2008 Outside Directors Stock Plan (20)
10.20#	Form of Restricted Stock Agreement (2008 Outside Directors Stock Plan)

10.21#	Form of Indemnity Agreement for Directors and Executive Officers (18)
10.22#	Outside Director Compensation Plan (22)
10.23#	2007 Senior Executive Incentive Plan (22)
10.24#	2008 Senior Executive Incentive Structure (21)
10.25#	2009 Senior Executive Incentive Plan (24)
10.26#	Change in Control Policy (21)
10.27#	Severance Policy (22)
10.28*	Amended and Restated Exclusive Distribution Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)
10.29*	Amended and Restated Development and Supply Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)
10.30*	License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated February 14, 2007 (15)
10.31*	Enhanze Technology License and Collaboration Agreement between Baxter Healthcare Corporation, Baxter Healthcare S.A. and Registrant, dated September 7, 2007 (17)
10.32*	License and Collaboration Agreement between F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and Registrant dated December 5, 2006 (13)
10.33	Sublease Agreement (11404 Sorrento Valley Road), effective as of July 2, 2007 (16)
10.34	Sublease Agreement (11388 Sorrento Valley Road), effective as of July 2, 2007 (16)
10.35	Standard Industrial Net Lease (11388 Sorrento Valley Road), effective as of July 26, 2007 (16)
10.36	Underwriting Agreement, dated June 23, 2009, between Halozyme Therapeutics, Inc. and Jefferies & Company, Inc., dated June 23, 2009 (25)
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

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(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 July 31, 2007.

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

2007.

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

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

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

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

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

(23) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q, filed November 7, 2008.

(24) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 9, 2009.

(25) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed June 23, 2009.

* 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.

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SIGNATURES

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

	Halozyme Therapeutics, Inc., a Delaware corporation
Dated: August 7, 2009	/s/ Jonathan E. Lim Jonathan E. Lim, MD President and Chief Executive Officer (Principal Executive Officer)
Dated: August 7, 2009	/s/ Kurt A. Gustafson Kurt A. Gustafson Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)