HALOZYME THERAPEUTICS INC
Form 10-Q
May 07, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2012

OR

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

For the transition period from _____ to _____.

Commission File Number 001-32335

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**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 [X] No [ ]

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 [X] No [ ]

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

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨	Smaller reporting company ¨
			(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 112,443,372 as of April 30, 2012.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2012 (Unaudited)	December 31, 2011 (Note)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 116,608,304	$ 52,825,527
Accounts receivable, net	5,550,830	2,262,465
Inventories	1,496,783	567,263
Prepaid expenses and other assets	8,910,059	8,332,242
Total current assets	132,565,976	63,987,497
Property and equipment, net	2,152,934	1,771,048
Total Assets	$ 134,718,910	$ 65,758,545
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,011,181	$ 7,556,859
Accrued expenses	7,184,794	5,615,574
Deferred revenue, current portion	6,484,800	4,129,407
Total current liabilities	16,680,775	17,301,840
Deferred revenue, net of current portion	36,130,767	36,754,583
Deferred rent, net of current portion	846,957	802,006
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock $0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock $0.001 par value; 150,000,000 shares authorized; 112,411,014 and 103,989,272 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	112,411	103,990
Additional paid-in capital	341,088,827	255,817,772
Accumulated deficit	(260,140,827)	(245,021,646)
Total stockholders equity	81,060,411	10,900,116
Total Liabilities and Stockholders Equity	$ 134,718,910	$ 65,758,545

Note: The condensed consolidated balance sheet at December 31, 2011 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.

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HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended March 31,	
	2012	**2011**
Revenues:		
Product sales, net	$ 187,411	$ 165,449
Revenues under collaborative agreements	7,252,768	7,378,445
Total revenues	7,440,179	7,543,894
Operating expenses:		
Cost of product sales	70,761	11,717
Research and development	15,891,109	13,785,797
Selling, general and administrative	6,618,707	3,405,966
Total operating expenses	22,580,577	17,203,480
Operating loss	(15,140,398)	(9,659,586)
Interest and other income, net	21,217	23,869
Net loss	$ (15,119,181)	$ (9,635,717)
Basic and diluted net loss per share	$ (0.14)	$ (0.10)
Shares used in computing basic and diluted net loss per share	107,589,514	100,927,402
Comprehensive loss	$ (15,119,181)	$ (9,635,717)

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Three Months Ended March 31,	
	2012	**2011**
Operating activities:		
Net loss	$ (15,119,181)	$ (9,635,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,154,928	931,070
Depreciation and amortization	237,793	326,181
Gain on disposals of equipment	(6,988)	(656)
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,288,365)	596,943
Inventories	(929,520)	(55,052)
Prepaid expenses and other assets	(577,817)	337,903
Accounts payable and accrued expenses	(3,609,171)	(2,771,781)
Deferred rent	49,129	(89,688)
Deferred revenue	1,731,577	(731,269)
Net cash used in operating activities	(19,357,615)	(11,092,066)
Investing activities:		
Proceeds from disposals of property and equipment	15,844	-
Purchases of property and equipment	-	(203,023)
Net cash provided by (used in) investing activities	15,844	(203,023)
Financing activities:		
Proceeds from issuance of common stock, net	81,476,845	-
Proceeds from exercise of stock options, net	1,647,703	1,868,540
Net cash provided by financing activities	83,124,548	1,868,540
Net increase (decrease) in cash and cash equivalents	63,782,777	(9,426,549)
Cash and cash equivalents at beginning of period	52,825,527	83,255,848
Cash and cash equivalents at end of period	$ 116,608,304	$ 73,829,299
Supplemental disclosure of non-cash investing and financing activities:		
Accounts payable for purchases of property and equipment	$ 628,535	$ 16,795

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization and Business

Halozyme Therapeutics, Inc. (referred to as we, us, Halozyme or the Company) is a biopharmaceutical company dedicated to developing an commercializing innovative products that advance patient care. Our research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique scientific expertise that allows us to pursue this target-rich environment for the development of future therapies.

Our research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, recombinant human hyaluronidase (rHuPH20), temporarily degrades hyaluronan, a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit. Our Enhanze technology is the platform for the delivery of proprietary small and large molecules. We apply our research products in partnership with other companies as well as for our own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing product and a limited number of product candidates; (iv) supporting the development of partnered product candidates and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). 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 currently have collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (Roche), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma), and Intrexon Corporation (Intrexon), to apply Enhanze technology to these partners biological therapeutic compounds. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from our partnerships.

2. Summary of Significant Accounting Policies

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 our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 12, 2012. 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 condensed consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and our wholly owned subsidiary, Halozyme, Inc. All intercompany accounts and transactions have been eliminated.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and

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accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management s estimates.

Adoption of Recent Accounting Pronouncements

Effective January 1, 2012, we adopted Financial Accounting Standards Board s (FASB) Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* and ASU No. 2011-12, Comprehensive Income (Topic 220): *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-5*. In these updates, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in these updates are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU Nos. 2011-05 and 2011-12 did not have a material impact on our consolidated financial position or results of operations. We have presented comprehensive loss in our condensed consolidated statements of comprehensive loss.

Effective January 1, 2012, we prospectively adopted the FASB s ASU No. 2011-04, *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS* . The amendments in ASU 2011-04 result in common fair value measurement and disclosure requirements in GAAP and International Financial Reporting Standards (IFRS). Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU No. 2011-04 did not have a material effect on our consolidated financial position or results of operations.

Inventories

Inventories are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by our contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

Raw materials inventories consist of raw materials used in the manufacture of our bulk drug material for *Hylenex* recombinant product. Work-in-process inventories consist of in-process *Hylenex* recombinant. Finished goods inventories consist of finished *Hylenex* recombinant product.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be realized. For products that have been approved by regulatory bodies such as the U.S. Food and Drug Administration (FDA), inventories used in clinical trials are expensed at the time the inventories are packaged for the clinical trials. Prior to receiving approval from the FDA or comparable regulatory agencies in foreign countries, costs related to purchases of the active pharmaceutical ingredients (API) and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized as inventories.

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Revenue Recognition

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

We recognize revenue in accordance with 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 or determinable; and (4) collectibility is reasonably assured.

Product Sales *Hylenex* recombinant was approved for marketing by the FDA in December 2005. From 2005 through January 7, 2011, Baxter had the worldwide market rights for *Hylenex* recombinant under the terms of the Hylenex Partnership. Baxter commercially launched *Hylenex* recombinant in October 2009. However, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the product manufactured by Baxter was not in compliance with the requirements of the underlying partnership. Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant to the market. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant.

In December 2011, we reintroduced *Hylenex* recombinant to the market, shipped initial stocking orders to our wholesaler customers and began promoting *Hylenex* recombinant through our sales force. We sell *Hylenex* recombinant in the United States to wholesale pharmaceutical distributors, who sell the product to hospitals and other end-user customers. The wholesale distributors take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales; however, we do allow the wholesale distributors to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to and ending twelve months following product expiration. Given our limited history of selling *Hylenex* recombinant and the lengthy return period, we currently cannot reliably estimate expected returns and chargebacks of *Hylenex* recombinant at the time the product is received by the wholesale distributors. Therefore, we do not recognize revenue upon delivery of *Hylenex* recombinant to the wholesale distributor until the point at which we can reliably estimate expected product returns and chargebacks from the wholesale distributors. Shipments of *Hylenex* recombinant are recorded as deferred revenue until evidence exists to confirm that pull-through sales to the hospitals or other end-user customers have occurred. We recognize revenue when the product is sold through from the distributors to the distributors customers. In addition, the costs of manufacturing *Hylenex* recombinant associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized. We estimate sell-through revenue and certain gross to net sales adjustments based on analysis of third-party information including information obtained from certain distributors with respect to their inventory levels and sell-through to the distributors customers. At the time we can reliably estimate product returns and chargebacks from the wholesale distributors, we will record a one-time increase in net product sales revenue related to the recognition of product sales revenue previously deferred.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesale distributors and hospitals and the levels of inventory within the distribution channels that may result in future discounts taken. We must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make an adjustment to these allowances in the future, which could have an effect on product sales revenue in the period of adjustment. Our product sales allowances include:

Distribution Fees. The distribution fees, based on contractually determined rates, arise from contractual agreements we have with certain wholesale distributors for distribution services they provide with respect to *Hylenex* recombinant. At the time the sale is made to the respective wholesale distributors, we record an allowance for distribution fees by reducing our accounts receivable and deferred revenue associated with such product sales.

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Prompt Payment Discounts. We offer cash discounts to certain wholesale distributors as an incentive to meet certain payment terms. We expect our customers will take advantage of this discount; therefore, at the time the sale is made to the respective wholesale distributors, we accrue the entire prompt payment discount, based on the gross amount of each invoice, by reducing our accounts receivable and deferred revenue associated with such product sales.

Chargebacks. We provide discounts to certain hospitals. These hospitals purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the hospitals paid for the product. Given our lack of historical sales data, we recognize chargebacks in the same period the related product sales revenue is recognized and reduce our accounts receivable accordingly.

Product Returns. The product returns reserve is based on management s best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The product returns reserve is recorded as a reduction of product sales revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.

Revenues under Collaborative Agreements We have entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of our proprietary rHuPH20 enzyme in the development and commercialization of the partners biologic compounds. The collaborative agreements contain multiple elements, including nonrefundable payments at the inception of the arrangements, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the partner and/or royalties on sales of products resulting from collaborative agreements. We analyze each element of the collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of fair value of the undelivered items, and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, we recognized revenue on nonrefundable upfront payments and license fees from these collaborative agreements over the period of significant involvement under the related agreements.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under our collaborative agreements include (i) the license to rHuPH20 technology, (ii) at the collaborator s request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator s request, supply of rHuPH20 API which is reimbursed at our cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable

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revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of rHuPH20 API, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the partner is fixed or determinable and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The terms of our collaborative agreements provide for milestone payments upon achievement of certain development and regulatory events and/or specified sales volumes of commercialized products by the collaborator.

Effective January 1, 2011, we adopted on a prospective basis the Milestone Method. Under the Milestone Method, we recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone,

2. The consideration relates solely to past performance, and

3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the vendor s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the vendor.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of rHuPH20 API is recognized when the API has met all specifications required for the collaborator s acceptance and title and risk of loss have transferred to the collaborator. We do not directly control when any collaborator will request research and development services or supply of rHuPH20 API; therefore, we cannot predict when we will recognize revenues in connection with research and development services and supply of rHuPH20 API. Royalties to be received based on sales of licensed products by our collaborators incorporating rHuPH20 will be recognized as earned.

The collaborative agreements typically provide the partners the right to terminate such agreements in whole or on a product-by-product or target-by-target basis at any time upon 90 days prior written notice to us. There are no performance, cancellation, termination or refund provisions in any of our collaborative agreements that contain material financial consequences to us.

Cost of Product Sales

Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight costs, internal costs and manufacturing overhead associated with the production of *Hylenex* recombinant. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories.

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.

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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 at such time when we do not expect the goods to be delivered or services to be performed.

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 as incurred.

Clinical Trial Expenses

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 progress of clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in 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.

Share-Based Compensation

Total share-based compensation expense related to all of our share-based awards was allocated as follows:

	Three Months Ended March 31,	
	2012	**2011**
Research and development	$ 1,127,283	$ 400,685
Selling, general and administrative	1,027,645	530,385
Share-based compensation expense	$ 2,154,928	$ 931,070
Net share-based compensation expense, per basic and diluted share	$ 0.02	$ 0.01
Share-based compensation expense from:		
Stock options	$ 1,133,571	$ 706,611
Restricted stock awards and restricted stock units	1,021,357	224,459
	$ 2,154,928	$ 931,070

Since we have a net operating loss carryforward as of March 31, 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the interim unaudited condensed consolidated statements of comprehensive loss. For the three months ended March 31, 2012 and 2011, employees exercised stock options to purchase 342,209 and 1,452,642 shares of common stock, respectively, for aggregate proceeds of approximately $1.6 million and $1.9 million, respectively.

As of March 31, 2012, total unrecognized estimated compensation cost related to non-vested stock options and non-vested restricted stock awards and restricted stock units granted prior to that date was approximately $11.8 million and $6.9 million, respectively, which is expected to be recognized over a weighted-average period of approximately 3.0 years and 2.8 years, respectively.

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Fair Value of Financial Instruments

We follow 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.

Our financial instruments include cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses. The carrying amounts of financial instruments approximate their fair values due to their short maturities. Cash equivalents of approximately $112.5 million and $51.8 million at March 31, 2012 and December 31, 2011, respectively, 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. We have no instruments that are classified within Level 2 and Level 3.

Segment Information

We operate our business in one segment, which includes all activities related to the research, development and commercialization of human enzymes that either transiently modify tissue to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. This segment also includes revenues and expenses related to (1) research and development activities conducted under our collaborative agreements with third parties and (ii) product sales of *Hylenex* recombinant. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

3. Collaborative Agreements

Roche Partnership

In December 2006, we and Roche entered into a license and collaborative agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and up to thirteen Roche target compounds (the Roche Partnership). As of March 31, 2012, Roche has elected a total of five exclusive targets and retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual maintenance fees to us. As of March 31, 2012, we have received $57 million from Roche, including the $20 million upfront license fee payment for the application of rHuPH20 to the initial three Roche exclusive targets, $20 million in connection with Roche s election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets, $13 million in clinical development milestone payments and a $4 million regulatory milestone payment. If Roche successfully develops all five exclusive targets and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $178 million, including up to $17 million for the achievement of clinical development milestones, up to $16 million for the achievement of regulatory milestones and up to $145 million for the achievement of sales-based milestones. Under the terms of the Roche Partnership, Roche will also pay us royalties on product sales for each target. For each of the additional targets, Roche may pay us upfront and milestone payments of up to $47 million per target, as well as royalties on product sales for each of the additional targets. Additionally, Roche will obtain access to our expertise in developing and applying rHuPH20 to Roche targets.

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Under the terms of the Roche Partnership, we were obligated to scale up the production of rHuPH20 and to identify a second source manufacturer that would help meet anticipated production obligations arising from the Roche Partnership.

Due to our continuing involvement obligations (for example, support activities associated with rHuPH20), 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. We have determined that the clinical and regulatory milestones are substantive; therefore, we expect to recognize such clinical and regulatory milestone payments as revenue upon achievement of the milestones. In addition, we have determined that the sales-based milestone payments are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, we will recognize such sales-based milestone payments as revenue upon achievement of the milestones.

In March 2012, Roche submitted a Line Extension Application to the European Medicines Agency for Herceptin® formulated with rHuPH20 (subcutaneous Herceptin). Upon achievement of this milestone, we recognized a regulatory milestone payment of $4 million as revenue under collaborative agreements in accordance with the Milestone Method for the three months ended March 31, 2012. For the three months ended March 31, 2011, we recognized $5 million as revenue under collaborative agreements in accordance with the Milestone Method related to the achievement of certain clinical milestone pursuant to the terms of the Roche Partnership.

Gammagard Partnership

In September 2007, we entered into a license and collaborative agreement with Baxter, under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20, with a current Baxter product, GAMMAGARD LIQUID (the Gammagard Partnership). As of March 31, 2012, we have received $13 million under the Gammagard Partnership, including the $10 million upfront license fee payment and a $3 million regulatory milestone payment. If Baxter successfully receives marketing approval for the licensed product candidate and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $34 million for the achievement of sales-based milestones. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard Partnership is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we are responsible for the supply of rHuPH20 enzyme. We perform research and development activities at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Partnership. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard Partnership.

Under the terms of the Gammagard Partnership, Baxter paid us a nonrefundable upfront payment of $10 million. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), the $10 million upfront payment was deferred and is being recognized over the term of the Gammagard Partnership.

We have determined that sales-based milestone payments are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, such payments will be recognized as revenue upon achievement of the milestones. There were no milestone payments recognized as revenue under collaborative agreements under the Gammagard Partnership for the three months ended March 31, 2012 and 2011.

ViroPharma and Intrexon Partnerships

Effective May 10, 2011, we and ViroPharma entered into a collaboration and license agreement, under which ViroPharma obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of ViroPharma s commercialized product, Cinryze® (C1 esterase inhibitor [human]) (the ViroPharma Partnership). In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibitor and to the hereditary angioedema indication, along with three additional orphan indications. As of March 31, 2012, we have received $12 million from ViroPharma, including the $9 million nonrefundable upfront license fee payment and a $3 million clinical development milestone payment. If ViroPharma successfully develops the licensed product candidate, we could receive additional milestone payments of up to $41 million for the achievement of development and regulatory milestones. In addition, so long as the agreement is in effect, we are

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entitled to receive a nonrefundable annual exclusivity fee of $1 million commencing on May 10, 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. ViroPharma is solely responsible for the development, manufacturing and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by ViroPharma. In addition, we are entitled to receive additional cash payments potentially totaling $10 million upon achievement of certain development and regulatory milestones for each product targeting the treatment of any of the three additional orphan indications. We are also entitled to receive royalties on future product sales by ViroPharma. ViroPharma may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to ViroPharma (in total or with respect to the terminated product, as applicable) will terminate.

Effective June 6, 2011, we and Intrexon entered into a collaboration and license agreement, under which Intrexon obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of Intrexon s recombinant human alpha 1-antitrypsin (rHuA1AT) (the Intrexon Partnership). In addition, the license provides Intrexon with exclusivity for a defined indication (Exclusive Field). As of March 31, 2012, we have received a nonrefundable upfront license fee payment of $9 million from Intrexon. If Intrexon successfully develops the licensed product candidate and achieves the pre-agreed sales target, we could receive additional milestone payments of up to $54 million, including $44 million for the achievement of development and regulatory milestones and $10 million for the achievement of a sales-based milestone. In addition, so long as the agreement is in effect, we are entitled to receive a nonrefundable annual exclusivity fee of $1 million commencing on June 6, 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. Intrexon is solely responsible for the development, manufacturing and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by Intrexon. In addition, we are entitled to receive additional cash payments potentially totaling $10 million for each product for use outside the Exclusive Field upon achievement of development and regulatory milestones. We are also entitled to receive royalties on product sales at a royalty rate which increases with net sales of product. Intrexon may terminate the agreement prior to expiration for any reason on a product-by-product basis upon 90 days prior written notice to us. Upon any such termination, the license granted to Intrexon (in total or with respect to the terminated product, as applicable) will terminate. Intrexon s chief executive officer, chairman of its board of directors and major shareholder is also a member of our board of directors.

We identified the deliverables at the inception of the ViroPharma and Intrexon agreements which are the license, research and development services and API supply. We have determined that the license, research and development services and API supply individually represent separate units of accounting, because each deliverable has standalone value. The estimated selling prices for these units of accounting was determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotech industry and entity-specific factors such as the terms of our previous collaborative agreements, our pricing practices and pricing objectives and the nature of the research and development services to be performed for the partners. The arrangement consideration was allocated to the deliverables based on the relative selling price method. Based on the results of our analysis, we determined that the upfront payment was earned upon the granting of the worldwide, exclusive right to our technology to the collaborator in both the ViroPharma Partnership and Intrexon Partnership. However, the amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the license was only to the extent of cash received. As a result, we recognized the $9 million upfront license fee received under the ViroPharma Partnership and the $9 million upfront license fee received under the Intrexon Partnership as revenues under collaborative agreements upon receipt of the upfront license fees.

We will recognize the exclusivity fees as revenues under collaborative agreements when they are earned. We will recognize reimbursements for research and development services as revenues under collaborative agreements as the related services are delivered. We will recognize revenue from sales of API as revenues under collaborative agreements when such API has met all required specifications by the partners and the related title and risk of loss and damages have passed to the partners. We cannot predict the timing of delivery of research and development services and API as they are at the partners requests.

We are eligible to receive additional cash payments upon the achievement by the partners of specified development, regulatory and sales-based milestones. We have determined that each of the development and

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regulatory milestones is substantive; therefore, we expect to recognize such development and regulatory milestone payments as revenues under collaborative agreements upon achievement in accordance with the Milestone Method. In addition, we have determined that the sales-based milestone payment is similar to a royalty payment and is not considered a milestone payment under the Milestone Method of revenue recognition; therefore, we will recognize the sales-based milestone payment as revenue upon achievement of the milestone because we have no future performance obligations associated with the milestone. There were no milestone payments recognized as revenue under the collaborative agreements under these partnerships for the three months ended March 31, 2012 and 2011.

4. Inventories

Inventories consist of the following:

	March 31, 2012	December 31, 2011
Raw materials	$ 853,885	$ 201,822
Work-in-process	314,185	290,647
Finished goods	328,713	74,794
	$ 1,496,783	$ 567,263

5. Property and Equipment, Net

Property and equipment, net consist of the following:

	March 31, 2012	December 31, 2011
Research equipment	$ 5,589,515	$ 5,231,763
Computer and office equipment	1,443,355	1,266,041
Leasehold improvements	1,078,167	1,019,147
	8,111,037	7,516,951
Accumulated depreciation and amortization	(5,958,103)	(5,745,903)
	$ 2,152,934	$ 1,771,048

Depreciation and amortization expense totaled approximately $238,000 and $326,000 for the three months ended March 31, 2012 and 2011, respectively.

6. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2012	December 31, 2011
Accrued outsourced research and development expenses	$ 3,546,961	$ 1,910,273

Accrued compensation and payroll taxes	2,578,720	3,223,936
Other accrued expenses	1,059,113	481,365
	$ 7,184,794	$ 5,615,574

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7. Deferred Revenue

Deferred revenue consists of the following:

	March 31, 2012	December 31, 2011
Collaborative agreements	$ 42,447,979	$ 40,716,806
Product sales	167,588	167,184
Total deferred revenue	42,615,567	40,883,990
Less current portion	6,484,800	4,129,407
Deferred revenue, net of current portion	$ 36,130,767	$ 36,754,583

Roche Partnership. Under the terms of the Roche Partnership, Roche paid $20 million to us in December 2006 as an initial upfront payment for the application of rHuPH20 to three pre-defined Roche biologic targets. As of March 31, 2012, Roche has paid an aggregate of $20 million in connection with Roche s election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets. Roche currently retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual license maintenance fees to us.

Due to our 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. We recognized revenue from the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Partnership in the amounts of approximately $503,000 and $491,000 for the three months ended March 31, 2012 and 2011, respectively. Deferred revenue relating to the upfront payment, exclusive designation fees and annual license maintenance fees under the Roche Partnership was $34.2 million and $31.7 million as of March 31, 2012 and December 31, 2011, respectively.

Gammagard Partnership. Under the terms of the Gammagard Partnership, Baxter paid us a nonrefundable upfront payment of $10 million. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), the $10 million upfront payment was deferred and is being recognized over the term of the Gammagard Partnership. We recognized revenue from the upfront payment under the Gammagard Partnership in the amounts of approximately $121,000 for each of the three months ended March 31, 2012 and 2011. Deferred revenue relating to the upfront payment under the Gammagard Partnership was $7.5 million and $7.6 million as of March 31, 2012 and December 31, 2011, respectively.

8. Net Income (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 restricted stock awards and unvested restricted stock units 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 our net loss, outstanding stock options, outstanding restricted stock units and unvested restricted stock awards totaling 7.5 million and 6.8 million were excluded from the calculation of diluted net loss per common share for the three months ended March 31, 2012 and 2011, respectively, because their effect is anti-dilutive.

9. Stockholders Equity

During the three months ended March 31, 2012 and 2011, we issued an aggregate of 342,209 and 1,452,642 shares of common stock, respectively, in connection with the exercises of stock options at a weighted average exercise price of $4.81 and $1.61 per share, respectively, for net proceeds of approximately $1.6 million and $1.9 million, respectively. Options to purchase approximately 6.3 million and 5.9 million shares of our common stock were outstanding as of March 31, 2012 and December 31, 2011, respectively. In addition, we issued 260,158 shares of common stock in connection with the grants of restricted stock awards during the three months ended March 31, 2012.

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On February 15, 2012, we completed an underwritten public offering and issued 7,820,000 shares of common stock, including 1,020,000 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriter. All of the shares were offered at a public offering price of $10.61 per share, generating approximately $81.5 million in net proceeds. Randal J. Kirk, a member of our board of directors, through his affiliates, purchased 1,360,000 shares of common stock in this offering at the public offering price of $10.61 per share for a total of approximately $14.4 million.

10. Commitments and Contingencies

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.

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

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

The following information should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q. Past financial or operating performance is not necessarily a reliable indicator of future performance, and our historical performance should not be used to anticipate results or future period trends.

Except for the historical information contained herein, this report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements reflect management s current forecast of certain aspects of our future. Words such as expect, anticipate, intend, plan, believe, seek, estimate, think, may, could, will, would, should, continue, potential, likely, opportunity and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of indentifying forward-looking statements in this report. Additionally, statements concerning future matters such as the development or regulatory approval of new products, enhancements of existing products or technologies, third party performance under key collaboration agreements, revenue and expense levels and other statements regarding matters that are not historical are forward-looking statements. Such statements are based on currently available operating, financial and competitive information and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially from those anticipated or implied in our forward-looking statements due to a number of factors including, but not limited to, those set forth below under the section entitled Risks Factors and elsewhere in this Quarterly Report on Form 10-Q and our most recent Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company dedicated to developing and commercializing innovative products that advance patient care. Our research targets the extracellular matrix, an area outside the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique scientific expertise that allows us to pursue this target-rich environment for the development of future therapies.

Our research focuses primarily on human enzymes that alter the extracellular matrix. Our lead enzyme, the recombinant human hyaluronidase (rHuPH20), temporarily degrades hyaluronan (HA), a matrix component in the skin, and facilitates the dispersion and absorption of drugs and fluids. We are also developing novel enzymes that may target other matrix structures for therapeutic benefit. Our Enhanze technology is the platform for the delivery of proprietary small and large molecules. We apply our research to develop products in partnership with other companies as well as for our own proprietary pipeline in therapeutic areas with significant unmet medical need, such as diabetes, oncology and dermatology.

Our operations to date have involved: (i) organizing and staffing our operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing our technology; (iii) undertaking product development for our existing products and a limited number of product candidates; (iv) supporting the development of partnered product candidates; and (v) selling *Hylenex*® recombinant (hyaluronidase human injection). 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 currently have collaborative partnerships with F. Hoffmann-La Roche, Ltd and Hoffmann-La Roche, Inc. (Roche), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma) and Intrexon Corporation (Intrexon) to apply Enhanze technology to the partners biological therapeutic compounds. Currently, we have received only limited revenue from the sales of *Hylenex* recombinant, in addition to other revenues from our partnerships.

We and our partners have product candidates in the research, preclinical and clinical stages, but future revenues from the sales and/or royalties of these product candidates will depend on our partners abilities and our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize product candidates.

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It may be years, if ever, before we and our partners 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 $260.1 million as of March 31, 2012.

Product and Product Candidates

We have one marketed product and multiple product candidates targeting several indications in various stages of development. The following table summarizes our proprietary product and product candidates as well as our partnered product candidates:

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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. We have combined rHuPH20 with a rapid acting analog insulin, e.g., insulin lispro (Humalog®) (Lispro-PH20), insulin aspart (Novolog®) (Aspart-PH20), and insulin glulisine (Apidra®), (each such combination, Analog-PH20), to accelerate their action. These Analog-PH20 combinations facilitate 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, Analog-PH20 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. 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 investigating the various attributes of our insulin candidates have been completed, are ongoing or planned. The status of some of these trials is summarized below:

In June 2011, we reported results from the first stage of an insulin pump study comparing Aspart-PH20 versus aspart alone at the Scientific Sessions of the American Diabetes Association in San Diego, California. The results demonstrated that Aspart-PH20 has pharmacokinetic and glucodynamic profiles that were accelerated and showed more consistent absorption and action rates over infusion set life as compared to analog alone, and the Aspart-PH20 also provided a reduction of post-meal glycemic excursions relative to aspart alone.

In October 2011, we announced positive results from the second stage of an insulin pump study in patients with type 1 diabetes at the Diabetes Technology Meeting in San Francisco, California, which took place from October 27 to 29, 2011. This Phase 1b study was conducted as a randomized, double-blind, crossover design, to determine insulin pharmacokinetics, glucodynamics, safety and tolerability of rHuPH20 as a single injection prior to the start of three days of commercially available mealtime insulin aspart pump infusion therapy. The data demonstrated that pre-administration of rHuPH20 led to a consistent and faster insulin exposure profile over the infusion set life and superior glucose control following meals. Compared to insulin aspart alone, pre-administration with rHuPH20 reduced the variability in insulin exposure and action profiles observed with continuous insulin infusion and provided a consistent ultrafast profile over three days of use. In the test meal setting, the consistent ultrafast profile with pre-administration of rHuPH20 led to consistently reduced postprandial excursions. Insulin aspart infusion with and without rHuPH20 pretreatment was similarly well tolerated.

In October 2011, we announced the positive results from two Phase 2 clinical trials of our ultrafast Analog-PH20 injection formulations in patients with type 1 and type 2 diabetes. More than 110 patients enrolled in each of the trials and received an insulin analog alone or an Analog-PH20 treatment for 12 weeks along with basal insulin, followed by the opposite treatment for an additional 12 weeks in a 2-way double blind crossover design. The primary endpoint of each study was a comparison of glycemic control, the main measurement that people with diabetes use to assess treatment effectiveness, as assessed by the change in HbA1C from baseline. Data regarding post-prandial glucose levels, the proportion of patients that safely achieve HbA1C targets, rates of hypoglycemia, weight change and additional endpoints were collected as well. Both trials met the primary endpoint of non-inferiority for HbA1C, which reflects average blood sugar level over a prolonged period of time, compared to the insulin analog comparator, with superior reductions in post-prandial glucose excursions in the Analog-PH20 arms. Compared to insulin analog alone, Analog-PH20 use resulted in a greater than 50% increase in the proportion of both type 1 and type 2 patients

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able to consistently achieve AACE (American Association of Clinical Endocrinologists) post-prandial glucose targets at both one and two hours. In the study of patients with type 1 diabetes, overall hypoglycemia (defined either as blood glucose £70 mg/dL or <56 mg/dL) was modestly but statistically significantly reduced for both definitions of hypoglycemia compared to analog alone; in the study of patients with type 2 diabetes hypoglycemia rates were comparable between treatment groups. Hypoglycemia events were generally mild, and adverse events with Analog-PH20 formulations were similar to those observed during the insulin analog comparator phase. We currently expect to present the detailed results of these studies at a major medical meeting in 2012.

We view Analog-PH20 for injection and pump therapy as distinct product opportunities that could be pursued separately. Based on the data we have seen thus far, we believe that a large biotech or pharmaceutical company with global access to the primary care markets would be best positioned to maximize the value of the injectable market, and therefore entering into a collaboration would be an attractive option for us to exploit this opportunity. We believe that the pre-administration of rHuPH20 could be the best product offering for the pump market. The next step will be for us to evaluate this opportunity using *Hylenex* recombinant in a clinical study (rHuPH20 is the underlying drug delivery technology in *Hylenex* recombinant). We expect to present results from this study at an appropriate scientific meeting in 2012.

PEGPH20

We are developing an investigational PEGylated form of rHuPH20 (PEGPH20), a new molecular entity as a candidate for the systemic treatment of tumors that accumulate HA. PEGylation refers to the attachment of polyethylene glycol to rHuPH20, now known as PEGPH20, which converts rHuPH20 from a transient and short-lived enzyme to a more stable entity in blood that can be used to treat systemic disease.

Certain cancers, including pancreatic, lung, breast, colon and prostate cancers, have been shown to accumulate high levels of HA. Aberrant accumulation of this component of the tumor s infrastructure supports a protective network that surrounds certain tumors. This pathologic accumulation of HA along with other matrix components creates a unique microenvironment for the growth of tumor cells compared to normal cells. We believe that depleting the HA component of the tumor architecture with PEGPH20 disrupts the tumor microenvironment and opens the previously constricted vessels to allow anti-cancer therapies to have greater access to the tumor, which may enhance the chemotherapy s treatment effect. Increased blood flow may also enhance radiotherapy treatment effect. We have generated data showing that disrupting the specialized environment around tumors will directly inhibit the growth. Because HA accumulates in about 25% of all solid tumors, we believe that PEGPH20 has the potential to help patients with many different kinds of cancer.

We are currently conducting a Phase 1 clinical trial with PEGPH20 in the treatment of solid tumors. This trial incorporates the use of oral dexamethasone as prophylactic treatment for all patients prior to receiving intravenous administration of PEGPH20 and subsequent post-dose oral dexamethasone. We are also conducting a Phase 2 clinical trial, with a Phase 1b run-in period, for patients with metastatic pancreatic cancer. In the on-going Phase 1b portion, the patients will receive PEGPH20 in combination with gemcitabine. The objective of the phase 1b is to identity the recommended phase 2 dose of PEGPH20 in combination with gemcitabine. The Phase 2 will be a randomized, double-blind, placebo-controlled study to assess safety, tolerability, and efficacy of PEGPH20 in combination with gemcitabine versus gemcitabine alone.

HTI-501

HTI-501, a recombinant human proteinase known as cathepsin L, is a lysosomal proteinase that acts by degrading collagen and is our first conditionally-active biologic. Collagen is an abundant protein in the body, particularly in connective tissue, and is present in high amounts in the extracellular matrix in the form of collagen fibers. Collagens are a class of helical proteins that are assembled into macromolecular fibrils and fibers. The collagen fiber network provides a structural scaffolding framework in the extracellular matrix. In the skin, these collagen fibers connect the superficial epithelial tissues to the underlying connective tissues. Collagen abnormalities contribute to a number of conditions, including frozen shoulder, Dupuytren s contracture, Peyronie s disease and cellulite.

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A conditionally active biologic is a molecule that is only active under certain physiological conditions. HTI-501 is active under mildly acidic conditions and inactive at the pH normally found in the tissue. The enzyme is combined with a low pH buffer and injected in its active state. The enzyme is only active locally and for a short period of time. Once the mildly acidic conditions of the HTI-501 administration have been neutralized by the body, the enzyme becomes inactive. We intend to harness this conditional activity to exert control over the duration and location of the enzyme s therapeutic activity, potentially improving the efficacy or safety of this product candidate for both medical and aesthetic conditions.

We are exploring HTI-501 as an approach to the treatment of edematous fibrosclerotic panniculopathy, also known as cellulite. The condition affects 80 to 90 percent of post-adolescent women and is prevalent in all races. The collagen fibers (fibrous septa) anchor the epidermis against the swelling of subcutaneous fat, which creates the dimpled appearance associated with the condition. We believe that HTI-501 acts by releasing the tension in the collagenous fibrous septa and smoothing the dimpled appearance of the skin. HTI-501 has the potential to be studied as a treatment for other conditions involving collagen, such as frozen shoulder, Dupuytren s contracture, Peyronie s disease, keloids and hypertrophic scarring.

In September 2011, we initiated a Phase 1/2 clinical trial of HTI-501 in women with moderate to severe cellulite. The Phase 1 dose escalation portion of the trial evaluates a single injection of different HTI-501 formulations into dimpled lesions of the skin followed by a Phase 2 portion of the trial where multiple lesions will be targeted with the optimal dose and formulation. Up to 48 and 76 subjects may be enrolled in the Phase 1 and Phase 2 portions of the trial, respectively. We presented interim results from the Phase 1 proof-of-concept and local tolerability study of HTI-501 at the 8th World Congress of the International Academy of Cosmetic Dermatology in Cancun, Mexico, which was held from January 31to February 3, 2012. In the ongoing Phase 1 portion of the clinical trial, no serious or severe adverse events have been reported and the injection has been well tolerated. The most common adverse event has been mild to moderate pain at the injection site that was generally bilateral (present at both investigational drug and buffer control injection sites), lasted a few minutes and did not require treatment. Data from this study support commencement of the future Phase 2 portion of the clinical trial.

Enhanze Technology

Enhanze technology is a proprietary delivery platform using rHuPH20. This enzyme temporarily degrades HA. We believe this temporary degradation creates an opportunistic window for the improved subcutaneous delivery of injectable biologics, such as monoclonal antibodies and other large therapeutic molecules, as well as small molecules and fluids. The HA reconstitutes its normal density within several days and, therefore, we anticipate that any effect of rHuPH20 on the architecture of the subcutaneous space is temporary. By using our rHuPH20 enzyme, many therapeutics that could normally only be injected intravenously can now be administered subcutaneously. This change in the route of delivery to subcutaneous from intravenous (IV), can often improve patient convenience, enhance pharmacokinetics, boost efficacy, extend the product lifecycle and reduce cost.

We currently have Enhanze technology partnerships with Roche, Baxter, ViroPharma and Intrexon. We are currently pursuing additional partnerships with biopharmaceutical companies that market drugs requiring or benefiting from injection via the subcutaneous route of administration.

Roche Partnership

In December 2006, we and Roche entered into an agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds (the Roche Partnership). 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 ten additional targets. As of March 31, 2012, Roche has elected a total of five exclusive targets and retains the option to develop and commercialize rHuPH20 with three additional 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.

In March 2012, Roche submitted a Line Extension Application to the European Medicines Agency for a compound, directed at one of the five Roche excusive targets, formulated with rHuPH20 (subcutaneous Herceptin®).

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In addition, clinical trials have commenced for compounds directed at two other Roche exclusive targets under the Roche Partnership. One compound formulated with rHuPH20 (subcutaneous MabThera®) is in a Phase 3 clinical trial and one compound formulated with rHuPH20 (subcutaneous Actemra®) has completed a Phase 1 clinical trial.

In October 2011, Roche announced positive top line results from the Phase 3 clinical trial in women with early HER2-positive breast cancer who received a fixed dose of a new subcutaneously delivered version of Roche s anticancer biologic, Herceptin (trastuzumab) (Herceptin SC). In the study, the subcutaneous formulation showed comparable results to Herceptin given as an IV infusion (Herceptin IV). Herceptin SC takes about 5 minutes to administer whereas Herceptin IV takes about 30-90 minutes to infuse. Roche is also developing an auto-injector device that should further simplify the process and could enable patients to be dosed at home or in the doctor s office rather than at an infusion clinic or hospital. The ready to use formulation may also significantly reduce pharmacy time as no medicine preparation time is required. This Phase 3 clinical trial was an open-label trial involving 596 women with HER2-positive early breast cancer. The trial was designed to compare trastuzumab concentration in the blood (pharmacokinetics), efficacy (pathologic complete response) and safety of Herceptin SC to that of Herceptin IV. The trial met its co-primary endpoints including trastuzumab concentration in the blood (serum concentrations) and efficacy. No new safety signals were observed and adverse events were overall consistent with Herceptin IV. 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 1.4 million new cases of breast cancer are diagnosed worldwide, and nearly 450,000 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 15-20% of people with breast cancer. Roche recently announced that data from this trial was presented at the European Breast Cancer Conference in Vienna, which was held from March 21 to 24, 2012.

In February 2011, Roche began a Phase 3 clinical trial for a subcutaneous formulation of MabThera (rituximab) (MabThera SC). The study investigates pharmacokinetics, efficacy and safety of MabThera SC. IV administered MabThera is approved for the treatment of non-Hodgkin s lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), types of cancer that affects lymphocytes (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. Roche has stated that they will present data from the program in 2012 and that they expect to file a marketing application to regulatory authorities in the European Union in 2012.

In 2009, Roche completed a Phase 1 clinical trial for a subcutaneous formulation of Actemra. This trial investigated the safety and pharmacokinetics of subcutaneous Actemra in patients with rheumatoid arthritis. The results from this Phase 1 trial suggest that further exploration may be warranted. Actemra administered intravenously is approved for the treatment of rheumatoid arthritis. Roche is separately developing a subcutaneous form of Actemra that does not use rHuPH20 and is being investigated for weekly or biweekly administration.

Additional information about the Phase 3 subcutaneous Herceptin and Phase 3 subcutaneous MabThera clinical trials can be found at www.clinicaltrials.gov and www.roche-trials.com. Information available on these websites is not incorporated into this report.

Baxter Gammagard Partnership

GAMMAGARD LIQUID is a Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system. In September 2007, we and Baxter entered into an agreement under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID (HyQ) (the Gammagard Partnership). Pending the successful completion of various regulatory and sales milestones, Baxter is 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 are responsible for the supply of rHuPH20. We perform research and development activities at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Partnership. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard License. In September 2011, Baxter submitted an application to the European Medicines Agency s Committee for Human Medicinal products seeking marketing approval for HyQ. Baxter filed a biologic license application (BLA) for HyQ in the U.S. in the second quarter of 2011. In April 2012, we and Baxter

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announced that the U.S. Food and Drug Administration (FDA) requested additional data to complete its review of Baxter s HyQ BLA. We and Baxter expect these requests will require additional time to complete and will delay the companies anticipated regulatory review and approval timeline.

ViroPharma Partnership

Effective May 10, 2011, we and ViroPharma entered into a collaboration and license agreement under which ViroPharma obtained a worldwide exclusive license for the use of rHuPH20 in the development of a subcutaneous injectable formulation of ViroPharma s commercialized product, Cinryze® (C1 esterase inhibitor [human]) (the ViroPharma Partnership). In addition, the license provides ViroPharma with exclusivity to C1 esterase inhibitor and to the hereditary angioedema indication, along with three additional orphan indications. ViroPharma is solely responsible for the development, manufacturing, regulatory approval and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of bulk formulation of rHuPH20 (active pharmaceutical ingredient or API), if requested by ViroPharma. We are also entitled to receive milestone payments and royalties on product sales by ViroPharma.

In March 2012, ViroPharma reported positive data from ViroPharma s Phase 2 subcutaneous trial of Cinryze in combination with Enhanze technology in patients with hereditary angioedema, a rare, debilitating and potentially fatal genetic disease. These data demonstrate that subcutaneous co-administration of Cinryze with rHuPH20 was easy to administer, well tolerated and resulted in sustained physiologically relevant C1 INH functional concentrations. This innovative combination administered subcutaneously as a single injection will be further evaluated for the prevention of hereditary angioedema attacks. The results were presented at the 2012 annual meeting of the American Academy of Allergy Asthma & Immunology, held from March 2 to 6, 2012 in Orlando, Florida. The open-label, multiple-dose Phase 2 clinical trial was conducted in 12 subjects with hereditary angioedema. The study was designed to evaluate the safety, pharmacokinetics and pharmacodynamics of subcutaneous administration of Cinryze in combination with rHuPH20. We believe this product candidate could improve flexibility and convenience, and potentially allow prevention-minded patients living with hereditary angioedema to self administer every three or four days, just as they do today with the current IV formulation, but with a single subcutaneous injection. ViroPharma announced that it plans to conduct a larger Phase 2 dose ranging clinical trial beginning in 2012.

Intrexon Partnership

Effective June 6, 2011, we and Intrexon entered into a collaboration and license agreement under which Intrexon obtained a worldwide exclusive license for the use of rHuPH20 enzyme in the development of a subcutaneous injectable formulation of Intrexon s recombinant human alpha 1-antitrypsin (rHuA1AT) (the Intrexon Partnership). In addition, the license provides Intrexon with exclusivity for a defined indication (Exclusive Field). Intrexon is solely responsible for the development, manufacturing, regulatory approval and marketing of any products resulting from this partnership. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by Intrexon. We are also entitled to receive milestone payments and royalties on product sales.

Hylenex Recombinant

Hylenex recombinant is a formulation of rHuPH20 that has received FDA approval to facilitate subcutaneous fluid administration for achieving hydration, increase the dispersion and absorption of other injected drugs and, in subcutaneous urography, improve resorption of radiopaque agents.

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Revenues

We generate revenues from product sales and collaborative agreements. Revenue from product sales depends on our ability to develop, manufacture, obtain regulatory approvals for and successfully commercialize our products and product candidates. Payments received under collaborative agreements may include nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for the manufacture of bulk formulation of rHuPH20 (active pharmaceutical ingredient or API) for partners and/or royalties, as applicable, on sales of products resulting from collaborative agreements. We analyze each element of our collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition. See *Critical Accounting Policies and Estimates Revenue Recognition Revenue Under Collaborative Agreements* below for our revenue recognition policies for payments received under collaborative agreements.

Costs and Expenses

Cost of Product Sales. Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight costs, internal costs and manufacturing overhead associated with the production of our products. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories.

Research and Development. 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. 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. Our research and development activities are primarily focused on the development of our various product candidates.

Since our inception in 1998 through March 31, 2012, we have incurred research and development expenses of $275 million. From January 1, 2009 through March 31, 2012, approximately 28% and 16% of our research and development expenses were associated with the development of our ultrafast insulin and PEGPH20 product candidates, respectively. Research and development expenses incurred for the three months ended March 31, 2012 and 2011 were as follows:

	Three Months Ended March 31,	
Programs	2012	2011
Product Candidates:		
Analog Insulin-PH20	$ 1,467,036	$ 6,477,617
PEGPH20	3,042,829	1,388,160
HTI-501	669,170	923,690
Hylenex recombinant	2,330,482	885,205
Enhanze partnerships	3,958,003	1,791,168
rHuPH20 platform (1)	2,956,594	1,818,587
Other	1,466,995	501,370
Total research and development expenses	$ 15,891,109	$ 13,785,797

(1) Includes research, development and manufacturing expenses related to our proprietary recombinant human PH20 enzyme, rHuPH20. These expenses were not designated to a specific program at the time the expenses were incurred.

Due to the uncertainty in obtaining the 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.

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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 (SG&A). Through the second quarter of 2011, our selling expenses, which include sales and marketing costs, primarily consisted of compensation, consulting fees and costs of market research studies related to our product and product candidates. In the third and fourth quarters of 2011, we expanded our commercial infrastructure, including hiring of sales and marketing management and sales representatives. In addition, we began incurring costs related to advertising, marketing and logistics services for *Hylenex* recombinant in connection with the reintroduction of *Hylenex* recombinant in December 2011.

Our general and administrative expenses consist primarily of compensation and other expenses related to our corporate operations and administrative employees, accounting and legal fees, other professional services 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 (U.S. GAAP). The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

We recognize revenue in accordance with 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 or determinable; and (4) collectibility is reasonably assured.

Product Sales

Hylenex recombinant was approved for marketing by the FDA in December 2005. From 2005 through January 7, 2011, Baxter had the worldwide market rights for *Hylenex* recombinant under the terms of the Hylenex

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Partnership. Baxter commercially launched *Hylenex* recombinant in October 2009. However, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the product manufactured by Baxter was not in compliance with the requirements of the underlying partnership. Effective January 7, 2011, we and Baxter mutually agreed to terminate the Hylenex Partnership. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant to the market. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant**.**

In December 2011, we reintroduced *Hylenex* recombinant to the market, shipped initial stocking orders to our wholesaler customers and began promoting *Hylenex* recombinant through our sales force. We sell *Hylenex* recombinant in the United States to wholesale pharmaceutical distributors, who sell the product to hospitals and other end-user customers. The wholesale distributors take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales; however, we do allow the wholesale distributors to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to and ending twelve months following product expiration. Given our limited experience history of selling *Hylenex* recombinant and the lengthy return period, we currently cannot reliably estimate expected returns and chargebacks of *Hylenex* recombinant at the time the product is received by the wholesale distributors. Therefore, we do not recognize revenue upon delivery of *Hylenex* recombinant to the wholesale distributor until the point at which we can reliably estimate expected product returns and chargebacks from the wholesale distributors. Shipments of *Hylenex* recombinant are recorded as deferred revenue until evidence exists to confirm that pull-through sales to the hospitals or other end-user customers have occurred. We recognize revenue when the product is sold through from the distributors to the distributors customers. In addition, the costs of manufacturing *Hylenex* recombinant associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized. We estimate sell-through revenue and certain gross to net sales adjustments based on analysis of third-party information including information obtained from certain distributors with respect to their inventory levels and sell-through to the distributors customers. At the time we can reliably estimate product returns and chargebacks from the wholesale distributors, we will record a one-time increase in net product sales revenue related to the recognition of product sales revenue previously deferred.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with wholesaler customers, hospitals and the levels of inventory within the distribution channels that may result in future discounts taken. We must make significant judgments in determining these allowances. If actual results differ from our estimates, we will be required to make an adjustment to these allowances in the future, which could have an effect on product sales revenue in the period of adjustment. Our product sales allowances include:

Distribution Fees. The distribution fees, based on contractually determined rates, arise from contractual agreements we have with certain wholesale distributors for distribution services they provide with respect to *Hylenex* recombinant. At the time the sale is made to the respective wholesale distributors, we record an allowance for distribution fees by reducing our accounts receivable and deferred revenue associated with such product sales.

Prompt Payment Discounts. We offer cash discounts to certain wholesale distributors as an incentive to meet certain payment terms. We expect our customers to take advantage of this discount. Therefore, at the time the sale is made to the respective wholesale distributors, we accrue the entire prompt payment discount, based on the gross amount of the invoice by reducing our accounts receivable and deferred revenue associated with such product sales.

Chargebacks. We provide discounts to certain hospitals. These hospitals purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the hospitals paid for the product. Given our lack of historical sales data, we recognize chargebacks in the same period the related product sales revenue is recognized and reduce our accounts receivable accordingly.

Product Returns. The product returns reserve is based on management s best estimate of the product sales recognized as revenue during the period that are anticipated to be returned. The product returns reserve is recorded as a reduction of product sales revenue in the same period the related product sales revenue is recognized and is included in accrued expenses.

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Revenues under Collaborative Agreements

We have entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of our proprietary rHuPH20 enzyme in the development and commercialization of the partners biologic compounds. The collaborative agreements contain multiple elements including nonrefundable payments at the inception of the arrangements, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the partner and/or royalties on sales of products resulting from collaborative agreements. We analyze each element of the collaborative agreements and consider a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of fair value of the undelivered items, and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, we recognized revenue on nonrefundable upfront payments and license fees from these collaborative agreements over the period of significant involvement under the related agreements.

For new collaborative agreements or material modifications of existing collaborative agreements entered into after December 31, 2010, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under our collaborative agreements include (i) the license to rHuPH20 technology, (ii) at the collaborator s request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator s request, supply of rHuPH20 API which is reimbursed at our cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace.

Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement.

Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of rHuPH20 API, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the partner is fixed or determinable and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

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The terms of our collaborative agreements provide for milestone payments upon achievement of certain development and regulatory events and/or specified sales volumes of commercialized products by the collaborator.

Effective January 1, 2011, we adopted on a prospective basis the Milestone Method. Under the Milestone Method, we recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity s performance to achieve the milestone,

2. The consideration relates solely to past performance, and

3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the vendor s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the vendor.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of rHuPH20 API is recognized when the API has met all specifications required for the collaborator s acceptance and title and risk of loss have transferred to the collaborator. We do not directly control when any collaborator will request research and development services or supply of rHuPH20 API; therefore, we cannot predict when we will recognize revenues in connection with research and development services and supply of rHuPH20 API. Royalties to be received based on sales of licensed products by our collaborators incorporating rHuPH20 will be recognized as earned.

The collaborative agreements typically provide the partners the right to terminate such agreements in whole or on a product-by-product or target-by-target basis at any time upon 90 days prior written notice to us. There are no performance, cancellation, termination or refund provisions in any of our collaborative agreements that contain material financial consequences to us.

Roche Partnership

In December 2006, we and Roche entered into the Roche Partnership under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with up to thirteen Roche target compounds. As of March 31, 2012, we have received $57 million from Roche, including the $20 million upfront license fee payment for the application of rHuPH20 to the initial three Roche exclusive targets, $20 million in connection with Roche s election of two additional exclusive targets and annual license maintenance fees for the right to designate the remaining targets as exclusive targets, $13 million in clinical development milestone payments and a $4 million regulatory milestone payment. If Roche successfully develops all five exclusive targets and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $178 million, including up to $17 million for the achievement of clinical development milestones, up to $16 million for the achievement of regulatory milestones and up to $145 million for the achievement of sales-based milestones. Under the terms of the Roche Partnership, Roche will also pay us royalties on product sales for each exclusive target. Roche currently retains the option to develop and commercialize rHuPH20 with three additional targets under the Roche Partnership, provided that it continues to pay annual maintenance fees to us. For each of the additional targets, Roche may pay us upfront and milestone payments of up to $47 million per target, as well as royalties on product sales, for each of the additional targets.

Due to our continuing involvement obligations (for example, support activities associated with rHuPH20), 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. We have determined that the clinical and regulatory milestones are substantive; therefore, we expect to recognize such clinical and regulatory milestone payments as revenue upon achievement. In addition, we have determined that the sales-based milestone payments

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are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, we will recognize such sales-based milestone payments as revenue upon achievement of the milestone. In March 2012, Roche submitted a Line Extension Application to the European Medicines Agency for Herceptin SC. Upon achievement of this milestone, we recognized a regulatory milestone payment of $4 million as revenue under collaborative agreements in accordance with the Milestone Method in the three months ended March 31, 2012. For the three months ended March 31, 2011, we recognized $5 million as revenue under collaborative agreements in accordance with the Milestone Method related to the achievement of certain clinical milestone pursuant to the terms of the Roche Partnership.

Gammagard Partnership

In September 2007, we and Baxter entered into the Gammagard Partnership under which Baxter obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with HyQ. As of March 31, 2012, we have received $13 million under the Gammagard Partnership, including the $10 million upfront license fee payment and a $3 million regulatory milestone payment. If Baxter successfully receives marketing approval for the licensed product candidate and achieves pre-agreed sales targets, we could receive additional milestone payments of up to $34 million for the achievement of sales-based milestones. In addition, Baxter will pay royalties on the sales, if any, of the products that result from the collaboration. The Gammagard Partnership is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Gammagard Partnership, while we are responsible for the supply of the rHuPH20 enzyme. We perform research and development activities at the request of Baxter, which are reimbursed by Baxter under the terms of the Gammagard Partnership. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Gammagard Partnership.

Due to our continuing involvement obligations (for example, support activities associated with rHuPH20), revenues from the upfront payment was deferred and are being recognized over the term of the Gammagard Partnership. We have determined that sales-based milestone payments are similar to royalty payments and are not considered milestone payments under the Milestone Method of revenue recognition; therefore, such payments will be recognized as revenue upon achievement of the milestone. There were no milestone payments recognized as revenue under the terms of the Gammagard Partnership for the three months March 31, 2012 and 2011.

ViroPharma and Intrexon Partnerships

Effective May 2011, we and ViroPharma entered into the ViroPharma Partnership. As of March 31, 2012, we have received $12 million from ViroPharma, including the $9 million nonrefundable upfront license fee payment and a $3 million clinical development milestone payment. If ViroPharma successfully develops the licensed product candidate, we could receive additional milestone payments of up to $41 million for the achievement of development and regulatory milestones. In addition, so long as the agreement is in effect, we are entitled to receive an annual exclusivity fee of $1 million commencing May 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by ViroPharma. In addition, we are entitled to receive additional cash payments potentially totaling $10 million upon achievement of certain development and regulatory milestones for each product targeting the treatment of any of the three additional orphan indications. We are also entitled to receive royalties on product sales by ViroPharma.

Effective June 2011, we and Intrexon entered into the Intrexon Partnership. As of March 31, 2012, we have received a nonrefundable upfront license fee payment of $9 million from Intrexon. If Intrexon successfully develops the licensed product candidate and achieves the pre-agreed sales target, we could receive additional milestone payments of up to $54 million, including $44 million for the achievement of development and regulatory milestones and $10 million for the achievement of a sales-based milestone. In addition, so long as the agreement is in effect, we are entitled to receive an annual exclusivity fee of $1 million commencing June 2012 and on each anniversary of the effective date of the agreement thereafter until a certain development event occurs. We are entitled to receive payments for research and development services and supply of rHuPH20 API if requested by Intrexon. In addition, we are entitled to receive additional cash payments potentially totaling $10 million for each product for use outside the Exclusive Field upon achievement of development and regulatory milestones. We are also entitled to receive royalties on product sales at a royalty rate which increases with net sales of product.

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We identified the deliverables at the inception of the ViroPharma and Intrexon Partnerships which are the license, research and development services and API supply. We have determined that the license, research and development services and API supply individually represent separate units of accounting, because each deliverable has standalone value. The estimated selling prices for these units of accounting were determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotech industry and entity-specific factors such as the terms of our previous collaborative agreements, our pricing practices and pricing objectives and the nature of the research and development services to be performed for the partners. The arrangement consideration was allocated to the deliverables based on the relative selling price method. Based on the results of our analysis, we determined that the upfront payment was earned upon the granting of the worldwide exclusive right to our technology to the collaborator in both the ViroPharma Partnership and Intrexon Partnership. However, the amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the license was only to the extent of cash received. As a result, we recognized the $9 million upfront license fee received under the ViroPharma Partnership and $9 million upfront license fee received under the Intrexon Partnership as revenues under collaborative agreements upon the receipt of such upfront license fees.

We will recognize the exclusivity fees as revenue under collaborative agreements when they are earned. We will recognize reimbursements for research and development services as revenue under collaborative agreements as the related services are delivered. We will recognize payments from sales of API as revenue under collaborative agreements when such API has met all required specifications by the partners and the related title and risk of loss and damages have passed to the partners. We cannot predict the timing of delivery of research and development services and API as they are at the partners requests.

We are eligible to receive additional cash payments upon the achievement by the partners of specified development, regulatory and sales-based milestones. We have determined that each of the development and regulatory milestones is substantive; therefore, we expect to recognize such development and regulatory milestone payments as revenue under collaborative agreements upon achievement in accordance with the Milestone Method. In addition, we have determined that the sales-based milestone payment is similar to a royalty payment and is not considered a milestone payment under the Milestone Method of revenue recognition; therefore, we will recognize the sales-based milestone payment as revenue upon achievement of the milestone because we have no future performance obligations associated with the milestone. There were no milestone payments recognized as revenue under collaborative agreements under these partnerships for the three months ended March 31, 2012 and 2011.

Share-Based Payments

We use the fair value method to account for share-based payments in accordance with the authoritative guidance for share-based compensation. The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model (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 rates 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 yields 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 share-based payments using an option-pricing model, such value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

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Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, clinical trials, research related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as 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 at such time when we do not expect the goods to be delivered or services to be performed.

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 as incurred.

Payments made 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 progress of clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in scope of contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Because of the uncertainty of possible future changes to the scope of work in clinical trial 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.

Inventories

Inventories are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by our contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

Raw materials inventories consist of raw materials used in the manufacture of our bulk drug material for *Hylenex* recombinant product. Work-in-process inventories consist of in-process *Hylenex* recombinant. Finished goods inventories consist of finished *Hylenex* recombinant product.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be realized. For products that have been approved by regulatory bodies such as the FDA, inventories used in clinical trials are expensed at the time the

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inventories are packaged for the clinical trials. Prior to receiving approval from the FDA or comparable regulatory agencies in foreign countries, costs related to purchases of the API and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized as inventories.

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 management s judgment in selecting any available alternative would not produce a materially different result. Please see our audited consolidated financial statements and notes thereto included in Part II, Item 8 of our Annual Report on Form 10-K for the year ended December 31, 2011, which contain accounting policies and other disclosures required by U.S. GAAP.

Results of Operations

Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011

Product Sales, Net Product sales, net were $187,000 for the three months ended March 31, 2012 compared to $165,000 for the three months ended March 31, 2011. Based on the reintroduction of *Hylenex* recombinant in December 2011, we expect product sales to increase in 2012 as compared to 2011.

Revenues Under Collaborative Agreements Revenues under collaborative agreements were $7.3 million for the three months ended March 31, 2012 compared to $7.4 million for the three months ended March 31, 2011. Revenues under collaborative agreements primarily consisted of the amortization of license fees and milestone payments received from Roche and Baxter of approximately $4.6 million and $5.7 million for three months ended March 31, 2012 and 2011, respectively. Revenues under collaborative agreements also included reimbursements for research and development services from our partners of approximately $2.4 million and $1.6 million for the three months ended March 31, 2012 and 2011, respectively. Research and development services rendered by us on behalf of our partners are at the request of the partners; therefore, 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 fluctuate in future periods based on our partners abilities to meet various clinical and regulatory milestones set forth in such agreements and our abilities to obtain new collaborative agreements.

Cost of Product Sales Cost of product sales were $71,000 for the three months ended March 31, 2012 compared to $12,000 for the three months ended March 31, 2011. Based on the reintroduction of *Hylenex* recombinant in December 2011, we expect cost of product sales to increase in 2012 as compared to 2011.

Research and Development Research and development expenses were $15.9 million for the three months ended March 31, 2012 compared to $13.8 million for the three months ended March 31, 2011. The increase of $2.1 million, or 15%, was primarily due to a $1.9 million increase in compensation costs, including a $727,000 increase in stock-based compensation, mainly due to an increase in headcount to 95 employees at March 31, 2012 from 77 employees at March 31, 2011. The increase was also due to a $2 million increase in manufacturing activities and $1.1 million increase in other research and development activities. These increases were partially offset by a $3.1 million decrease in clinical trial activities mainly related to the ultrafast insulin program. We expect research and development costs to increase in 2012 as compared to 2011 as we continue with our clinical trial programs and continue to develop and manufacture our product candidates.

Selling, General and Administrative SG&A expenses were $6.6 million for the three months ended March 31, 2012 compared to $3.4 million for the three months ended March 31, 2011. The increase of $3.2 million, or 94%, was primarily due to increases of $2.1 million in compensation costs, including a $497,000 increase in stock-based compensation, and $375,000 in sales and marketing expenses mainly associated with the reintroduction of *Hylenex* recombinant in December 2011. SG&A headcount increased to 41 employees at March 31, 2012 from 24 employees at March 31, 2011. In connection with the reintroduction of *Hylenex* recombinant in December 2011, we expect SG&A expenses to increase in 2012 as compared to 2011.

Interest and Other Income, Net Interest and other income, net was $21,000 for the three months ended March 31, 2012 compared to $24,000 for the three months ended March 31, 2011.

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Net Loss Net loss for the three months ended March 31, 2012 was $15.1 million, or $0.14 per common share, compared to $9.6 million, or $0.10 per common share for the three months ended March 31, 2011. The increase in net loss was primarily due to an increase in operating expenses for the three months ended March 31, 2012 as compared to the same period in 2011.

Liquidity and Capital Resources

Overview

Our principal sources of liquidity are our existing cash and cash equivalents. As of March 31, 2012, we had cash and cash equivalents of approximately $116.6 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.

We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months. Currently, we anticipate total net cash burn of approximately $55.0 to $60.0 million for the year ending December 31, 2012, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones under our existing collaborative agreements. We do not expect our revenues to be sufficient to fund operations for several years. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing collaborations and cash that we may raise through future transactions. We may finance future cash needs through any one of the following financing vehicles: (i) the public offering of securities; (ii) new collaborative agreements; (iii) expansions or revisions to existing collaborative relationships; (iv) private financings; and/or (v) other equity or debt financings.

We are currently a Well-Known Seasoned Issuer and may file automatic shelf registration statements at any time with the SEC. In February 2012, we filed an automatic shelf registration statement on Form S-3 (Registration No. 333-179444) with the SEC. On February 15, 2012, we sold approximately 7.8 million shares of our common stock at a public offering price of $10.61 per share, generating approximately $81.5 million in net proceeds. We may, in the future, offer and sell equity, debt securities and warrants to purchase any of such securities, either individually or in units 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 may 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, financing will be obtained on favorable terms. If we are unable to raise sufficient funds, we may 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 and covenants that may restrict our ability to operate our business.

Cash Flows

Net cash used in operations was $19.4 million during the three months ended March 31, 2012 compared to $11.1 million of net cash used in operations during the three months ended March 31, 2011. This change was primarily due to the increase in net loss of $5.5 million adjusted for non-cash items including stock-based compensation and depreciation and amortization in addition to changes in working capital for the three months ended March 31, 2012 as compared to the same period in 2011. The increase in net loss was due to the increase in operating expenses for the three months ended March 31, 2012 as compared to the same period in 2011.

Net cash provided by investing activities was $16,000 during the three months ended March 31, 2012 compared to net cash used in investing activities of $203,000 during the three months ended March 31, 2011. This was primarily due to a decrease in purchases of property and equipment during the three months ended March 31, 2012.

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Net cash provided by financing activities was $83.1 million during the three months ended March 31, 2012 compared to $1.9 million during the three months ended March 31, 2011. Net cash provided by financing activities for the three months ended March 31, 2012 consisted of $81.5 million in net proceeds from the sale of our common stock in February 2012 and $1.6 million in net proceeds from stock option exercises. Net cash provided by financing activities for the three months ended March 31, 2011 consisted of proceeds from stock option exercises.

Off-Balance Sheet Arrangements

As of March 31, 2012, 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 such relationships.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies Adoption of Recent Accounting Pronouncements*, in the Notes to Condensed Consolidated Financial Statements for a discussion of recent accounting pronouncements and their effect, if any, on us.

Risk Factors

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 revenues from product sales, licensing fees, milestone payments and research reimbursements 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, research reimbursements 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 March 31, 2012, we have incurred aggregate net losses of approximately $260.1 million.

If our proprietary and partnered product candidates do not receive and maintain regulatory approvals, or if approvals are not obtained in a timely manner, such failure or delay would substantially impair our ability to generate revenues.

Approval from the FDA is necessary to manufacture and market pharmaceutical products in the United States, and the other countries in which we anticipate doing business have similar requirements. 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 applications 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 the desired product launch schedule for a product candidate. We, and our partners, attempt to provide guidance as to the timing for the filing and acceptance of such regulatory approvals, but such filings and approvals may not occur on the originally anticipated timeline, or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our or our partnered product candidates for failure to collect sufficient clinical or animal safety data and require us or our partners to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs. For example, in April 2012 we and Baxter announced that the FDA requested additional data to complete its review of Baxter s HyQ BLA, which we expect will delay the anticipated regulatory and approval timeline. Only two of our partnered product candidates are currently in the regulatory approval process and there are no proprietary product candidates currently in the regulatory approval process. We and our partners may not be successful in obtaining such approvals for any potential products in a timely manner, or at all. See *Our proprietary and partnered product candidates may not receive regulatory approvals for a variety of reasons, including unsuccessful clinical trials* for additional information relating the approval of product candidates.

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Additionally, in order to continue to manufacture and market pharmaceutical products, we must maintain our regulatory approvals. If we or any of our partners are unsuccessful in maintaining our regulatory approvals, our ability to generate revenues would be adversely affected.

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. (Avid) and Cook Pharmica LLC (Cook) to produce bulk API. These manufacturers each produce API under cGMP for clinical uses. In addition, Avid currently produces API for *Hylenex* recombinant. 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 have been required to significantly scale up our commercial API production at Cook during the last two years. If Cook is unable to obtain status as a current Good Manufacturing Practices (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.

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.

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

rHuPH20 is a key technological component of Enhanze technology, our ultrafast insulin program, our PEGPH20 program, *Hylenex* recombinant and other proprietary and partnered products and product candidates. An adverse development for rHuPH20 (e.g., an adverse regulatory determination relating to rHuPH20, 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.

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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 and other jurisdictions, regulatory approval can be delayed, limited or not granted for many reasons, including, among others:

- clinical results may not meet prescribed endpoints for the studies or otherwise provide sufficient data to support the efficacy of our product candidates;
- clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates;
- regulatory review may not find a product candidate safe or effective enough to merit either continued testing or final approval;
- regulatory review may not find that the data from preclinical testing and clinical trials justifies approval, or they may require additional studies that would significantly delay or make continued pursuit of approval commercially unattractive;
- a regulatory agency 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 regulatory approval for such a trial;
- a regulatory agency may not approve our manufacturing processes or facilities, or the processes or facilities of our partners, our contract manufacturers or our raw material suppliers;
- a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities, or the existing processes or facilities of our partners, our contract manufacturers or our raw material suppliers;
- a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations or raise new issues or concerns late in the approval process; or
- a product candidate may be approved only for indications that are narrow or under conditions that place the product at a competitive disadvantage, which may limit the sales and marketing activities for such product candidate or otherwise adversely impact the commercial potential of a product.

If a proprietary or partnered product candidate is not approved 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 the 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

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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.

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 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, or if the third parties we identify fail to perform their obligations, the progress of clinical trials could be delayed or even suspended and the commercialization of approved product candidates could be delayed or prevented. For example, *Hylenex* recombinant was voluntarily recalled in May 2010 because a portion of the *Hylenex* recombinant manufactured by Baxter was not in compliance with the requirements of the underlying *Hylenex* recombinant agreements. During the second quarter of 2011, we submitted the data that the FDA had requested to support the reintroduction of *Hylenex* recombinant. The FDA approved the submitted data and granted the reintroduction of *Hylenex* recombinant and we reintroduced *Hylenex* recombinant to the market in December 2011. In June 2011, we entered into a commercial manufacturing and supply agreement with Baxter, under which Baxter will fill, finish and package *Hylenex* recombinant product for us. Under our commercial manufacturing and supply agreement with Baxter, Baxter has agreed to fill and finish *Hylenex* recombinant product for us for a limited period of time. The initial term of the commercial manufacturing and supply agreement with Baxter expires on December 31, 2012 and is renewable for one additional year upon mutual agreement. In June 2011, we entered into a services agreement with a third party manufacturer for the technology transfer and manufacture of *Hylenex* recombinant. While we expect to enter into a commercial manufacturing and supply agreement with a new manufacturer of *Hylenex* recombinant, if we are unable to find a suitable manufacturer of *Hylenex* recombinant prior to the expiration of the commercial manufacturing and supply agreement with Baxter or if a new manufacturer encounters difficulties in the manufacture, fill, finish or packaging of *Hylenex* recombinant, our business and financial condition could be adversely effected.

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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, *Hylenex* recombinant, 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. These third parties would be largely responsible for the speed and scope of sales and marketing efforts, and may not dedicate the resources necessary to maximize product opportunities. Our ability to cause these third parties to increase the speed and scope of their efforts may also 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. For example, in January 2011 we and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements.

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, and our partners, 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.

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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.

We may wish to raise 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 may wish to raise 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 may 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 when needed, 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 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.

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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 products and 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, such as Gregory Frost, Ph.D., our President and Chief Executive Officer, we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained. For example, Dr. Frost has been with us from soon after our inception, and he possesses a substantial amount of knowledge about our development efforts. If we were to lose his services, we would experience delays in meeting our product development schedules. We currently have 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. 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.

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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 March 31, 2012 were $13.50 and $5.54, respectively. We expect our stock price to continue to be subject to significant volatility and, in addition to the other risks and uncertainties described

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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 waiting to be 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 may negatively affect our stock price.

We are currently a Well-Known Seasoned Issuer and may file automatic shelf registration statements at any time with the SEC. In addition, we currently have the ability to offer and sell additional equity, debt securities and warrants to purchase such securities, either individually or in units, under an effective automatic shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our shelf registration statements could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into our common stock.

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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

Our products must receive regulatory approval before they can be sold, and compliance with the extensive government regulations 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 (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. 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 may impose onerous, costly and time-consuming requirements such as additional clinical or animal testing. The FDA or other foreign regulatory agency may, at any time, halt our and our partners development and commercialization activities due to safety concerns. In addition, even if our products are approved, regulatory agencies may also take post-approval action limiting or revoking our ability to sell our products. Any of these regulatory actions may adversely affect the economic benefit we may derive from our products and therefore harm our financial condition.

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

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

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

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

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We currently own or license several 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. A European patent, EP1603541, claiming rHuPH20 was granted to us on November 11, 2009 with claims to the human PH20 glycoprotein, PEGylated variants, a method of producing the glycoprotein produced by recombinant methods, and pharmaceutical compositions with other agents, including antibodies, insulins, cytokines, a chemotherapeutic agent and additional therapeutic classes. A third party opposed this patent in the European Patent Office in 2010, but withdrew the opposition in March 2012. We are currently attempting to resolve the opposition with the European Patent Office, and although we expect to obtain European patent protection that would be no less broad than claims previously issued in a counterpart United States patent (U.S. Patent No. 7,767,429), there can be no assurance that we will be able to do so. Any 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 result in us having no or limited protection against generic or biosimilar competition against our product candidates which would 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, or other proceedings in other jurisdictions, to determine the priority, validity or enforceability of our patents. 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, the Leahy-Smith America Invents Act (HR 1249) was signed into law in September 2011, which among other changes to the U.S. patent laws, changes patent priority from first to invent to first to file, implements a post-grant opposition system for patents and provides for a prior user defense to infringement. These judicial and legislative changes have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

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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.

In March 2010, the United States adopted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the Healthcare Reform Act). This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, the Healthcare Reform Act imposes a non-deductible

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excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs that we believe will impact our revenues from our products. In addition, as part of the Healthcare Reform Act s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program, we will also be required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries under this prescription drug program. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

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. The competitors for *Hylenex* recombinant will include, but are not limited to ISTA Pharmaceuticals, Inc. For our Analog-PH20 product candidates, such competitors may include Biodel Inc., Eli Lily, Sanofi Aventis, Novo Nordisk 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 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 March 31, 2012, 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. If a 10% change in interest rates were to have occurred on March 31, 2012, this change would not have had a material effect on the fair value of our investment portfolio as of that date nor our net loss for the three months then ended. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control Over Financial Reporting

There have been no significant changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2012 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.

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 uncertainties regarding the regulatory approval of proprietary and partnered product candidates. 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.

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Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit	Title
2.1	Agreement and Plan of Merger, dated November 14, 2007, by and between the Registrant and the Registrant s predecessor Nevada corporation (1)
3.1	Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on October 7, 2007 (2)
3.2	Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock (1)
3.3	Bylaws, as amended (2)
4.1	Amended Rights Agreement between Corporate Stock Transfer, as rights agent, and Registrant, dated November 12, 2007 (3)
10.1	Underwriting Agreement between Halozyme Therapeutics, Inc. and Barclays Capital Inc., dated February 10, 2012 (4)
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
101	The following materials from the Halozyme Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 formatted in eXtensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) related notes, tagged as block of text*.

* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

(1) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed November 20, 2007 (File No. 001-32335).

(2) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed December 12, 2011 (File No. 001-32335).

(3) Incorporated by reference to the Registrant s Annual Report on Form 10-K, filed March 14, 2008 (File No. 001-32335).

(4) Incorporated by reference to the Registrant s Current Report on Form 8-K, filed February 10, 2012 (File No. 001-32335).

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SIGNATURES

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

Halozyme Therapeutics, Inc.,
a Delaware corporation

Dated: May 7, 2012

/s/ Gregory I. Frost, Ph.D.
Gregory I. Frost, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Dated: May 7, 2012

/s/ Kurt A. Gustafson
Kurt A. Gustafson
Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)