HALOZYME THERAPEUTICS INC
Form 10-Q
August 06, 2010

Table of Contents

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, 2010

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 (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 92,024,742 as of August 2, 2010.

HALOZYME THERAPEUTICS, INC.
INDEX

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2010 (Unaudited)	December 31, 2009 (Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 41,312,426	$ 67,464,506
Accounts receivable	2,253,771	4,243,909
Inventory	1,081,876	1,159,551
Prepaid expenses and other assets	4,676,229	1,573,777
Total current assets	49,324,302	74,441,743
Property and equipment, net	2,161,549	2,708,016
Total Assets	$ 51,485,851	$ 77,149,759
Liabilities and Stockholders (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 2,101,349	$ 2,820,491
Accrued expenses	4,134,661	6,083,854
Deferred revenue	4,825,735	5,492,604
Total current liabilities	11,061,745	14,396,949
Deferred revenue, net of current portion	53,857,056	54,989,588
Deferred rent, net of current portion	684,315	859,833
Commitments and contingencies (Note 11)		
Stockholders (deficit) 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; 92,010,298 and 91,681,756 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively	92,010	91,682
Additional paid-in capital	181,739,270	178,821,852
Accumulated deficit	(195,948,545)	(172,010,145)
Total stockholders (deficit) equity	(14,117,265)	6,903,389
Total Liabilities and Stockholders (Deficit) Equity	$ 51,485,851	$ 77,149,759

Note: The balance sheet at

December 31, 2009 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2009	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009
Revenues:				
Product sales	$ 199,530	$ 179,951	$ 597,340	$ 258,158
Revenues under collaborative agreements	3,013,823	1,246,205	6,057,744	3,940,369
Total revenues	3,213,353	1,426,156	6,655,084	4,198,527
Operating expenses:				
Cost of product sales	83,539	45,097	89,199	49,301
Research and development	11,924,406	14,561,137	23,391,610	28,601,224
Selling, general and administrative	3,357,486	3,903,642	7,114,499	7,390,464
Total operating expenses	15,365,431	18,509,876	30,595,308	36,040,989
Operating loss	(12,152,078)	(17,083,720)	(23,940,224)	(31,842,462)
Interest and other income, net	1,155	23,695	1,824	57,073
Net loss	$ (12,150,923)	$ (17,060,025)	$ (23,938,400)	$ (31,785,389)
Basic and diluted net loss per share	$ (0.13)	$ (0.21)	$ (0.26)	$ (0.38)
Shares used in computing basic and diluted net loss per share	91,766,799	82,990,107	91,689,909	82,807,253

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2009
Operating activities:		
Net loss	$ (23,938,400)	$ (31,785,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,420,286	1,870,766
Depreciation and amortization	799,629	680,071
Loss on disposal of equipment	9,609	2,685
Changes in operating assets and liabilities:		
Accounts receivable	1,990,138	6,371,317
Inventory	77,675	(362,211)
Prepaid expenses and other assets	(3,102,452)	(120,436)
Accounts payable and accrued expenses	(2,706,739)	(616,029)
Deferred rent	(144,717)	26,616
Deferred revenue	(1,799,401)	9,234,991
Net cash used in operating activities	(26,394,372)	(14,697,619)
Investing activities:		
Purchases of property and equipment	(255,168)	(746,709)
Net cash used in investing activities	(255,168)	(746,709)
Financing activities:		
Proceeds from exercise of stock options	497,460	581,299
Proceeds from issuance of common stock, net		38,174,371
Proceeds from exercise of warrants, net		2,213,515
Net cash provided by financing activities	497,460	40,969,185
Net (decrease) increase in cash and cash equivalents	(26,152,080)	25,524,857
Cash and cash equivalents at beginning of period	67,464,506	63,715,906
Cash and cash equivalents at end of period	$ 41,312,426	$ 89,240,763
Supplemental disclosure of non-cash investing and financing activities:		
Accounts payable for purchases of property and equipment	$ 7,603	$ 32,788

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

1. Organization and Business

Halozyme Therapeutics, Inc. (Halozyme or the Company) is a biopharmaceutical company 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 based primarily 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 multiple proprietary programs in various stages of research and development. In addition, the Company has entered into a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (Roche) to apply EnhanzeÔ Technology to Roche s biological therapeutic compounds for up to 13 targets. The Company has also entered into two key partnerships with Baxter Healthcare Corporation (Baxter) to apply Enhanze Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUIDÔ and to develop and supply active pharmaceutical ingredient (API) for HYLENEX® (hyaluronidase human injection). Baxter is responsible for the execution of HYLENEX clinical development, sales and marketing strategy. There are two marketed products that utilize the Company s technology: HYLENEX, a product used as an adjuvant to enhance 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 API to the third party that produces Cumulase, in addition to other 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, 2009. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented, with such adjustments consisting only of normal recurring adjustments. Operating results for interim periods are not necessarily indicative of the operating results for an entire fiscal year.

The 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.

3. Pending Adoption of Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-17, Revenue Recognition (Topic 605): *Milestone Method of Revenue Recognition*. ASU No. 2010-17 states that the milestone method is a valid application of the proportional performance model

6

when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. The guidance in ASU No. 2010-17 is effective for fiscal years beginning on or after June 15, 2010 and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented. Early adoption is permitted provided that the revised guidance is retrospectively applied to the beginning of the year of adoption. The Company does not expect the adoption of ASU No. 2010-17 to have a material impact on its consolidated financial position or results of operations.

In September 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605): *Multiple-Deliverable Revenue Arrangements*. ASU No. 2009-13 requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. ASU No. 2009-13 eliminates the use of the residual method of allocation and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue for an arrangement with multiple deliverables subject to Accounting Standards Code 605-25. The guidance in ASU No. 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. The Company does not expect the adoption of ASU No. 2009-13 to have a material impact on its consolidated financial position or results of operations.

4. Summary of Significant Accounting Policies

Fair Value Measurements

The Company follows the authoritative guidance for fair value measurements and disclosures, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The framework for measuring fair value provides a hierarchy that prioritizes the inputs to valuation techniques used in measuring fair value as follows:

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 equivalents of approximately $38.1 million at June 30, 2010 are carried at fair value and are classified within Level 1 of the fair value hierarchy because they are valued based on quoted market prices for identical securities.

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 the authoritative guidance for revenue recognition. 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 and API for 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 returns of API 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. On May 17, 2010, the Company and Baxter notified the U.S. Food and Drug Administration (FDA) of the voluntary recall of HYLENEX due to the discovery of small flake-like glass particles in some vials of HYLENEX. In connection with the recall, the Company did not recognize any royalty revenues from the product sales in the quarter ended June 30, 2010 based on management s assessment that these product sales will be returned.

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, API for Cumulase and the API for HYLENEX. Cost of product sales associated with the sales of API for HYLENEX is recognized as the product is released which may result in irregular quarterly fluctuations that may not correspond to the amount of revenue recognized from product sales for such quarters.

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 other regulatory authorities or when other significant risk factors are abated. Management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain and has expensed these amounts for accounting purposes.

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.

Share-Based Compensation

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,**	
	2010	**2009**	**2010**	**2009**
Research and development	$ 671,667	$ 506,762	$ 1,357,868	$ 968,008
Selling, general and administrative	519,834	542,048	1,062,418	902,758
Share-based compensation expense before tax	1,191,501	1,048,810	2,420,286	1,870,766
Related income tax benefit				
Share-based compensation expense, net of tax	$ 1,191,501	$ 1,048,810	$ 2,420,286	$ 1,870,766
Net share-based compensation expense per basic and diluted share	$ 0.01	$ 0.01	$ 0.03	$ 0.02
Share-based compensation expense from:				
Stock options	$ 1,037,626	$ 737,474	$ 2,096,392	$ 1,418,465
Restricted stock awards	153,875	311,336	323,894	452,301
	$ 1,191,501	$ 1,048,810	$ 2,420,286	$ 1,870,766

Since the Company has a net operating loss carryforward as of June 30, 2010, 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, 2010 and 2009, employees exercised stock options to

Table of Contents

purchase 8,728 and 320,313 shares of common stock, respectively, for aggregate proceeds of approximately $34,000 and $347,000, respectively. For the six months ended June 30, 2010 and 2009, employees exercised stock options to purchase 208,542 and 448,430 shares of common stock, respectively, for aggregate proceeds of approximately $497,000 and $581,000, respectively.

As of June 30, 2010, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock awards granted prior to that date was approximately $9.3 million and $844,000, respectively, which is expected to be recognized over a weighted-average period of approximately 2.7 years and six months, respectively.

5. Inventory

Inventory at June 30, 2010 and December 31, 2009 consists of raw materials used in production of HYLENEX and Cumulase products.

6. Property and Equipment

Property and equipment, net consists of the following:

	June 30, 2010	December 31, 2009
Research equipment	$ 4,042,565	$ 3,838,307
Computer and office equipment	1,271,826	1,333,924
Leasehold improvements	987,935	981,140
	6,302,326	6,153,371
Accumulated depreciation and amortization	(4,140,777)	(3,445,355)
	$ 2,161,549	$ 2,708,016

Depreciation and amortization expense totaled approximately $389,000 and $351,000 for the three months ended June 30, 2010 and 2009, respectively, and $800,000 and $680,000 for the six months ended June 30, 2010 and 2009, respectively.

7. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2010	December 31, 2009
Accrued compensation and payroll taxes	$ 2,435,681	$ 2,945,498
Accrued outsourced research and development expenses	905,065	2,609,819
Accrued expenses	793,915	528,537
	$ 4,134,661	$ 6,083,854

8. Deferred Revenue

Deferred revenue consists of the following:

	June 30, 2010	December 31, 2009
Collaborative agreements	$ 47,938,303	$ 50,390,400
Product sales	10,744,488	10,091,792
Total deferred revenue	58,682,791	60,482,192

Less current portion	4,825,735	5,492,604
Deferred revenue, net of current portion	$ 53,857,056	$ 54,989,588

Table of Contents

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, and up to thirteen Roche target compounds resulting from the collaboration. Roche paid $20.0 million to the Company in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. In addition, through June 30, 2010 Roche paid an aggregate of approximately $17.0 million in connection with Roche s election of two additional exclusive targets and annual license fees for the right to designate the remaining targets as exclusive targets.

Due to the Company s continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), revenues from the upfront payment, exclusive designation fees and annual license 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 license maintenance fees under the Roche Partnership in the amounts of approximately $530,000 and $458,000 for the three months ended June 30, 2010 and 2009, respectively, and $1.1 million and $900,000 for the six months ended June 30, 2010 and 2009, respectively.

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 (for example, support activities associated with rHuPH20 enzyme), 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 amounts of approximately $140,000 and $152,000 for the three months ended June 30, 2010 and 2009, respectively, and $279,000 and $303,000 for the six months ended June 30, 2010 and 2009, respectively.

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 (for example, support activities associated with rHuPH20 enzyme), 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 amounts of approximately $135,000 and $147,000 for the three months ended June 30, 2010 and 2009, respectively, and $270,000 and $293,000 for the six months ended June 30, 2010 and 2009, respectively.

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. The Company recognized revenue from product-based payments in the amounts of approximately $0 and $30,000 for the three months ended June 30, 2010 and 2009, respectively, and $332,000 and $57,000 for the six months ended June 30, 2010 and 2009, respectively.

9. Net Loss Per Share

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,	
	2010	**2009**
Stock options and awards	8,892,438	8,010,845
Warrants		1,756,286

	8,892,438	9,767,131

Table of Contents

10. Stockholders (Deficit) Equity

During the six months ended June 30, 2010 and 2009, holders of the Company s outstanding options exercised rights to purchase approximately 209,000 and 448,000 common shares, respectively, at weighted exercise prices of $2.39 and $1.30 per share, respectively, for net proceeds of approximately $497,000 and $581,000, respectively. Options to purchase approximately 8.7 million and 7.8 million shares of the Company s common stock were outstanding as of June 30, 2010 and December 31, 2009, respectively.

During the six months ended June 30, 2009, holders of the Company s outstanding warrants exercised warrants to purchase approximately 1.4 million shares of common stock at an exercise price of $1.81 per share for net proceeds of approximately $2.2 million. There were no warrants outstanding as of June 30, 2010 and December 31, 2009.

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.

On May 16, 2010, the Company delivered a notice of breach to Baxter due to Baxter s failure to provide HYLENEX in accordance with the terms of existing development and supply contracts. In the event that Baxter is unable to remedy all material breaches within the timeframe specified in the agreements (as much as 120 days following the delivery of the notice of breach), the Company may terminate the HYLENEX relationship. In the event that the HYLENEX agreements are terminated by the Company, Baxter may challenge the Company s right to terminate such agreements and litigation may be necessary to resolve the dispute. In addition, Baxter has contested the claims made in our initial notice of breach and asserted their own breach claims against us. We believe these claims are without merit and we expect to prevail in any dispute relating to the HYLENEX agreements.

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 based primarily 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 both normal tissues throughout the body, such as skin and cartilage, and abnormal tissues such as tumors. Our primary technology is based on our proprietary recombinant human PH20 enzyme, or rHuPH20, a human synthetic version of hyaluronidase. The PH20 enzyme is a naturally occurring enzyme that temporarily degrades HA, 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 through 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 multiple proprietary programs in various stages of research and development. In addition, we have entered into a key partnership with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc., or Roche, to apply EnhanzeÔ Technology to Roche s biological therapeutic compounds for up to 13 targets. We have also entered into two key partnerships with Baxter Healthcare Corporation, or Baxter, to apply Enhanze Technology to Baxter s biological therapeutic compound, GAMMAGARD LIQUIDÔ and to develop and supply active pharmaceutical ingredient, or API, for HYLENEX®. There are two marketed products that utilize our technology: HYLENEX, a product used as an adjuvant to enhance the dispersion and absorption of other injected drugs and fluids, and Cumulase®, a product used for *in vitro* fertilization, or IVF. On May 17, 2010, we and Baxter notified the U.S. Food and Drug Administration (FDA) of the voluntary recall of HYLENEX due to the discovery of small flake-like glass particles in some vials of HYLENEX. Currently, we receive only limited revenue from the sales of API for HYLENEX and the sales of API to the third party that produces Cumulase, in addition to other revenues from our partnerships with Baxter and Roche.

13

Table of Contents

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 $195.9 million as of June 30, 2010.

In January 2010, we filed a shelf registration statement on Form S-3 (Registration No. 333-164215) which allows us, from time to time, to offer and sell up to $100.0 million of equity or debt securities. 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.

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 products and product candidates as well as our partnered products and product candidates:

Table of Contents

Ultrafast Insulin Program

Our lead proprietary program focuses on the formulation of rHuPH20 with prandial (mealtime) insulins 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 regular insulin (such combinations are referred to as Insulin-PH20) or a rapid acting analog insulin, i.e., insulin lispro (Humalog®), insulin aspart (Novolog®) and insulin glulisine (Apidra®) (such combinations are referred to as Analog-PH20), facilitates faster insulin dispersion in, and absorption from, the subcutaneous space into the vascular compartment leading to faster insulin response. By making mealtime insulin onset faster, i.e., providing earlier insulin to the blood and thus earlier glucose 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.

The primary goal of our ultrafast insulin program is to develop a best-in-class insulin product, with demonstrated clinical benefits for type 1 and 2 diabetes mellitus patients, in comparison to the current standard of care analog products that participate in the growing $3.8 billion prandial insulin market. We are developing Insulin-PH20 and Analog-PH20 in parallel to explore a maximum range of value creating opportunities. With a more rapidly absorbed, faster acting insulin product, we seek to demonstrate one or more significant improvements relative to existing treatment, such as improved glycemic control, less hypoglycemia, and less weight gain. A number of Phase 1 and Phase 2 clinical pharmacology trials, and registration trial-enabling treatment studies in connection with our ultrafast insulin program are ongoing or planned, that will investigate the various attributes of our insulin product candidates. The status of some of these trials is summarized below:

In September 2009, we initiated a Phase 1 clinical study designed to assess the effects of three approved prandial insulin analogs administered with rHuPH20 compared to each of the analogs alone, each delivered at a standardized dose. This randomized, six-way cross-over design, euglycemic clamp study compared the postprandial pharmacokinetics and glucodynamics of the insulin analogs with and without rHuPH20. This study was completed in February 2010. The clinical trial results showed that the addition of rHuPH20 to three different mealtime insulin analogs accelerated their absorption. The acceleration produced by the coadministration of rHuPH20 produced significantly more pronounced insulin action during the first two hours after injection followed by a more rapid diminution of insulin effects compared to the analogs alone. The coinjection of PH20 with lispro, aspart and glulisine results in a more physiologic fast-in, fast-out profile and accelerates the glucodynamic profile for each analog. The results from this study were presented at the American Diabetes Association, or ADA, 70th Scientific Sessions in Orlando in June 2010.

In July 2009, we initiated a Phase 2 clinical study in patients with type 2 diabetes mellitus. This randomized cross-over design study was designed to compare the postprandial glycemic excursions following a standardized test meal for three treatment regimens: insulin lispro with rHuPH20, regular insulin with rHuPH20 and lispro alone, each delivered at an individually optimized dose. The clinical trial results showed that injection of insulin lispro with rHuPH20 reduces both hyperglycemic excursions and incidence of hypoglycemia relative to insulin lispro alone, and that the optimum dose of insulin lispro was reduced when coinjected with rHuPH20. This study was completed in March 2010, and results from this study were also presented at the ADA 70th Scientific Sessions in Orlando in June 2010.

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 included dose optimization, patients were randomized to regular insulin with rHuPH20 or lispro and treated for three months. At the end of three months, patients were crossed over to the other study treatment for another three months. This study was designed to evaluate the safety and efficacy of Insulin-PH20 relative to a standard of care therapy, Humalog. The study is now complete, and we intend to present results of the study at the Tenth Annual Diabetes Technology Meeting, November 2010, in Bethesda, Maryland.

In the third quarter of 2010, we intend to initiate two randomized double-blind Phase 2 clinical trials, one in patients with type 1 diabetes and the other in patients with type 2 diabetes, each designed to compare two

Table of Contents

investigational drug products, Aspart-PH20 and Lispro-PH20, for medical benefits such as improved glycemic control (A1C), reduced hypoglycemia, and/or reduced weight gain relative to a standard of care therapy. Each study will have a primary objective of demonstrating non-inferiority in A1C although they will also have sufficient power to demonstrate a meaningful improvement in A1C for either investigational drug relative to the active comparator in either patient population.

PEGPH20

We are investigating a PEGylated version of 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 one minute to approximately 48-72 hours. An estimated 20% to 30% of solid tumors, including prostate, breast, pancreas and colon, accumulate significant amounts of HA that forms a halo-like coating over the surface of the tumor. The quantity of HA produced by the tumor 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 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, liposomal doxorubicin and gemcitabine 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-escalation, multicenter, pharmacokinetic and pharmacodynamic, safety study, in which patients with advanced solid tumors are receiving intravenous administration of PEGPH20 as a single agent. Based on initial data from this trial, and after consultation with the FDA, lower doses of PEGPH20 are now employed at a lower dosing frequency. The study is actively enrolling and in a dose escalation phase. In July 2010, we initiated a second Phase 1 clinical trial with PEGPH20 in the treatment of solid tumors. The new trial will incorporate the use of oral dexamethasone as a pretreatment for all patients prior to receiving intravenous administration of PEGPH20.

Enhanze Technology

Enhanze Technology, a proprietary drug delivery enhancement platform 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. 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, some of which currently require intravenous administration. Potential benefits of subcutaneous administration of these biologics include life cycle management, patient convenience, reductions in infusion reactions and benefits to payors.

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

Table of Contents

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. Roche elected to add a fourth exclusive target to the three original exclusive targets in December 2008 and a fifth exclusive target in June 2009. 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.

Compounds directed at three of the Roche exclusive targets have previously commenced clinical trials. One compound is in a Phase 1 clinical trial, one compound has completed a Phase 1 clinical trial and the third compound is in a Phase 3 clinical trial. In October 2009, Roche commenced the first Phase 3 clinical trial for a compound directed at an exclusive target. This Phase 3 clinical trial is for a subcutaneously delivered version of Roche s anticancer biologic, Herceptin (trastuzumab). The study will investigate the pharmacokinetics, efficacy and safety of subcutaneous Herceptin in patients with HER2-positive breast cancer as part of adjuvant treatment. Herceptin is approved to treat HER2-positive breast cancer and currently is given intravenously. Breast cancer is the most common cancer among women worldwide. Each year, more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually. In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumor cells. This is known as HER2 positivity and affects approximately 20-25% of women with breast cancer.

In September 2009, Roche began a Phase 1 clinical trial for a subcutaneous formulation of MabThera® (rituximab). The study will investigate the pharmacokinetics and tolerability of subcutaneous MabThera in patients with follicular lymphoma as part of maintenance treatment. Intravenously administered MabThera is approved for the treatment of non-Hodgkin s lymphoma (NHL), a type of cancer that affects lymphocytes, or white blood cells. An estimated 66,000 new cases of NHL were diagnosed in the U.S. in 2009 with approximately 125,000 new cases reported worldwide.

Additional information about the Phase 3 subcutaneous Herceptin and Phase 1 subcutaneous MabThera clinical trials can be found at www.clinicaltrials.gov and www.roche-trials.com.

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, 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, Baxter commenced a Phase 3 clinical trial for GAMMAGARD LIQUID with rHuPH20, and in July 2009, the enrollment for this study was completed.

HYLENEX Partnership

HYLENEX is a formulation of rHuPH20 that, when injected under the skin, enhances 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.

In October 2009, Baxter commenced the commercial launch of HYLENEX recombinant (hyaluronidase human injection) for use in pediatric rehydration at the 2009 American College of Emergency Physicians (ACEP) scientific assembly (Boston). 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, (ii) cytostatic and cytotoxic chemotherapeutic agents and (iii) proprietary small molecule drugs, the rights to which have been retained by Halozyme.

On May 16, 2010, we delivered a notice of breach to Baxter due to Baxter s failure to provide HYLENEX in accordance with the terms of existing development and supply contracts. The notice of breach was sent after Baxter informed us that a portion of the HYLENEX produced by Baxter was not in compliance with the requirements of the underlying agreements with Baxter. In the event that Baxter is unable to remedy all material breaches within the timeframe specified in the agreements (as much as 120 days following the delivery of the notice of breach), we may terminate the HYLENEX relationship. Baxter has contested the claims made in our initial notice of breach and asserted their own breach claims against us. We believe these claims are without merit and we expect to prevail in any dispute relating to the HYLENEX agreements.

On May 17, 2010, we and Baxter notified the FDA of the voluntary recall of HYLENEX due to the discovery of small flake-like glass particles in some vials of HYLENEX. This action was taken as a precautionary measure in order to ensure patient safety. No medical events associated with noncompliant HYLENEX products have been reported. Our clinical assessment is that the health risk posed by the noncompliant HYLENEX product is low. Neither the rHuPH20 bulk enzyme nor any other products containing the enzyme are affected by the HYLENEX recall. Since the announcement of the recall, we have worked to identify the root cause of the noncompliant HYLENEX and we are currently preparing materials to present to the FDA in connection with the proposed reintroduction of HYLENEX. We hope to meet with the FDA in August 2010, and we will not be able to predict the timing for HYLENEX reintroduction until after meeting with the FDA.

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 payments 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.

Elements of our collaborative partnerships include nonrefundable license fees, reimbursements of research and development services, various clinical, regulatory or sales milestones and future product-based or royalty payments, as applicable. Due to our ongoing involvement obligations under these partnerships, we recorded the nonrefundable license fees and annual license 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 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 API for Cumulase and HYLENEX. Cost of product sales associated with the sales of API for HYLENEX is recognized as the product is released which may result in irregular quarterly fluctuations that may not correspond to the amount of revenue recognized from product sales for such quarters.

Research and Development. Our research and development expenses include salaries and benefits, research-related manufacturing services, clinical trials, contract research services, supplies and materials, facilities and other overhead costs and other outside expenses. 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, 2010, we have incurred research and development expenses of $173.1 million. From January 1, 2007 through June 30, 2010, approximately 21% and 15% of our research and development expenses were associated with the development of our ultrafast insulin and PEGPH20 product candidates, respectively. Due to the uncertainty in obtaining FDA and other regulatory approvals, 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 as our product candidates advance 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 existing resource levels, 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.

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 revenues in accordance with the authoritative guidance on revenue recognition. 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 sales of API for 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 returns of API 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 we earn such revenue from the sales of HYLENEX by Baxter. On May 17, 2010, we and Baxter notified the FDA of the voluntary recall of HYLENEX due to the discovery of small flake-like glass particles in some vials of HYLENEX. In connection with the recall, we did not recognize any royalty revenues from the product sales in the quarter ended June 30, 2010 based on management s assessment that these product sales will be returned.

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 use the fair value method to account for share-based payments in accordance with the authoritative guidance for stock compensation. 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. 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 stock in the foreseeable future, we estimated the dividend yield to be 0%. Forfeitures are 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.

If factors change and we employ different assumptions for determination of fair value in future periods, the share-based compensation expense that we record 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. 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 authoritative guidance on stock compensation 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, 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 our 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 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 regulatory bodies such as the FDA or when other significant risk factors are abated. Management has viewed future economic benefits for all of our licensed technology or product candidates to be uncertain and has expensed these amounts for accounting purposes.

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

Table of Contents

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 raw materials used in production, work in process and finished goods inventory on hand related to our HYLENEX and Cumulase products. Inventory is valued at lower of cost or market (net realizable value) using the first-in, first-out method. Inventory is reviewed periodically for slow-moving or obsolete status. To the extent that its net realizable value is lower than cost, an impairment would be recorded.

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, 2009, which contain accounting policies and other disclosures required by U.S. GAAP.

Results of Operations

Three Months Ended June 30, 2010 Compared to Three Months Ended June 30, 2009

Product Sales Product sales were $200,000 for the three months ended June 30, 2010 compared to $180,000 for the three months ended June 30, 2009. The increase of $20,000 was primarily due to the increase in sales of API for HYLENEX; offset in part by a decrease in recognition of the product-based payments. Based on the voluntary recall of HYLENEX announced in May 2010, we expect total product sales to decrease in future periods until HYLENEX is reintroduced to the market.

Revenues Under Collaborative Agreements Revenues under collaborative agreements were approximately $3.0 million for the three months ended June 30, 2010 compared to $1.2 million for the three months ended June 30, 2009. Revenues under collaborative agreements consisted of the amortization of license fees received from Baxter and Roche of approximately $804,000 and $756,000 for the three months ended June 30, 2010 and 2009, respectively, and reimbursements for research and development services from Baxter of $894,000 and $276,000 and Roche of $1.2 million and $214,000 for the three months ended June 30, 2010 and 2009, respectively. Such reimbursements are for research and development services rendered by us at the request of Roche and Baxter 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.

Cost of Product Sales Cost of product sales were $84,000 for the three months ended June 30, 2010 compared to $45,000 for the three months ended June 30, 2009. The increase of $39,000 was primarily due to the increase in the sales of HYLENEX API. Based on the voluntary recall of HYLENEX announced in May 2010, we expect total cost of product sales to decrease in future periods until HYLENEX is reintroduced to the market.

Research and Development Research and development expenses were $11.9 million for the three months ended June 30, 2010 compared to $14.6 million for the three months ended June 30, 2009. The decrease of $2.7 million, or 18%, was primarily due to a $1.6 million decrease in research-related manufacturing activities and a $1.6 million decrease in clinical trial expenses mainly related to the ultrafast insulin program. The decrease was partially offset by increases in other research activities. We expect 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 $3.4 million for the three months ended June 30, 2010 compared to $3.9 million for the three months ended June 30, 2009. The decrease of $546,000 or 14% is mainly due to the decrease in salaries expense and bonus accrual.

Interest and Other Income, Net Interest and other income consisted of interest income of $6,000 for the three months ended June 30, 2010 compared to $24,000 for the three months ended June 30, 2009. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2010 as compared to the same period in 2009. Interest and other income (expense) also included other expense of $5,000 and $0 for the three months ended June 30, 2010 and 2009, respectively.

Net Loss Net loss was $12.2 million, or $0.13 per common share, for the three months ended June 30, 2010 compared to $17.1 million, or $0.21 per common share, for the three months ended June 30, 2009. The decrease in net loss was primarily due to the decrease in operating expenses and the increase in revenues.

Six Months Ended June 30, 2010 Compared to Six Months Ended June 30, 2009

Product Sales Product sales were $597,000 for the six months ended June 30, 2010 compared to $258,000 for the six months ended June 30, 2009. The increase of $339,000 was primarily due to an increase in recognition of the product-based payments from the increased sales of HYLENEX and an increase in the sales of HYLENEX API. Based on the voluntary recall of HYLENEX announced in May 2010, we expect total product sales to decrease in future periods until HYLENEX is reintroduced to the market.

Revenues Under Collaborative Agreements Revenues under collaborative agreements were approximately $6.1 million for the six months ended June 30, 2010 compared to $3.9 million for the six months ended June 30, 2009. Revenues under collaborative agreements consisted of the amortization of license fees and milestone payments received from Baxter and Roche of approximately $1.6 million and $2.5 million for the six months ended June 30, 2010 and 2009, respectively, and reimbursements for research and development services from Baxter of $2.4 million and $700,000 and Roche of $1.8 million and $744,000 for the six months ended June 30, 2010 and 2009, respectively. Such reimbursements are for research and development services rendered by us at the request of Roche and Baxter 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.

Cost of Sales Cost of sales were $89,000 for the six months ended June 30, 2010 compared to $49,000 for the six months ended June 30, 2009. The increase of $40,000 was primarily due to the increase in the sales of HYLENEX API. Based on the voluntary recall of HYLENEX announced in May 2010, we expect total cost of product sales to decrease in future periods until HYLENEX is reintroduced to the market.

Research and Development Research and development expenses were $23.4 million for the six months ended June 30, 2010 compared to $28.6 million for the six months ended June 30, 2009. The decrease of $5.2 million, or 18%, was primarily due to $4.1 million decrease in research-related manufacturing activities and a $2.6 million decrease in clinical trial expenses mainly related to the ultrafast insulin program. The decrease was partially offset by the increased compensation costs of $1.5 million primarily due to the increase in our research and development headcount. At June 30, 2010, our headcount for research and development functions totaled 108 employees, compared with 98 employees at June 30, 2009. We expect 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 $7.1 million for the six months ended June 30, 2010 compared to $7.4 million for the six months ended June 30, 2009. The decrease of approximately $276,000, or 4%, was primarily due to the decrease in compensation costs.

Interest and Other Income Interest and other income consisted of interest income of $9,000 and $62,000 for the six months ended June 30, 2010 and 2009, respectively. The decrease in interest income was primarily due to lower interest rates and lower average cash and cash equivalent balances in 2010 as compared to the same period in

2009. Interest and other income (expense) also included other expense of $7,000 and $5,000 for the six months ended June 30, 2010 and 2009, respectively.

Net Loss Net loss was $23.9 million, or $0.26 per common share, for the six months ended June 30, 2010 compared to $31.8 million, or $0.38 per common share for the six months ended June 30, 2009. The decrease in net loss was primarily due to the decrease in operating expenses and the increase in revenues.

Liquidity and Capital Resources

Overview

Our principal sources of liquidity are our existing cash and cash equivalents. As of June 30, 2010, we had cash and cash equivalents of approximately $41.3 million. We will continue to have significant cash requirements to support product development activities. The amount and timing of cash requirements will depend on the success of our clinical development programs, regulatory and market acceptance, and the resources we devote to research and other commercialization activities.

Currently, we anticipate total net cash burn of approximately $40.0 to $45.0 million for the year ending December 31, 2010, 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 at least 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 or private issuance of securities; (ii) new collaborative agreements; and/or (iii) expansions or revisions to existing collaborative relationships.

In January 2010, we filed a shelf registration statement on Form S-3 (Registration No. 333-164215) which allows us, from time to time, to offer and sell up to $100.0 million of equity or debt securities. 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 existing cash and cash equivalents will not be adequate to fund our operations until we become cash flow positive, if ever. We cannot be certain that additional financing will be available when needed or, if available, on favorable terms. If we do not obtain additional funds during the second half of 2010, we will need to delay, scale back or eliminate some or all of our research and development programs, delay the launch of our product candidates, if approved, and/or restructure our operations. 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, the issuance of warrants that may ultimately dilute existing stockholders when exercised, as well as covenants that may restrict our ability to operate our business.

Cash Flows

Net cash used in operations was $26.4 million for the six months ended June 30, 2010 compared to $14.7 million of net cash used in operations for the six months ended June 30, 2009. The change was primarily due to a $13.6 million decrease in receipts from partnership payments as compared to the same period in 2009. The decrease was partially offset by decreased operating expenses of $5.4 million in the six months ended June 30, 2010 as compared to the same period in 2009.

Net cash used in investing activities was $255,000 for the six months ended June 30, 2010 compared to $747,000 for the six months ended June 30, 2009. This was primarily due to a decrease in purchases of property and equipment in the six months ended June 30, 2010.

Net cash provided by financing activities was $497,000 for the six months ended June 30, 2010 compared to $41.0 million for the six months ended June 30, 2009. Net cash provided by financing activities in 2010 primarily consisted of net proceeds from stock option exercises. Net cash provided by financing activities for the six months ended June 30, 2009 consisted of $38.2 million in net proceeds from the sale of our common stock in June 2009 and $2.8 million in net proceeds from warrant and stock option exercises.

Off-Balance Sheet Arrangements

As of June 30, 2010, 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.

Relative to expenses incurred in our operations, we have generated only minimal revenue from product sales, licensing fees and milestone payments to date and we may never generate sufficient revenues from future product sales, licensing fees and milestone payments to offset expenses. Even if we ultimately 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, 2010, we have incurred aggregate net losses of approximately $195.9 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 and other 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 a cGMP-approved manufacturing facility, or if either Avid or Cook: (i) are unable to retain status as cGMP-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 have not 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. We have attempted to mitigate the impact of supply interruption through the establishment of excess API inventory, but there can be no assurances that this safety stock will be maintained or that it will be sufficient to address any delays, interruptions or other problems experienced by Avid and/or Cook. 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; (ii) delay or prevent the effective commercialization of proprietary or partnered products and/or (iii) cause us to breach contractual obligations to deliver API to our partners. 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.

Our key partners are responsible for providing certain proprietary materials that are essential components of our partnered product candidates, and any failure to supply these materials could delay the development and commercialization efforts for these partnered product candidates and/or damage our collaborative partnerships.

Our partners are responsible for providing certain proprietary materials that are essential components of our partnered product candidates. For example, Roche is responsible for producing the Herceptin and MabThera required for its subcutaneous product candidates and Baxter is responsible for producing the GAMMAGARD LIQUID for its product candidate. If a partner, or any applicable third party service provider of a partner, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of either components of the partnered product candidate or the partnered product candidate itself, such difficulties could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of partnered product candidates; and/or (ii) delay or prevent the effective commercialization of partnered products. Such delays could have a material adverse effect on our business and financial condition. For example, Baxter received a Warning Letter from the FDA in January 2010 regarding Baxter s GAMMAGARD LIQUID manufacturing facility in Lessines, Belgium. The FDA indicated in March 2010 that the issues raised in the Warning Letter had been addressed by Baxter and we do not expect these issues to impact the development of the GAMMAGARD LIQUID product candidate.

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

We have entered into multiple 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.

For example, in May 2010, we delivered a notice of breach to Baxter Healthcare Corporation due to Baxter s failure to provide HYLENEX in accordance with the terms of existing development and supply contracts. The notice of breach was sent after Baxter informed us that HYLENEX produced by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements. In the event that Baxter is unable to remedy all material breaches within the timeframe specified in the agreements (as much as 120 days following the delivery of the notice of breach), we may terminate the HYLENEX relationship. Baxter has contested the claims made in our initial notice of breach and asserted their own breach claims against us, but we believe these claims are without merit and we expect to prevail in any dispute relating to the HYLENEX agreements. In the event that the HYLENEX agreements with Baxter are terminated, either by us or by Baxter, we do not anticipate any revisions to corporate strategy or any material impact on our ability to enter into additional collaborative agreements, provided that an ongoing dispute regarding HYLENEX could limit our ability to license HYLENEX to a new partner.

If we have problems with third parties that either distribute API on our behalf or prepare, fill, finish and package our products and product candidates for distribution, our commercialization and development efforts for our products and product candidates could be delayed or stopped.

We rely on third parties to store and ship API on our behalf and to also 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 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. 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.

For example, because a portion of the HYLENEX produced by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. Since the announcement of the recall, we have worked to identify the root cause of the noncompliant HYLENEX and we are currently preparing materials to present to the FDA in connection with the proposed reintroduction of HYLENEX. We hope to meet with the FDA in August 2010, and we will not be able to predict the timing for HYLENEX reintroduction until after meeting with the FDA.

In order to continue operations at current levels, we will require additional capital in the next twelve months and there can be no assurance that we will be able to obtain such funds.

During the next twelve months, we will require additional capital to continue the development of our product candidates or for other current 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 will need to raise additional capital in the future through one or more financing vehicles that may be available to us. Potential financing vehicles include: (i) the public or private issuance of securities; (ii) new collaborative agreements; and/or (iii) expansions or revisions to existing collaborative relationships.

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 additional capital is not available on favorable terms, we will be required to significantly reduce operating expenses through the restructuring of our operations. 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 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. Our sales, marketing and distribution capabilities 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.

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 ultrafast 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 and other regulatory approvals is extensive, time-consuming and costly, and there is no guarantee that the FDA or other regulatory bodies 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 or delay 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 applicable regulatory 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. In the United States, 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 key partners, our contract manufacturers or our raw material suppliers;
- the FDA may identify problems or other deficiencies in our existing manufacturing processes or facilities, or the existing processes or facilities of our key partners, our contract manufacturers or our 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 regulatory 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;
- 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.

For example, because a portion of the HYLENEX produced by Baxter was not in compliance with the requirements of the underlying HYLENEX agreements, HYLENEX was voluntarily recalled in May 2010. Since the announcement of the recall, we have worked to identify the root cause of the noncompliant HYLENEX and we are currently preparing materials to present to the FDA in connection with the proposed reintroduction of HYLENEX. We hope to meet with the FDA in August 2010, and we will not be able to predict the timing for HYLENEX reintroduction until after meeting with the FDA.

If proprietary or partnered product candidates are approved by regulatory bodies such as 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 approved product label;
- the effectiveness of our sales and marketing efforts and the effectiveness of the sales and marketing efforts of our partners;
- the introduction of generic competitors; and
- the extent to which reimbursement for our products and related treatments will be available from third party payors.

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 applicable regulatory bodies such as 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.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our operations, including laboratories, offices and other research facilities, are located in a three building campus in San Diego, California. We depend on our facilities and on our partners, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, interruptions in the supply of natural resources, political and governmental changes, wildfires and other fires, floods, explosions, actions of animal rights activists, earthquakes and civil unrest could disrupt our operations or those of our partners, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs.

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, 2010 were $9.11 and $5.22, 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;
- 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 regulatory 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 applicable regulatory bodies such as 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;
- the sale of additional debt and/or equity securities by us;
- our failure to obtain financing on acceptable terms; or
- a restructuring of our operations.

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 $100.0 million of additional equity or debt securities under an 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.

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.

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.

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.

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. Pending the reintroduction of HYLENEX, the competitors for HYLENEX will include, but are not limited to, Sigma-Aldrich Corporation, ISTA Pharmaceuticals, Inc. and Amphastar Pharmaceuticals, Inc. For our Insulin-PH20 and Analog-PH20 product candidates, 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 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 typically invest all, or substantially all, of our cash in money market funds that invest primarily in government securities. Our investment policy also permits investments in a variety of securities including commercial paper 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, 2010, 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 decisions 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 onForm 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, 2010, 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 disputes, including litigation, relating to claims arising out of operations in the normal course of our business. Any of these claims could subject us to costly legal expenses 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.

On May 16, 2010, we delivered a notice of breach to Baxter due to Baxter s failure to provide HYLENEX in accordance with the terms of existing development and supply contracts. In the event that Baxter is unable to remedy all material breaches within the timeframe specified in the agreements (as much as 120 days following the delivery of the notice of breach), we may terminate the HYLENEX relationship. In the event that the HYLENEX agreements are terminated by us, Baxter may challenge our right to terminate such agreements and litigation may be necessary to resolve the dispute. In addition, Baxter has contested the claims made in our initial notice of breach and asserted their own breach claims against us. We believe Baxter s claims are without merit and we expect to prevail in any dispute relating to the HYLENEX agreements.

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 section provides updated information in certain areas, particularly with respect to our notice of breach to Baxter under the HYLENEX agreements, the subsequent voluntary recall of HYLENEX product and our need for additional capital over the next twelve months. We do not believe the 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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. (Removed and Reserved)

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit	Title
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

Table of Contents

SIGNATURES

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

	Halozyme Therapeutics, Inc., a Delaware corporation
Dated: August 6, 2010	/s/ Jonathan E. Lim Jonathan E. Lim, MD President and Chief Executive Officer (Principal Executive Officer)
Dated: August 6, 2010	/s/ Kurt A. Gustafson Kurt A. Gustafson Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)