HALOZYME THERAPEUTICS INC
Form 10-Q
November 10, 2014

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

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

For the quarterly period ended September 30, 2014
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 ý 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 ý 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 ý	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 ý

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 125,387,083 as of November 5, 2014.

HALOZYME THERAPEUTICS, INC.
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PART I — FINANCIAL INFORMATION
Item 1. Financial Statements
HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except per share data)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$46,375	$27,357
Marketable securities, available-for-sale	88,089	44,146
Accounts receivable, net	8,275	9,097
Inventories	6,916	6,170
Prepaid expenses and other assets	8,945	8,425
Total current assets	158,600	95,195
Property and equipment, net	3,249	3,422
Prepaid expenses and other assets	2,277	2,676
Restricted cash	500	500
Total Assets	$164,626	$101,793
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$4,342	$3,135
Accrued expenses	15,023	14,369
Deferred revenue, current portion	5,153	7,398
Current portion of long-term debt, net	10,075	—
Total current liabilities	34,593	24,902
Deferred revenue, net of current portion	47,572	45,745
Long-term debt, net	39,762	49,772
Other long-term liabilities	2,759	1,364
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock - $0.001 par value; 20,000 shares authorized; no shares issued and outstanding	—	—
Common stock - $0.001 par value; 200,000 shares authorized; 125,546 and 114,533 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	125	115
Additional paid-in capital	485,014	361,930
Accumulated other comprehensive (loss) income	(46)	17
Accumulated deficit	(445,153)	(382,052)
Total stockholders' equity (deficit)	39,940	(19,990)
Total Liabilities and Stockholders' Equity (Deficit)	$164,626	$101,793

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except per share data)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Revenues:				
Product sales, net	$9,617	$10,025	$27,679	$14,634
Royalties	2,895	—	5,382	—
Revenues under collaborative agreements	2,094	5,988	11,896	27,667
Total revenues	14,606	16,013	44,957	42,301
Operating expenses:				
Cost of product sales	5,141	683	16,585	2,706
Research and development	19,904	25,689	59,968	75,714
Selling, general and administrative	8,587	8,135	27,589	22,991
Total operating expenses	33,632	34,507	104,142	101,411
Operating loss	(19,026)	(18,494)	(59,185)	(59,110)
Other income (expense):				
Investment and other income, net	122	52	287	165
Interest expense	(1,376)	(850)	(4,203)	(2,547)
Net Loss	$(20,280)	$(19,292)	$(63,101)	$(61,492)
Basic and diluted net loss per share	$(0.16)	$(0.17)	$(0.52)	$(0.55)
Shares used in computing basic and diluted net loss per share	124,041	112,765	122,157	112,554

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	$(20,280)	$(19,292)	$(63,101)	$(61,492)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on marketable securities	(49)	55	(63)	16
Total Comprehensive Loss	$(20,329)	$(19,237)	$(63,164)	$(61,476)

See accompanying notes to condensed consolidated financial statements.

HALOZYME THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(63,101)	$(61,492)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	11,065	7,140
Depreciation and amortization	1,304	893
Non-cash interest expense	1,610	1,037
Amortization of premiums on marketable securities, net	1,062	816
Changes in operating assets and liabilities:		
Accounts receivable, net	822	(8,819)
Inventories	(746)	(1,176)
Prepaid expenses and other assets	98	2,018
Restricted cash	—	(100)
Accounts payable and accrued expenses	1,693	16,071
Deferred revenue	(418)	9,532
Other liabilities	32	(39)
Net cash used in operating activities	(46,579)	(34,119)
Investing activities:		
Purchases of marketable securities	(89,117)	(48,947)
Proceeds from maturities of marketable securities	43,816	—
Purchases of property and equipment	(1,132)	(939)
Net cash used in investing activities	(46,433)	(49,886)
Financing activities:		
Proceeds from issuance of common stock, net	107,713	—
Proceeds from issuance of common stock under equity incentive plans, net	4,317	1,996
Net cash provided by financing activities	112,030	1,996
Net increase (decrease) in cash and cash equivalents	19,018	(82,009)
Cash and cash equivalents at beginning of period	27,357	99,501
Cash and cash equivalents at end of period	$46,375	$17,492

See accompanying notes to condensed consolidated financial statements.

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

1. Organization and Business

Halozyme Therapeutics, Inc. is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding 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 technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

Our proprietary enzymes can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or to alter abnormal tissue structures for clinical benefit. We have chosen to exploit our technology and expertise in a balanced way to modulate both risk and spend by: (1) developing our own proprietary products in therapeutic areas with significant unmet medical needs, such as oncology, diabetes and dermatology, and (2) licensing our technology to biopharmaceutical companies to collaboratively develop products which combine our technology with the collaborators' proprietary compounds.

The majority of the product candidates in our current pipeline are based on rHuPH20, a patented human recombinant hyaluronidase enzyme. rHuPH20 temporarily breaks down hyaluronic acid, a naturally occurring substance that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. We have one proprietary commercial product, Hylenex® recombinant, which we market ourselves, used to increase the dispersion and absorption of other injected drugs.

Our proprietary development pipeline consists of multiple clinical stage product candidates in oncology, diabetes and dermatology. Our lead oncology program is PEGPH20, a new molecular entity, under development for the systemic treatment of tumors that accumulate hyaluronic acid. We are currently in Phase 2 clinical testing for PEGPH20 in pancreatic cancer. We currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (“Roche”), Pfizer Inc. (“Pfizer”) and Baxter Healthcare Corporation (“Baxter”), with one product approved in the U.S. and three products approved in Europe from which we are receiving royalties and several others at various stages of development.

We were founded in 1998 and reincorporated from the State of Nevada to the State of Delaware in November 2007. Except where specifically noted or the context otherwise requires, references to “Halozyme,” “the Company,” “we,” “our,” and “us” in these Notes to Condensed Consolidated Financial Statements refer to Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc., and Halozyme, Inc.'s wholly owned subsidiary, Halozyme Holdings Ltd.

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, 2013, filed with the SEC on February 28, 2014. 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 accompanying condensed consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc., and Halozyme, Inc.'s wholly owned subsidiary, Halozyme Holdings Ltd. 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 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.

Pending Adoption of Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2013-11, Income Taxes (Topic 740), Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (“ASU 2013-11”). The provisions of ASU 2013-11 require entities to present unrecognized tax benefits as a decrease in a net operating loss, similar tax loss or tax credit carryforward if certain criteria are met. The determination of whether a deferred tax asset is available is based on the unrecognized tax benefit and the deferred tax asset that exists at the reporting date and presumes disallowance of the tax position at the reporting date. The guidance will eliminate the diversity in practice in the presentation of unrecognized tax benefits but will not alter the way in which entities assess deferred tax assets for realizability. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2014. The amendments should be applied prospectively to unrecognized tax benefits that exist at the effective date. Early adoption is permitted. The adoption of ASU 2013-11 will not have a material impact on our consolidated financial position or results of operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”). ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early application is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements — Going Concern (“ASU 2014-15”). The provisions of ASU 2014-15 provide that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 is effective for the annual reporting period ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The adoption of ASU 2014-15 will not have a material impact on our consolidated financial position or results of operations.

Cash Equivalents and Marketable Securities

Cash equivalents consist of highly liquid investments, readily convertible to cash, that mature within ninety days or less from date of purchase. Our cash equivalents consist of money market funds.

Marketable securities are investments with original maturities of more than ninety days from the date of purchase that are specifically identified to fund current operations. Marketable securities are considered available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date which reflects management's intention to use the proceeds from the sale of these investments to fund our operations, as necessary. Such available-for-sale investments are carried at fair value with unrealized gains and losses recorded in other comprehensive gain (loss) and included as a separate component of stockholders' equity (deficit). The cost of marketable securities is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in investment and other income, net in the consolidated statements of operations. We use the specific identification method for calculating realized gains and losses on marketable securities sold. Realized gains and losses and declines in value judged to be other-than-temporary on marketable securities, if any, are included in investment and other income, net in the consolidated statements of operations.

Restricted Cash

Under the terms of the leases of our facilities, we are required to maintain letters of credit as security deposits during the terms of such leases. At September 30, 2014 and December 31, 2013, restricted cash of $0.5 million was pledged as collateral for the letters of credit.

Fair Value of Financial Instruments

The authoritative guidance for fair value measurements establishes a three tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Our financial instruments include cash equivalents, available-for-sale marketable securities, accounts receivable, prepaid expenses, accounts payable, accrued expenses and long-term debt. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Further, based on the borrowing rates currently available to us for loans with similar terms, we believe the fair value of long-term debt approximates its carrying value.

Available-for-sale marketable securities consist of corporate debt securities, commercial paper and certificates of deposit and were measured at fair value using Level 2 inputs. Level 2 financial instruments are valued using market prices on less active markets and proprietary pricing valuation models with observable inputs, including interest rates, yield curves, maturity dates, issue dates, settlement dates, reported trades, broker-dealer quotes, issue spreads, benchmark securities or other market related data. We obtain the fair value of Level 2 investments from our investment manager, who obtains these fair values from a third-party pricing service. We validate the fair values of Level 2 financial instruments provided by our investment manager by comparing these fair values to a third-party pricing source.

The following table summarizes, by major security type, our cash equivalents and marketable securities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	September 30, 2014			December 31, 2013		
	Level 1	Level 2	Total estimated fair value	Level 1	Level 2	Total estimated fair value
Cash equivalents:						
Money market funds	$38,911	$—	$38,911	$5,710	$—	$5,710
Available-for-sale marketable securities:						
Corporate debt securities	—	79,097	79,097	—	35,147	35,147
Commercial paper	—	8,992	8,992	—	5,999	5,999
Certificate of deposit	—	—	—	—	3,000	3,000
	$38,911	$88,089	$127,000	$5,710	$44,146	$49,856

There were no transfers between Level 1 and Level 2 of the fair value hierarchy in the three and nine months ended September 30, 2014. We have no instruments that are classified within Level 3 as of September 30, 2014 and December 31, 2013.

Inventories

Inventories are stated at lower of cost or market. Cost 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 we expect to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

Prior to receiving marketing approval from the U.S. Food and Drug Administration (“FDA”) or comparable regulatory agencies in foreign countries, costs related to purchases of bulk rHuPH20 and raw materials and the manufacturing of the product candidates are recorded as research and development expense. All direct manufacturing costs incurred after receiving marketing approval are capitalized as inventory. Inventories used in clinical trials are expensed at the time the inventories are packaged for the clinical trials.

As of September 30, 2014 and December 31, 2013, inventories consisted of $3.3 million and $2.6 million of Hylenex recombinant inventory, respectively, and $3.6 million and $3.5 million of bulk rHuPH20, respectively, for use in the manufacture of Roche's collaboration products. Roche received European marketing approval for Herceptin SC® and MabThera® SC in August 2013 and March 2014, respectively. As such, direct manufacturing costs of bulk rHuPH20 for these collaboration products incurred after the receipt of the European marketing approvals are capitalized as inventory.

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 supply of bulk rHuPH20, and/or royalties on sales of products resulting from collaborative arrangements. We recognize revenues in accordance with the authoritative guidance for revenue recognition. We recognize revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

Product Sales, Net

Hylenex Recombinant

In December 2011, we reintroduced Hylenex recombinant to the market. We sell Hylenex recombinant in the U.S. to wholesale pharmaceutical distributors, who sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although we offer discounts to certain group purchasing organizations ("GPOs"), hospitals and government programs. The wholesalers take the 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.

Prior to December 31, 2013, Hylenex recombinant had a limited sales history, and we could not reliably estimate expected returns and chargebacks of the product at the time the product was sold to the wholesalers. Accordingly, we deferred the recognition of revenue on sales of Hylenex recombinant to wholesalers, and instead, recognized revenue at the time when evidence existed to confirm that pull-through sales from wholesalers to the hospitals or other end-user customers had occurred or the right of return no longer existed, whichever occurred earlier. At the time product sales revenue was recognized, we recorded allowances for product returns and chargebacks based on our best estimates at the time. Shipments of product that were not recognized as revenue were treated as deferred revenue.

At December 31, 2013, we had developed sufficient historical experience and data to reasonably estimate future returns and chargebacks of Hylenex recombinant. As a result, effective December 31, 2013 we began recognizing Hylenex recombinant product sales and related cost of product sales at the time title transfers to the wholesalers.

Upon recognition of revenue from product sales of Hylenex recombinant, we record certain sales reserves and allowances as a reduction to gross revenue. These reserves and allowances include:

- Product Returns. We allow the wholesalers to return product that is damaged or received in error. In addition, we accept unused product to be returned beginning six months prior to and ending twelve months following product expiration. Our estimates for expected returns of expired products are based primarily on an ongoing analysis of historical return patterns.
- Distribution Fees. The distribution fees, based on contractually determined rates, arise from contractual agreements we have with certain wholesalers for distribution services they provide with respect to Hylenex recombinant. These fees are generally a fixed percentage of the price of the product purchased by the wholesalers.
- Prompt Payment Discounts. We offer cash discounts to certain wholesalers as an incentive to meet certain payment terms. We estimate prompt payment discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates.
- Other Discounts and Fees. We provide discounts to end-user members of certain GPOs under collective purchasing contracts between us and the GPOs. We also provide discounts to certain hospitals, who are members of the GPOs,

with which we do not have contracts. The end-user members purchase products from the wholesalers at a contracted discounted price, and the wholesalers then charge back to us the difference between the current retail price and the price the end-users paid for the product. We also incur GPO administrative service fees for these transactions. In addition, we provide predetermined discounts under certain government programs. Our estimate for these chargebacks and fees take into consideration contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates.

Allowances for product returns and chargebacks are based on amounts owed or to be claimed on the related sales. We believe that our estimated product returns for Hylenex recombinant requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. In order to develop a methodology to reliably estimate future returns and provide a basis for recognizing revenue on sales to wholesale distributors, we analyzed many factors, including, without limitation: (1) actual Hylenex recombinant product return history, taking into account product expiration dating at the time of shipment, (2) re-order activities of the wholesalers as well as their customers and (3) levels of inventory at the wholesale channel. We have monitored actual return history on an individual product lot basis since product launch. We considered the dating of product at the time of shipment into the distribution channel and changes in the estimated levels of inventory within the distribution channel to estimate our exposure for returned product. We considered historical chargebacks activity and current contract prices to estimate our exposure for returned product. Based on such data, we believe we have the information needed to reasonably estimate product returns and chargebacks.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Because of the shelf life of Hylenex recombinant and our lengthy return period, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. If actual results differ from our estimates, we will be required to make adjustments to these allowances in the future, which could have an effect on product sales revenue and earnings in the period of adjustments.

Bulk rHuPH20

Subsequent to receiving marketing approval from the FDA or comparable regulatory agencies in foreign countries, sales of bulk rHuPH20 for use in collaboration commercial products are recognized as product sales when the materials have met all the specifications required for the customer's acceptance and title and risk of loss have transferred to the customer. Following the receipts of European marketing approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA® product in May 2013, revenue from the sales of bulk rHuPH20 for these collaboration products are recognized as product sales. For the three months ended September 30, 2014 and 2013, we recognized product sales of bulk rHuPH20 for Roche collaboration products in the amounts of $5.8 million and $7.9 million, respectively, and zero for both periods for the Baxter collaboration products. For the nine months ended September 30, 2014 and 2013, we recognized product sales of bulk rHuPH20 for Roche collaboration products of $17.7 million and $7.9 million, respectively, and zero and $1.1 million, respectively, for the Baxter collaboration product.

Revenues under Collaborative Agreements

We have license and collaboration agreements under which the collaborators obtained worldwide rights for the use of our proprietary rHuPH20 enzyme in the development and commercialization of the collaborators’ biologic compounds. The collaborative agreements contain multiple elements including nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specified milestones designated in the collaborative agreements, annual maintenance fees, reimbursements of research and development services, payments for supply of bulk rHuPH20 for the collaborator and/or royalties 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 of each element.

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 our 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 bulk rHuPH20 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 collaborator 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 not contingent upon the delivery of additional items or meeting other specified performance conditions. 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.

Nonrefundable 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 bulk rHuPH20, 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 collaborator is fixed or determinable and collectibility 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. We account for milestone payments in accordance with the provisions of ASU No. 2010-17, Revenue Recognition - 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 entity'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 reasonably assured. Revenue from the manufacture of bulk rHuPH20 is recognized when the materials have 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 bulk rHuPH20; therefore, we cannot predict when we will recognize revenues in connection with research and development services and supply of bulk rHuPH20.

Since we receive royalty reports 60 days after quarter end, royalty revenue from sales of collaboration products by our collaborators will be recognized in the quarter following the quarter in which the corresponding sales occurred.

The collaborative agreements typically provide the collaborators the right to terminate such agreement in whole or on a product-by-product or target-by-target basis at any time upon 30 to 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.

Refer to Note 4, Collaborative Agreements, for further discussion on our collaborative agreements.

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 and bulk rHuPH20 for use in approved collaboration products. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories and the write-off of any inventories that do not meet certain product specifications, if any.

Prior to European marketing approvals of Roche's collaboration products, Herceptin SC in August 2013 and MabThera SC in March 2014, and Baxter's collaboration product, HYQVIA in May 2013, all costs related to the manufacturing of bulk rHuPH20 for these collaboration products were charged to research and development expenses in the periods such costs were incurred. Therefore, cost of product sales of these bulk rHuPH20 for the three and nine months ended September 30, 2014 and 2013 was materially reduced due to the exclusion of the manufacturing costs that were charged to research and development expenses in the periods prior to receiving marketing approvals.

For the three months ended September 30, 2014, cost of product sales of bulk rHuPH20 excluded $0.8 million in manufacturing costs, of which $0.7 million and $0.1 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively. For the three months ended September 30, 2013, cost of product sales of bulk rHuPH20 excluded $6.5 million in manufacturing costs, of which $6.3 million and $0.2 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively.

For the nine months ended September 30, 2014, cost of product sales of bulk rHuPH20 excluded $1.0 million in manufacturing costs, of which $0.9 million and $0.1 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively. For the nine months ended September 30, 2013, cost of product sales of bulk rHuPH20 excluded $7.4 million in manufacturing costs, of which $6.4 million and $1.0 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively. As of December 31, 2013, bulk rHuPH20 inventory for collaboration products excluded $1.0 million in manufacturing costs. All of the zero-cost inventory has been sold as of September 30, 2014.

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trial expenses, 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. After receiving approval from the FDA or comparable regulatory agencies in foreign countries for a product, costs related to purchases and manufacturing of bulk rHuPH20 for product are capitalized as inventory. The manufacturing costs of bulk rHuPH20 for the collaboration products, Herceptin SC, MabThera SC and HYQVIA, incurred after the receipt of the European marketing approvals are capitalized as inventory.

In accordance with certain research and development agreements, we are obligated to make certain upfront payments upon execution of the agreement. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed or such time when 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 for a particular research and development project that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are expensed as research and development costs at the time the costs are incurred. We have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

Clinical Trial Expenses

Payments in connection with our clinical trials are often made under contracts with multiple contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials 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 the 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. Historically, we have had no material changes in clinical trial expense accruals that had a material impact on our consolidated results of operations or financial position.

Share-Based Compensation

We record compensation expense associated with stock options and other share-based awards in accordance with the authoritative guidance for stock-based compensation. The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense on a straight-line basis, net of estimated forfeitures, over the requisite service period of the award. Share-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$2,295	$1,089	$5,735	$3,352
Selling, general and administrative	1,881	1,215	5,330	3,788
Share-based compensation expense	$4,176	$2,304	$11,065	$7,140

Since we have a net operating loss carryforward as of September 30, 2014, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2014.

As of September 30, 2014, total unrecognized estimated compensation cost related to non-vested stock options was $17.0 million, which was expected to be recognized over a weighted-average period of approximately 2.7 years. Unvested restricted stock awards ("RSAs") and restricted stock units ("RSUs") as of September 30, 2014 was approximately $13.4 million, which was expected to be recognized over a weighted-average period of approximately 2.2 years.

Net Loss Per Share

Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Stock options, unvested RSAs and unvested RSUs are considered common stock 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, unvested RSAs and unvested RSUs totaling approximately 9.8 million and 8.6 million were excluded from the calculation of diluted net loss per common share for the three and nine months ended September 30, 2014 and 2013, respectively, because their effect is anti-dilutive.

Segment Information

We operate our business in one segment, which includes all activities related to the research, development and commercialization of our proprietary enzymes that can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or to alter abnormal tissue structures for clinical benefit. This segment also includes revenues and expenses related to (i) research and development and bulk rHuPH20 manufacturing 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. Marketable Securities

Available-for-sale marketable securities consisted of the following (in thousands):

	September 30, 2014			
Description	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$79,143	$11	$(57)	$79,097
Commercial paper	8,992	—	—	8,992
	$88,135	$11	$(57)	$88,089

	December 31, 2013			
Description	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$35,130	$20	$(3)	$35,147
Commercial paper	5,999	—	—	5,999
Certificates of deposit	3,000	—	—	3,000
	$44,129	$20	$(3)	$44,146

As of September 30, 2014, $79.0 million of our available-for-sale marketable securities were scheduled to mature within the next 12 months, and $9.1 million were scheduled to mature between twelve and eighteen months from September 30, 2014. There were $43.8 million of marketable securities that matured during the nine months ended September 30, 2014. As of September 30, 2014, we had thirteen available-for-sale marketable securities in a gross unrealized loss position, all of which had been in such position for less than twelve months. Based on our review of these marketable securities, we believe we had no other-than-temporary impairments on these marketable securities as of September 30, 2014 because we do not intend to sell these marketable securities and it is not more likely than not that we will be required to sell these marketable securities before the recovery of their amortized cost basis.

4. Collaborative Agreements

Roche Collaboration

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 Collaboration”). As of September 30, 2014, 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. Roche received European marketing approval in August 2013 for its collaboration product, Herceptin SC, for the treatment of patients with HER2-positive breast cancer and launched Herceptin SC in the European Union (“EU”) in September 2013.

In March 2014, Roche received European marketing approval for its collaboration product, MabThera SC, for the treatment of patients with common forms of non-Hodgkin lymphoma (“NHL”). In June 2014, Roche launched MabThera SC in the EU which triggered a $5.0 million sales-based payment to us for the achievement of the first commercial sale pursuant to the terms of the Roche Collaboration. Due to our continuing involvement obligations, revenue from the sales-based payment will be deferred and amortized over the remaining term of the Roche Collaboration.

Roche assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Roche Collaboration, while we are responsible for the supply of bulk rHuPH20. We are entitled to receive reimbursements for providing research and development services and bulk rHuPH20 to Roche at its request.

Under the terms of the Roche Collaboration, Roche pays us a royalty on each product commercialized under the agreement consisting of a mid-single digit percent of the net sales of such product. Unless terminated earlier in accordance with its terms, the Roche Collaboration continues in effect until the expiration of Roche's obligation to pay royalties. Roche has the obligation to pay royalties with respect to each product in each country, during the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country.

As of September 30, 2014, we have received $77.5 million from Roche, including the $20.0 million upfront license fee payment for the application of rHuPH20 to the initial three Roche exclusive targets, $21.5 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, $13.0 million in clinical development milestone payments, $8.0 million in regulatory milestone payments and $15.0 million in sales-based payments. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20), revenues from the upfront payment, exclusive designation fees, annual license maintenance fees and sales-based payments were deferred and are being recognized over the term of the Roche Collaboration.

For the three months ended September 30, 2014 and 2013, we recognized approximately $0.8 million and $0.6 million, respectively, of Roche deferred revenues as revenues under collaborative agreements. For the nine months ended September 30, 2014 and 2013, we recognized approximately $7.3 million and $3.9 million, respectively, of Roche deferred revenues as revenues under collaborative agreements. In addition, for the three and nine months ended September 30, 2014, we recognized zero and $2.0 million, respectively, of Roche deferred revenue of bulk rHuPH20 as product sales revenue. The total of Roche deferred revenues was approximately $42.8 million and $41.6 million as of September 30, 2014 and December 31, 2013, respectively.

Baxter Collaboration

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 HYQVIA, a combination of Baxter's current product GAMMAGARD LIQUID™ and rHuPH20 (the “Baxter Collaboration”). In May 2013, the European Commission granted Baxter marketing authorization in all EU Member States for the use of HYQVIA (solution for subcutaneous use), a combination of GAMMAGARD LIQUID and rHuPH20 in dual vial units, as replacement therapy for adult patients with primary and secondary immunodeficiencies. Baxter launched HYQVIA in the first EU country in July 2013 and in additional EU countries in the second half of 2013 and in 2014. The FDA approved HYQVIA for treatment of adult patients with primary immunodeficiency in September 2014. In October 2014, Baxter announced the launch and first shipments of HYQVIA in the U.S.

The Baxter Collaboration is applicable to both kit and formulation combinations. Baxter assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Baxter Collaboration, while we are responsible for the supply of bulk rHuPH20. We perform research and development activities and supply bulk rHuPH20 at the request of Baxter, and are reimbursed by Baxter under the terms of the Baxter Collaboration. In addition, Baxter has certain product development and commercialization obligations in major markets identified in the Baxter Collaboration.

Unless terminated earlier in accordance with its terms, the Baxter Collaboration continues in effect until the expiration of Baxter's obligation to pay royalties. Baxter has the obligation to pay royalties, with respect to each product in each country, during the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country.

As of September 30, 2014, we have received $17.0 million under the Baxter Collaboration, including the $10.0 million upfront license fee payment, a $3.0 million regulatory milestone payment and a $4.0 million sales-based payment. Baxter pays us a royalty on HYQVIA consisting of a mid-single digit percent of the net sales of such product. Due to our continuing involvement obligations (for example, support activities associated with rHuPH20 enzyme), the upfront and sales-based payments were deferred and are being recognized over the term of the Baxter Collaboration. We recognized revenue from the upfront and sales-based payments in the amount of approximately $0.2 million for both the three months ended September 30, 2014 and 2013, and $0.6 million and $0.4 million for the nine months ended September 30, 2014 and 2013, respectively. Deferred revenue relating to the upfront and sales-based payments under the Baxter Collaboration was approximately $9.9 million and $10.5 million as of September 30, 2014 and December 31, 2013, respectively.

Other Collaborations

In December 2012, we and Pfizer entered into a collaboration and license agreement, under which Pfizer has the worldwide license to develop and commercialize products combining rHuPH20 enzyme with Pfizer proprietary biologics directed at up to six targets (the “Pfizer Collaboration”). Targets may be selected on an exclusive or non-exclusive basis. As of September 30, 2014, we have received $12.0 million under the Pfizer Collaboration, including $11.0 million in upfront and license fee payments for the licenses to four specified exclusive targets and two additional targets which Pfizer has the right to elect in the future upon payment of additional fees. Unless terminated earlier in accordance with its terms, the Pfizer Collaboration continues in effect until the later of (i) expiration of the last to expire of the valid claims of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers a product developed under the collaboration, and (ii) expiration of the last to expire royalty term for a product developed under the collaboration. The royalty term of a product developed under the Pfizer Collaboration, with respect to each country, consists of the period equal to the longer of: (a) the duration of any valid claim of our patents covering rHuPH20 or other specified patents developed under the collaboration which valid claim covers the product in such country or (b) ten years following the date of the first commercial sale of such product in such country. Pfizer may terminate the agreement prior to expiration for any reason in its entirety or on a target-by-target basis upon 30 days prior written notice to us. Upon any such termination, the license granted to Pfizer (in total or with respect to the terminated target, as applicable) will terminate, provided, however, that in the event of expiration of the agreement, the licenses granted will become perpetual, non-exclusive and fully paid-up.

In May 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 and commercialization of a subcutaneous injectable formulation of ViroPharma's commercialized product, Cinryze® (C1 esterase inhibitor [human]) (the “ViroPharma Collaboration”). The ViroPharma Collaboration was terminated effective May 2014.

In June 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 and commercialization of a subcutaneous injectable formulation of Intrexon's recombinant human alpha 1-antitrypsin (rHuA1AT) (the “Intrexon Collaboration”). The Intrexon Collaboration was terminated effective May 2014.

Pursuant to the terms of our collaboration agreements with Roche and Pfizer, we are entitled to receive additional milestone payments for the successful development of the elected targets in the aggregate of up to approximately $55.0 million upon achievement of specified clinical development milestone events and up to approximately $12.0 million upon achievement of specified regulatory milestone events in connection with specified regulatory filings and receipt of marketing approvals.

5. Certain Balance Sheet Items

Accounts receivable, net consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Accounts receivable from product sales to collaborators	$5,774	$4,495
Accounts receivable from other product sales	2,179	1,505
Accounts receivable from revenues under collaborative agreements	1,194	3,707
Subtotal	9,147	9,707
Allowance for distribution fees and discounts	(872)	(610)
Total accounts receivable, net	$8,275	$9,097

Inventories consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	$1,252	$1,137
Work-in-process	3,699	4,280
Finished goods	1,965	753
Total inventories	$6,916	$6,170

Prepaid expenses and other assets consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Prepaid manufacturing expenses	$5,840	$5,884
Prepaid research and development expenses	3,347	3,522
Other prepaid expenses	1,654	1,339
Other assets	381	356
Total prepaid expenses and other assets	11,222	11,101
Less long-term portion	2,277	2,676
Total prepaid expenses and other assets, current	$8,945	$8,425

Property and equipment, net consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Research equipment	$8,506	$7,714
Computer and office equipment	2,080	1,949
Leasehold improvements	1,519	1,408
Subtotal	12,105	11,071
Accumulated depreciation and amortization	(8,856)	(7,649)
Property and equipment, net	$3,249	$3,422

Depreciation and amortization expense totaled approximately $0.5 million and $0.3 million for the three months ended September 30, 2014 and 2013, respectively, and approximately $1.3 million and $0.9 million for the nine months ended September 30, 2014 and 2013, respectively.

Accrued expenses consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued outsourced research and development expenses	$6,840	$3,377
Accrued compensation and payroll taxes	4,555	7,075
Accrued outsourced manufacturing expenses	2,202	3,233
Other accrued expenses	1,849	1,235
Total accrued expenses	15,446	14,920
Less long-term accrued outsourced research and development expenses	423	551
Total accrued expenses, current	$15,023	$14,369

Long-term accrued outsourced research and development is included in other long-term liabilities in the condensed consolidated balance sheets.

Deferred revenue consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Collaborative agreements	$52,725	$51,185
Product sales	—	1,958
Total deferred revenue	52,725	53,143
Less current portion	5,153	7,398
Deferred revenue, net of current portion	$47,572	$45,745

6. Long-Term Debt, Net

In December 2013, we entered into an Amended and Restated Loan and Security Agreement (the “Loan Agreement”) with Oxford Finance LLC (“Oxford”) and Silicon Valley Bank (“SVB”) (collectively, the “Lenders”), amending and restating in its entirety our original loan agreement with the Lenders, dated December 2012. The Loan Agreement provided for an additional $20 million principal amount of new term loan, bringing the total term loan balance to $50 million. The proceeds are to be used for working capital and general business requirements. The amended term loan facility matures on January 1, 2018.

Consistent with the original loan, the Loan Agreement provides for a 7.55% interest rate on the term loan and a final payment equal to 8.5% of the original principal amount, or $4.25 million, which is due when the term loan becomes due or upon the prepayment of the facility. The amended term loan repayment schedule provides for interest only payments in arrears for the first 12 months, followed by consecutive equal monthly payments of principal and interest in arrears starting in February 2015 and continuing through the maturity date. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 1% to 3% depending upon when the prepayment occurs.

In connection with the term loan, the debt offering costs have been recorded as a debt discount in our condensed consolidated balance sheets which, together with the final payment and fixed interest rate payments, are being amortized and recorded as interest expense throughout the life of the term loan using the effective interest rate method.

The amended term loan is secured by substantially all of the assets of the Company and our subsidiary, Halozyme, Inc., except that the collateral does not include any intellectual property (including licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; make payments on any subordinated debt; and enter into transactions with any of our affiliates outside of the ordinary course of business or permit our subsidiaries to do the same. In addition, subject to certain exceptions, we are required to maintain with SVB our primary deposit accounts, securities accounts and commodities, and to do the same for our domestic subsidiary.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement, which could harm our financial condition.

As of September 30, 2014, we were in compliance with all material covenants under the Loan Agreement and there was no material adverse change in our business, operations or financial condition.

Interest expense, including amortization of the debt discount, related to the long-term debt totaled approximately $1.4 million and $0.9 million for the three months ended September 30, 2014 and 2013, respectively, and approximately $4.2 million and $2.5 million, for the nine months ended September 30, 2014 and 2013, respectively. Accrued interest, which is included in other long-term liabilities, was $1.5 million and $18,000 as of September 30, 2014 and December 31, 2013, respectively.

7. Stockholders' Equity (Deficit)

During the nine months ended September 30, 2014 and 2013, we issued an aggregate of 1,078,748 and 726,538 shares of common stock, respectively, in connection with the exercises of stock options at a weighted average exercise price of $4.87 and $3.26 per share, respectively, for net proceeds of approximately $5.2 million and $2.4 million, respectively. For the nine months ended September 30, 2014 and 2013, we issued 176,743 and 85,782 shares of common stock, respectively, upon vesting of certain RSUs. The RSU holders surrendered 67,704 and 58,061 RSUs, respectively, to pay for minimum withholding taxes totaling approximately $0.9 million and $0.4 million, respectively. In addition, we issued 978,972 and 465,245 shares of common stock in connection with the grants of RSAs during the nine months ended September 30, 2014 and 2013, respectively. Stock options and unvested RSUs totaling approximately 8.4 million and 7.4 million shares of our common stock were outstanding as of September 30, 2014 and December 31, 2013, respectively.

In February 2014, we completed an underwritten public offering and issued 8,846,153 shares of common stock, including 1,153,846 shares sold pursuant to the full exercise of an over-allotment option granted to the underwriters. All of the shares were offered at a public offering price of $13.00 per share, generating approximately $107.7 million in net proceeds.

8. 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.

9. Subsequent Event

In November 2014, we completed a corporate reorganization to focus our resources on advancing our PEGPH20 oncology proprietary program and Enhanze collaborations. This reorganization resulted in a reduction in the workforce of approximately 13%. We will incur a one-time charge in the fourth quarter of 2014 resulting from this workforce reduction that will be largely offset by reduced compensation expenses during the quarter.

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

As used in this report, unless the context suggests otherwise, references to "Halozyme," "the Company," "we," "our," "ours," a "us" refer to Halozyme Therapeutics, Inc., its wholly owned subsidiary, Halozyme, Inc. and Halozyme Inc.'s wholly owned subsidiary, Halozyme Holdings Ltd. References to "Notes" refer to the Notes to Condensed Consolidated Financial Statements included herein (refer to Item 1 of Part 1).

The following information should be read in conjunction with the interim unaudited condensed consolidated financial statements and Notes thereto included in Item 1 of this Quarterly Report on Form 10-Q, as well as the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2013, included in our Annual Report on Form 10-K for the year ended December 31, 2013. 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.

This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact are, or may be deemed to be, forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "ma "will," "would," "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words intended to identify forward-looking statements, but are not the exclusive means of identifying 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, timing and success of the launch of new products by us or by our collaborators, 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 reflect management's current forecast of certain aspects of our future, 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. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of the Quarterly Report.

Overview

Halozyme is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding 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 technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

Our proprietary enzymes can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or can be used to alter abnormal tissue structures for clinical benefit. We have chosen to exploit our technology and expertise in a balanced way to modulate both risk and spend by: (1) developing our own proprietary products in therapeutic areas with significant unmet medical needs, such as oncology, diabetes and dermatology, and (2) licensing our technology to biopharmaceutical companies to collaboratively develop products which combine our technology with the collaborators' proprietary compounds.

The majority of our approved product and product candidates are based on rHuPH20, our patented recombinant human hyaluronidase enzyme. rHuPH20 temporarily breaks down hyaluronic acid (HA), a naturally occurring substance that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. 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. We refer to the application of rHuPH20 to facilitate the delivery of other drugs or fluids as Enhanze™ technology. rHuPH20 is also the active ingredient in our first

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commercially approved product, Hylenex® recombinant. Additionally, we are expanding our scientific work in the extracellular matrix by developing other enzymes and agents that target its unique aspects, potentially giving rise to new molecular entities that can be indicated in endocrinology, oncology and dermatology.

Our proprietary development pipeline consists of multiple clinical stage product candidates in oncology, diabetes and dermatology. Our lead oncology program is PEGPH20 (PEGylated recombinant human hyaluronidase), a new molecular entity, under development for the systemic treatment of tumors that accumulate HA. We are currently in Phase 2 clinical testing for PEGPH20 in pancreatic cancer, and we intend to initiate a clinical trial in non-small cell lung cancer by the end of 2014. We have also been investigating Hylenex recombinant for use as pre-treatment in patients with Type 1 diabetes using pumps and recombinant human cathepsin L (HTI-501) for the treatment of cellulite.

Our recent receipt of Fast Track and Orphan Drug designations for PEGPH20, new pre-clinical data further supporting the pan-tumor potential for PEGPH20 and strong investigator interest in both pancreatic and lung cancer trials have confirmed PEGPH20 as our priority product candidate for investment. As a result of corporate strategy reviews, we have made the decision to seek collaborations with third parties or explore other strategic alternatives in order to exploit our diabetes and dermatology programs.

We currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Pfizer Inc. (Pfizer) and Baxter Healthcare Corporation (Baxter), with one product approved in the U.S. and three products approved for marketing in Europe from which we are receiving royalties and several others at various stages of development.

We were founded in 1998 and reincorporated from the State of Nevada to the State of Delaware in November 2007. Our operations to date have involved: (i) building infrastructure for and staffing our operations; (ii) acquiring, developing and securing proprietary protection for our technology; (iii) developing our proprietary product pipeline; (iv) entering into and supporting our collaborations with other companies to advance licensed product candidates; and (v) selling our own approved commercial product, Hylenex recombinant. Currently, we have received only limited revenue from the sales of Hylenex recombinant, in addition to other revenues from our collaborations.

Future revenues from the sales and/or royalties of our product candidates which have not been approved or have recently been approved will depend on the ability of Halozyme and our collaborators to develop, manufacture, secure regulatory approvals for and commercialize the product candidates. We have incurred net operating losses each year since inception, with an accumulated deficit of approximately $445.2 million as of September 30, 2014.

Our key accomplishments for the third quarter of 2014 and recent events include:

- We completed a corporate strategy review, including a portfolio review, which resulted in a decision to focus our resources on advancing PEGPH20 and to expand utilization of our Enhanze platform. The recent Fast Track and Orphan Drug designations for PEGPH20, new pre-clinical data further supporting the pan-tumor potential for PEGPH20 and strong investigator interest in both pancreatic and lung cancer trials have confirmed PEGPH20 as our priority product for investment. With respect to our program investigating Hylenex recombinant for use with insulin pumps, while discussions with the U.S. Food and Drug Administration (FDA) are ongoing, we have learned that the FDA will likely request additional clinical data for a label update translating to potentially higher projected costs and longer time to market than had originally anticipated. In the ongoing weeks, we intend to continue to seek clarity with the FDA on what data will be required, if any. Once we have gained clarity as to the regulatory requirements for a label update, we intend to enter into collaborations with third parties or explore other strategic alternatives in order to exploit this opportunity. There can be no assurance that we will be able to consummate any such arrangements with a third party to exploit this opportunity. In addition, we have determined that with all patients having completed 12 months on the trial at this time, we do not need additional data contribution from the second year of the CONSISTENT 1 trial and we will be stopping the trial. Our decisions have resulted in a reduction in our workforce of approximately 13% in November 2014.

- In October 2014, Baxter announced the launch and first shipments of HYQVIA [Immune Globulin Infusion 10% (Human) with rHuPH20], Baxter's subcutaneous immunoglobulin treatment for adult patients with primary immunodeficiency in the U.S. HYQVIA was approved by the FDA in September 2014, and is the first subcutaneous immune globulin (IG) treatment approved for primary immunodeficiency patients with a dosing regimen requiring only one infusion up to once per month (every three to four weeks) and one injection site per infusion to deliver a full monthly therapeutic dose of IG. The majority of primary immunodeficiency patients today receive intravenous infusions in a doctor’s office or infusion center, and current subcutaneous IG treatments require weekly or bi-weekly treatment with multiple infusion sites per treatment. The FDA's approval of HYQVIA is a significant milestone for us as it represents the first U.S. approved Biologics License Application (BLA) which utilizes our rHuPH20 platform.
- In September 2014, the FDA granted Fast Track designation for our program investigating PEGPH20 in combination with gemcitabine and nab-paclitaxel for the treatment of patients with metastatic pancreatic cancer to demonstrate an improvement in overall survival. The Fast Track designation process was developed by the FDA to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases and address unmet medical needs.
- In September 2014, the FDA removed the clinical hold on patient enrollment and dosing of PEGPH20 in an ongoing Phase 1b/2 clinical trial conducted by SWOG, a cancer research cooperative group funded by the National Cancer Institute. The trial is designed to evaluate our investigational drug PEGPH20 in combination with modified FOLFIRINOX chemotherapy (mFOLFIRINOX) in patients with metastatic pancreatic adenocarcinoma. The study will resume under a revised protocol, and patient enrollment is anticipated to recommence upon review and approval of the amended protocol by the Independent Review Boards at the participating clinical trial sites.
- In October 2014, the FDA granted Orphan Drug designation for PEGPH20 for the treatment of pancreatic cancer. The mission of the FDA Office of Orphan Products Development (OOPD) is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.
- In October 2014, we announced the issuance of U.S. Patent No. 8,846,034 claiming methods for selecting a subject for treatment of a hyaluronan-associated disease with an anti-hyaluronan agent, such as PEGPH20, as well as diagnostic agents for the detection and quantification of hyaluronan in a biological sample in patients.
- In October 2014, we announced that the FDA approved new contract manufacturing facilities used in the production of Hylenex recombinant. The new facilities are the Cook Pharmica manufacturing facility in Bloomington, Indiana for the production of bulk rHuPH20 and the Patheon® facility in Greenville, North Carolina, for production of finished Hylenex product. The approval of new production sites enables us to substantially increase our manufacturing capacity for Hylenex recombinant.

Product and Product Candidates

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

Proprietary Pipeline

Hylenex Recombinant (hyaluronidase human injection)

Hylenex recombinant is a formulation of rHuPH20 that has received FDA approval to facilitate subcutaneous fluid administration for achieving hydration, to increase the dispersion and absorption of other injected drugs and, in subcutaneous urography, to improve resorption of radiopaque agents. We reintroduced Hylenex recombinant to the market in December 2011 after resolution of Baxter's voluntary recall and the return by Baxter of marketing rights to us. Hylenex recombinant is currently the number one prescribed branded hyaluronidase.

PEGPH20

We are developing PEGPH20 as a candidate for the systemic treatment of tumors that accumulate HA. 'PEG' refers to the attachment of polyethylene glycol to rHuPH20, thereby creating PEGPH20. One of the novel properties of PEGPH20 is that it lasts for an extended duration in the bloodstream and, therefore, can be used to maintain therapeutic effect to treat systemic disease.

Cancer malignancies, including pancreatic, lung, breast, colon and prostate cancers, often accumulate high levels of HA and therefore we believe that PEGPH20 has the potential to help patients with these types of cancer. Among solid tumors, pancreatic ductal adenocarcinoma is associated with the highest frequency of HA overexpression.

Over 100,000 patients in the U.S. and EU are diagnosed with pancreatic cancer annually and are frequently diagnosed in late stage of the disease. The 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 microenvironment with PEGPH20 remodels the tumor microenvironment, resulting in tumor growth inhibition. Removal of HA from the tumor microenvironment results in opening up of previously constricted blood vessels to allow increased blood flow, increasing the access of activated immune cells and factors in the blood into the tumor micro environment. If PEGPH20 is administered in conjunction with other anti-cancer therapies, the increase in blood flow may allow anti-cancer therapies to have greater access to the tumor, which may enhance the treatment effect of therapeutic modalities like chemotherapies, monoclonal antibodies and other agents.

In June 2013, we presented the results from a Phase 1b clinical study of PEGPH20 in combination with gemcitabine for the treatment of patients with stage IV metastatic pancreatic cancer (Phase 1b PEGPH20 Clinical Study) at the 2013 American Society of Clinical Oncology (ASCO) Annual meeting. This study enrolled 28 patients with previously untreated stage IV pancreatic ductal adenocarcinoma. Patients were treated with one of three doses of PEGPH20 (1.0, 1.6 and 3.0 µg/kg twice weekly for four weeks, then weekly thereafter) in combination with gemcitabine 1000 mg/m2 administered intravenously. In this study, the overall response rate (complete response + partial response in at least one assessment) was 42 percent (10 of 24 patients, 95 percent CI 22 - 62 percent, of which 29 percent (7/10) were confirmed on at least a second scan) for those treated at therapeutic dose levels of PEGPH20 (1.6 and 3.0 µg/kg) as assessed by an independent radiology review.

In September 2013, at the European Cancer Congress 2013, we presented exploratory post-hoc analysis of progression free survival and overall survival of a small subset of patients treated with PEGPH20 with available biopsy samples and HA scores in the Phase 1b study. Both progression free survival and overall survival were longer in patients who had been treated with PEGPH20 with high levels of tumor HA compared to patients with low levels of tumor HA. The observation that patients with tumors characterized by high levels of HA may respond best to PEGPH20 has resulted in our effort to develop a companion diagnostic to enable pre-selection of these patients.

In the second quarter of 2013, we initiated Study 202, a Phase 2 multicenter, randomized clinical trial evaluating PEGPH20 as a first-line therapy for patients with stage IV metastatic pancreatic cancer. The study was designed to enroll 124 patients who would receive gemcitabine and nab-paclitaxel (ABRAXANE)™ either with or without PEGPH20. The primary endpoint is to measure the improvement in progression-free survival in patients receiving PEGPH20 and those who are not. In April 2014, the trial was put on clinical hold by Halozyme and the FDA to assess a possible difference in the thromboembolic event rate between the group of patients treated with PEGPH20, nab-paclitaxel and gemcitabine versus the group of patients treated with nab-paclitaxel and gemcitabine without PEGPH20. We subsequently amended the Study 202 protocol, and on June 4, 2014, the FDA informed us that we could continue Study 202 under the revised protocol, which excludes patients that are at a greater risk for thromboembolic events, provides for prophylaxis of all patients with low molecular weight heparin, and added evaluation of the thromboembolic event rate as a co-primary end point. In July 2014, we resumed enrollment and dosing of patients in Study 202 with the goal of enrolling a similar number of additional patients to the over 100 patients already accrued in the clinical trial, to allow a thorough statistical analysis of the results. We and the data monitoring committee for Study 202 continue to closely monitor the occurrence of thromboembolic events in enrolled patients after the protocol amendments. The continuation of Study 202 may be halted again if the protocol changes do not result in a reduction of thromboembolic events in accordance with event rate rules established in the protocol, or for other safety reasons.

In September 2014, the FDA granted Fast Track designation for our program investigating PEGPH20 in combination with gemcitabine and nab-paclitaxel for the treatment of patients with metastatic pancreatic cancer to demonstrate an improvement in overall survival. The Fast Track designation process was developed by the FDA to facilitate the development, and expedite the review of drugs to treat serious or life-threatening diseases and address unmet medical needs.

In October 2014, the FDA granted Orphan Drug designation for PEGPH20 for the treatment of pancreatic cancer. The FDA OOPD's mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.
In October 2013, SWOG, a cancer research cooperative group of more than 4,000 researchers in over 500 institutions around the world, initiated a 144 patient Phase 1b/2 randomized clinical trial of PEGPH20 in combination with modified FOLFIRINOX chemotherapy (mFOLFIRINOX) compared to mFOLFIRINOX treatment alone in patients with metastatic pancreatic adenocarcinoma (funded by the National Cancer Institute) currently remains on hold pending discussions with the FDA on revision of the protocol to address the risk of thromboembolic events. In September 2014, the FDA removed the clinical hold on patient enrollment and dosing of PEGPH20 in this SWOG cooperative study. The study has resumed under a revised protocol, and patient enrollment is anticipated to recommence upon review and approval of the amended protocol by the Independent Review Boards at the participating clinical trial sites. As with Study 202, the occurrence of thromboembolic events will be closely monitored in enrolled patients after the protocol amendments, and the continuation of this study may be halted again in accordance with event rate rules established in the protocol, or for other safety reasons.
In October 2014, we announced the issuance of U.S. Patent No. 8,846,034 claiming methods for selecting a subject for treatment of a hyaluronan-associated disease with an anti-hyaluronan agent, such as PEGPH20, as well as diagnostic agents for the detection and quantification of hyaluronan in a biological sample in patients.
We plan to initiate a Phase 1b/2 trial to evaluate PEGPH20 in second line in combination with docetaxel (Taxotere®) in Non-Small Cell Lung Cancer (NSCLC) patients in December 2014. In the planned study, we expect to evaluate and identify the dose, dosing regimen and safety of PEGPH20 plus docetaxel in previously treated patients with NSCLC. Upon identification of the dose and dosing regimen, we plan to expand the trial to evaluate safety and efficacy.
Ultrafast Insulin Program
Our ultrafast insulin program combines rHuPH20 with prandial (mealtime) insulin intended for the diabetes market. Diabetes mellitus is an increasingly prevalent, costly condition associated with substantial morbidity and mortality. Attaining and maintaining target blood sugar levels to seek to minimize the long-term clinical risks is a key treatment goal for people living with diabetes.
The primary goal of our ultrafast insulin program is to enable a best-in-class prandial insulin product, with demonstrated clinical benefits for diabetes mellitus patients, in comparison to the current standard of care analog insulin products. Towards that goal, we are investigating pairing rHuPH20 with prandial insulin to facilitate faster insulin dispersion in, and absorption from, the subcutaneous space into the vascular compartment, intended to lead to a faster insulin response and a shorter duration of action similar to the response found in people without diabetes. A number of clinical trials investigating the various attributes of our product candidates have been completed.
We currently view two distinct opportunities to enter the prandial insulin market:
The first opportunity (what we refer to as the Continuous Subcutaneous Insulin Injection (CSII) market) is to pre-treat the insulin infusion site with Hylenex recombinant at the time of infusion site change (once every 3 days). Pump therapy is growing in the U.S. among patients with Type 1 and Type 2 diabetes. We believe that the pre-treatment of the infusion site with Hylenex recombinant could provide faster onset and shorter duration of insulin action.
For the CSII market, we have published interim data from a clinical study evaluating the use of Hylenex recombinant with analog insulin pump therapy in patients with Type 1 diabetes that showed pre-administration of Hylenex recombinant provided what appeared to be “faster-on” and “faster-off” effects than current rapid insulin analogs. Copies of these publications can be found at
http://www.halozyme.com/Technology/Journals-Abstracts-And-Posters/default.aspx. Data from the double-blind cross-over study showed that pre-treatment of the infusion site with Hylenex recombinant, at the time of infusion set change, accelerated the absorption and shortened the action of mealtime insulin, provided a more consistent insulin action profile and improved post-prandial glucose control.
In the first quarter of 2013, we initiated CONSISTENT 1, a clinical trial evaluating the safety and efficacy of Hylenex recombinant and a new formulation of Hylenex recombinant when used as pretreatment of the insulin infusion site in patients with

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Type 1 diabetes. With enrollment completed in the third quarter of 2013, the trial has enrolled 455 patients with Type 1 diabetes who were randomized 3:1 to either rapid acting analog insulin (RAI) delivered by CSII with Hylenex recombinant pretreatment of the infusion site or standard CSII using RAI alone. Subjects randomized to the Hylenex recombinant group administer 150 units of Hylenex recombinant once every three days through each new infusion cannula, immediately prior to initiation of insulin delivery. In the first quarter of 2014, we announced top-line results from the trial, namely that the trial's primary endpoint of non-inferiority for A1C at six months between pre-treatment with Hylenex recombinant in comparison to no pre-treatment was achieved. The data from the trial also indicated that there was a potential reduction in the rate of hypoglycemic events associated with pre-treatment with Hylenex recombinant in comparison to no pre-treatment. Glycemic excursions after meals and glucose variability were not different between the Hylenex recombinant treatment groups versus the control group. The most common treatment related adverse event in the Hylenex recombinant groups was mild infusion site discomfort. With this exception, adverse events were similar across the treatment and control groups.

In parallel with our clinical activities, we have been in dialog with the FDA regarding the requirements for updating the Hylenex recombinant label in a manner that would support future promotion in this indication. While discussions with the FDA are ongoing, we have learned that the FDA will likely request additional clinical data for a label update translating to potentially higher projected costs and longer time to market than had originally anticipated. In the ongoing weeks, we intend to continue to seek clarity with the FDA on what data will be required, if any. In addition, we have determined that with all patients having completed 12 months on the trial at this time, we do not need additional data contribution from the second year of the CONSISTENT 1 trial, and we will be stopping the trial and summarizing the data for all patients treated for 12 months. After evaluating our options, we have decided that except for any costs in connection with closing out the CONSISTENT 1 trial, we do not intend to incur substantial additional expenses for the program. Once we have gained clarity as to the regulatory requirements for a label update, we intend to enter into collaborations with third parties or explore other strategic alternatives in order to exploit this opportunity.

The second opportunity (what we refer to as the Multiple Daily Injection (MDI) market) is to combine rHuPH20 with an FDA approved RAI, e.g., insulin lispro (Humalog®) (Lispro-PH20), insulin aspart (Novolog®) (Aspart-PH20) and insulin glulisine (Apidra®) (Glulisine-PH20), (each such combination, analog-PH20), to accelerate their action. Based on the need for broad commercial reach to successfully introduce a new prandial insulin to the injection market, we believe that to maximize value, partnering with a large biotechnology or pharmaceutical company with global access to both the primary care and endocrinology markets will be required.

With regard to the MDI opportunity, we published data from two treatment studies - one in Type 1 diabetes patients and one in Type 2 diabetes patients. Copies of these publications can be found at http://www.halozyme.com/Technology/Journals-Abstracts-And-Posters/default.aspx. Both studies met their primary endpoints of A1C non-inferiority and improved post-prandial glucose control compared to patients who were treated with RAI alone. Additionally, data from the Type 1 diabetes treatment study indicated that Analog-PH20 formulations reduced hypoglycemia compared to RAI alone.

HTI-501

HTI-501, an engineered drug formulation variant of cathepsin L (a lysosomal proteinase), that acts by degrading collagen, 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.

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 neutral pH normally found in the tissue. The enzyme is combined with a mildly acidic 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.

One potential application of HTI-501 is for the treatment of edematous fibrosclerotic panniculopathy, also known as cellulite. The condition affects the great majority of post-adolescent women and is prevalent in all races. We believe that 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 deposited under the skin may release the tension in the collagenous fibrous septa and thereby smoothing the dimpled appearance of the skin. HTI-501 may also be potentially utilized 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 for HTI-501 outside the U.S. in women with moderate to severe cellulite. Dosing for the Phase 1 dose-escalation portion of the trial was completed in 2012 and in the third quarter of 2013 for the Phase 2 portion. The last patient follow up visit was in the first quarter of 2014.

In March 2014, we reported top line data from this proof of concept Phase 1/2 clinical trial evaluating the use of HTI-501 in the treatment of cellulite. The primary endpoint of the clinical trial was met, showing a statistically significant improvement in the appearance of cellulite in the areas of the patients' skin treated with HTI-501 as determined by physician assessment 28 days after treatment compared to the same skin areas prior to treatment and skin areas treated with vehicle control. In follow up, the effect, as assessed by physician assessment, was maintained at three and six months. The HTI-501 enzyme and its formulation were well tolerated in this trial at all doses and formulations tested, with no serious or severe adverse events. The most common side effects were mild to moderate transient injection site discomfort and mild to moderate injection site bruising, resolving within about two weeks without intervention.

We currently do not have an investigational new drug application (IND) in the U.S., which would be required for us to conduct clinical trials in the U.S. for HTI-501. In order for us to file an IND, we will need to conduct significant development work including preclinical studies and manufacturing development. We are seeking collaborations with third parties and exploring other strategic alternatives for further development and commercialization of this product candidate. There can be no assurance that we will be able to consummate an arrangement with a third party to exploit this opportunity.

Collaborations

Roche Collaboration

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 Collaboration). Roche initially had the exclusive right to apply rHuPH20 to only three pre-defined Roche biologic targets with the option to exclusively develop and commercialize rHuPH20 with ten additional targets. As of September 30, 2014, 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.

In September 2013, Roche launched a SC formulation of Herceptin (trastuzumab) (Herceptin SC) in Europe for the treatment of patients with HER2-positive breast cancer. This formulation utilizes our recombinant human hyaluronidase (rHuPH20) and is administered in two to five minutes, rather than 30 to 90 minutes with the standard intravenous form. Roche received European marketing approval for Herceptin SC in August 2013. The European Commission's approval was based on data from Roche's Phase 3 HannaH study which showed that the subcutaneous formulation of Herceptin was associated with comparable efficacy (pathological complete response, pCR) to Herceptin administered intravenously in women with HER2-positive early breast cancer and resulted in non-inferior trastuzumab plasma levels. Overall, the safety profile in both arms of the HannaH study was consistent with that expected from standard treatment with Herceptin and chemotherapy in this setting. No new safety signals were identified. Breast cancer is the most common cancer among women worldwide. Each year, about 1.4 million new cases of breast cancer are diagnosed worldwide, and over 450,000 women will die of the disease annually. In HER2-positive breast cancer, increased quantities of the human epidermal growth factor receptor 2 (HER2) are present on the surface of the tumor cells. This is known as "HER2 positivity" and affects approximately 15% to 20% of women with breast cancer. HER2-positive cancer is a particularly aggressive form of breast cancer.

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In June 2014, Roche launched MabThera SC in Europe for the treatment of patients with common forms of non-Hodgkin lymphoma (NHL). This formulation utilizes our patented Enhanze technology and is administered in approximately five minutes compared to the approximately 2.5 hour infusion time for intravenous MabThera. The European Commission approved MabThera SC in March 2014. The European Commission's approval was based primarily on data from Roche's Phase 3 pivotal clinical studies, which was recently published in The Lancet Oncology. NHL is a type of cancer that affects lymphocytes (white blood cells). NHL represents approximately 85% of all lymphomas diagnosed and was responsible for approximately 200,000 annual deaths worldwide in 2012. Lymphomas are a cancer of the lymphatic system (composed of lymph vessels, lymph nodes and organs) which helps to keep the bodily fluid levels balanced and to defend the body against invasion by disease. Lymphoma develops when white blood cells (usually B-lymphocytes) in the lymph fluid become cancerous and begin to multiply and collect in the lymph nodes or lymphatic tissues such as the spleen. Some of these cells are released into the bloodstream and spread around the body, interfering with the body's production of healthy blood cells. In December 2012, at the annual meeting of the American Society of Hematology, Roche presented positive data from the first stage of its two-stage Phase 3 clinical study investigating pharmacokinetics, efficacy and safety of MabThera SC. The primary endpoint in the first stage of the study was met, showing that the MabThera SC injection resulted in non-inferior MabThera concentrations in the blood compared to IV-infused MabThera (MabThera IV).

Additional information about the Phase 3 Herceptin SC and Phase 3 MabThera SC 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 Collaboration

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 (HYQVIA) (the Baxter Collaboration). GAMMAGARD LIQUID is a current Baxter product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system.

In October 2014, Baxter announced the launch and first shipments of Baxter’s HYQVIA product for treatment of adult patients with primary immunodeficiency in the U.S. HYQVIA was approved by the FDA in September 2014 and is the first subcutaneous IG treatment approved for primary immunodeficiency patients with a dosing regimen requiring only one infusion up to once per month (every three to four weeks) and one injection site per infusion to deliver a full therapeutic dose of IG. The majority of primary immunodeficiency patients today receive intravenous infusions in a doctor’s office or infusion center, and current subcutaneous IG treatments require weekly or bi-weekly treatment with multiple infusion sites per treatment. The FDA's approval of HYQVIA is a significant milestone for us as it represents the first U.S. approved BLA which utilizes our rHuPH20 platform.

In May 2013, the European Commission granted Baxter marketing authorization in all EU Member States for the use of HYQVIA (solution for subcutaneous use) as replacement therapy for adult patients with primary and secondary immunodeficiencies. Baxter launched HYQVIA in the first EU country in July 2013 and in additional EU countries in the second half of 2013 and in 2014.

Pfizer Collaboration

In December 2012, we and Pfizer entered into a collaboration and license agreement, under which Pfizer has the worldwide license to develop and commercialize products combining rHuPH20 enzyme with Pfizer proprietary biologics directed to up to six targets in primary care and specialty care indications. Targets may be selected on an exclusive or non-exclusive basis. In September 2013, Pfizer elected the fourth therapeutic target on an exclusive basis. In December 2013, Pfizer announced that one of the targets is proprotein convertase subtilisin/kexin type 9, also known as PCSK9. The PCSK9 gene provides instructions for making a protein that helps regulate the amount of cholesterol in the bloodstream. Pfizer is also developing Rivipansel directed to another target under the collaboration to treat vaso-occlusive crisis in individuals with sickle cell disease.

For a further discussion of the material terms of our collaboration agreements, refer to Note 4, Collaborative Agreements, to our condensed consolidated financial statements.

Results of Operations

Three Months Ended September 30, 2014 Compared to Three Months Ended September 30, 2013

Product Sales, Net – Product sales, net were $9.6 million for the three months ended September 30, 2014 compared to $10.0 million for the three months ended September 30, 2013. The decrease of $0.4 million was due to a $2.2 million decrease in product sales of bulk rHuPH20 for Roche's collaboration products. The decrease was offset in part by a $1.7 million, or 93%, increase in Hylenex recombinant product sales to $3.6 million for the three months ended September 30, 2014 from $1.9 million for the same period in 2013. Subsequent to the receipt of the European marketing approval of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014, revenue from bulk rHuPH20 supply for these collaboration products was recorded as product sales revenue, instead of revenues under our collaborative agreements.

Royalties – Royalty revenue was $2.9 million for the three months ended September 30, 2014 compared to zero for the three months ended September 30, 2013. This amount relates primarily to sales of Herceptin SC by Roche. Roche launched Herceptin SC in September 2013 and MabThera SC in June 2014 in Europe. Baxter launched HYQVIA in July 2013 in Europe. We recognize royalties on sales of the collaboration products by the collaborators in the quarter following the quarter in which the corresponding sales occurred. We expect royalty revenue to increase in future periods reflecting expected increase in the sales of products under collaborations.

Revenues Under Collaborative Agreements – Revenues under collaborative agreements were as follows (in thousands):

	Three Months Ended September 30,		
	2014	2013	Change
Upfront payments, license maintenance fees and amortization of deferred upfront, license fees and product-based payments:			
Roche	$801	$575	$226
Baxter	192	174	18
Pfizer	—	1,500	(1,500)
	993	2,249	(1,256)
Reimbursements for research and development services and supply of bulk rHuPH20:			
Roche(1)	472	3,209	(2,737)
Baxter(1)	603	329	274
Pfizer	26	136	(110)
Other	—	65	(65)
	1,101	3,739	(2,638)
Total revenues under collaborative agreements	$2,094	$5,988	$(3,894)

(1) Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, revenue from supply of bulk rHuPH20 for those products to the collaborators was recorded as product sales.

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Revenue from reimbursements for research and development services and bulk rHuPH20 supply decreased in the three months ended September 30, 2014, compared to the same period in 2013 mainly due to revenue from supply of bulk rHuPH20 for Herceptin SC and MabThera SC being recognized as product sales revenue in the current period, as opposed to revenue from reimbursements for research and development services in the same period in 2013. Research and development services rendered by us on behalf of our collaborators are at the request of the collaborators; therefore, the amount of future revenues related to reimbursable research and development services and supply of bulk rHuPH20 is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to fluctuate in future periods based on our collaborators' 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 $5.1 million for the three months ended September 30, 2014 compared to $0.7 million for the three months ended September 30, 2013. The increase of $4.5 million in cost of product sales was due to the increased cost of product sales related to bulk rHuPH20 product sales for Roche collaboration products.

Prior to European marketing approvals of Roche's collaboration products, Herceptin SC in August 2013 and MabThera SC in March 2014, and Baxter's collaboration HYQVIA product in May 2013, all costs related to the manufacturing of bulk rHuPH20 for these collaboration products were charged to research and development expenses in the periods such costs were incurred. Therefore, cost of product sales of bulk rHuPH20 for these collaboration products for the three months ended September 30, 2014 and 2013 was materially reduced due to the exclusion of the manufacturing costs that were charged to research and development expenses in the periods prior to receiving marketing approvals.

For the three months ended September 30, 2014, cost of product sales of bulk rHuPH20 excluded $0.8 million in manufacturing costs, of which $0.7 million and $0.1 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively. For the three months ended September 30, 2013, cost of product sales of bulk rHuPH20 excluded $6.5 million in manufacturing costs, of which $6.3 million and $0.2 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively.

The estimated selling price of the zero-cost inventory of bulk rHuPH20 for collaboration products on hand as of September 30, 2013 was approximately $4.0 million. We sold all this inventory as of September 30, 2014. After this zero-cost inventory had been consumed, the cost of product sales is expected to be approximately 83% of bulk rHuPH20 product sales revenue.

Research and Development – Research and development expenses consist of external costs, salaries and benefits and allocation of facilities and other overhead expenses related to research manufacturing, clinical trials, preclinical and regulatory activities. Research and development expenses incurred were as follows (in thousands):

	Three Months Ended September 30,		
Programs	2014	2013	Change
Product Candidates:			
PEGPH20	$9,996	$4,617	$5,379
Ultrafast insulin program	4,890	7,122	(2,232)
Hylenex recombinant	1,342	2,570	(1,228)
HTI-501	154	904	(750)
Enhanze collaborations(1)	1,605	8,076	(6,471)
rHuPH20 platform(2)	1,060	1,640	(580)
Other	857	760	97
Total research and development expenses	$19,904	$25,689	$(5,785)

(1) Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, the manufacturing costs of bulk rHuPH20 for these collaboration products were capitalized as inventory.

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

Research and development expenses relating to our PEGPH20 program for the three months ended September 30, 2014 increased by 117%, compared to the same period in 2013 primarily due to the increased clinical trial activities relating to Study 202. Research and development expenses relating to our ultrafast insulin program for the three months ended September 30, 2014 decreased by 31% primarily due to decreased clinical trial activities. Research and development expenses relating to Hylenex recombinant program for the three months ended September 30, 2014 decreased by 48%, compared to the same period in 2013 mainly due to the completion of the technology transfer and validation campaign with a second manufacturer for Hylenex recombinant at the end of 2013. Research and development expenses relating to our Enhanze collaborations for the three months ended September 30, 2014 decreased by 80%, compared to the same period in 2013 primarily due to a $3.2 million decrease resulting from capitalizing manufacturing costs for approved collaboration products as inventory in the current period and a $2.5 million decrease in other outsourced manufacturing activities to support Roche and Baxter. Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, the manufacturing costs of bulk rHuPH20 for these collaboration products were capitalized as inventory. We expect research and development expenses to increase in future periods reflecting expected increases in our PEGPH20 development activities.

Selling, General and Administrative – Selling, general and administrative (SG&A) expenses were $8.6 million for the three months ended September 30, 2014 compared to $8.1 million for the three months ended September 30, 2013. The increase of $0.5 million, or 6%, was primarily due to an increase in patent expenses in the current period. We expect SG&A expenses to increase modestly in future periods.

Interest Expense – Interest expense was $1.4 million for the three months ended September 30, 2014 compared to $0.9 million for the three months ended September 30, 2013. The increase of $0.5 million was due to the $20.0 million increase in the principal balance in December 2013.

Nine Months Ended September 30, 2014 Compared to Nine Months Ended September 30, 2013

Product Sales, Net – Product sales, net was $27.7 million for the nine months ended September 30, 2014 compared to $14.6 million for the nine months ended September 30, 2013. The increase of $13.0 million was primarily due to a $9.7 million increase in product sales of bulk rHuPH20 for Roche collaboration products. The increase was also due to a $4.0 million, or 80%, increase in Hylenex recombinant product sales to $9.0 million for the nine months ended September 30, 2014 from $5.0 million for the same period in 2013. Subsequent to the receipt of the European marketing approval of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, revenue from bulk rHuPH20 supply for these collaboration products was recorded as product sales revenue, instead of revenues under collaborative agreements.

Royalties – Royalty revenue was $5.4 million for the nine months ended September 30, 2014 compared to zero for the nine months ended September 30, 2013. This amount relates primarily to sales of Herceptin SC made by Roche. Roche launched Herceptin SC in September 2013 and Baxter launched HYQVIA in July 2013. We recognized royalties on sales of the collaboration products by the collaborators in the quarter following the quarter in which the corresponding sales occurred.

Revenues Under Collaborative Agreements – Revenues under collaborative agreements were as follows (in thousands):

	Nine Months Ended September 30,		
	2014	2013	Change
Upfront payments, license maintenance fees and amortization of deferred upfront, license fees and product-based payments:			
Roche	$2,222	$1,606	$616
Pfizer	1,000	1,500	(500)
Baxter	574	415	159
ViroPharma	—	1,000	(1,000)
Intrexon	—	1,000	(1,000)
	3,796	5,521	(1,725)
Reimbursements for research and development services and supply of bulk rHuPH20:			
Roche(1)	6,819	18,581	(11,762)
Baxter(1)	1,124	3,239	(2,115)
Pfizer	121	145	(24)
Other	36	181	(145)
	8,100	22,146	(14,046)
Total revenues under collaborative agreements	$11,896	$27,667	$(15,771)

(1) Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, revenue from supply of bulk rHuPH20 for those products to the collaborators was recorded as product sales.

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Revenue from reimbursements for research and development services and bulk rHuPH20 supply decreased in the nine months ended September 30, 2014, compared to the same period in 2013 mainly due to revenue from supply of bulk rHuPH20 for Roche collaboration products being recognized as product sales revenue in the current period, as opposed to revenue from reimbursements for research and development services in the same period in 2013. The decrease was also due to a decrease in reimbursements for manufacturing services to support the launches by Roche and Baxter. Research and development services rendered by us on behalf of our collaborators are at the request of the collaborators; therefore, the amount of future revenues related to reimbursable research and development services and supply of bulk rHuPH20 is uncertain. We expect the non-reimbursement revenues under our collaborative agreements to continue to fluctuate in future periods based on our collaborators’ 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 $16.6 million for the nine months ended September 30, 2014 compared to $2.7 million for the nine months ended September 30, 2013. The increase of $13.9 million was primarily due to the increased cost of product sales related to bulk rHuPH20 product sales for Roche collaboration products. Prior to European marketing approvals of Roche's collaboration products, Herceptin SC in August 2013 and MabThera SC in March 2014, and Baxter's collaboration HYQVIA product in May 2013, all costs related to the manufacturing of bulk rHuPH20 for these collaboration products were charged to research and development expenses in the periods such costs were incurred. Therefore, cost of product sales of bulk rHuPH20 for these collaboration products for the nine months ended September 30, 2014 and 2013 was materially reduced due to the exclusion of the manufacturing costs that were charged to research and development expenses in the periods prior to receiving marketing approvals.

For the nine months ended September 30, 2014, cost of product sales of bulk rHuPH20 excluded $1.0 million in manufacturing costs, of which $0.9 million and $0.1 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively. For the nine months ended September 30, 2013, cost of product sales of bulk rHuPH20 excluded $7.4 million in manufacturing costs, of which $6.4 million and $1.0 million were charged to research and development expenses in the nine months ended September 30, 2013 and twelve months ended December 31, 2012, respectively.

The estimated selling price of the zero-cost inventory of bulk rHuPH20 for collaboration products on hand as of September 30, 2013, was approximately $4.0 million. We sold all of this inventory as of September 30, 2014. After this zero-cost inventory had been consumed, the cost of product sales is expected to be approximately 83% of bulk rHuPH20 product sales revenue.

Research and Development – Research and development expenses consist of external costs, salaries and benefits and allocation of facilities and other overhead expenses related to research manufacturing, clinical trials, preclinical and regulatory activities. Research and development expenses incurred were as follows (in thousands):

Programs	Nine Months Ended September 30, 2014	2013	Change
Product Candidates:			
PEGPH20	$23,968	$13,301	$10,667
Ultrafast insulin program	17,372	17,918	(546)
Hylenex recombinant	4,563	8,549	(3,986)
HTI-501	1,302	2,172	(870)
Enhanze collaborations[1]	6,013	27,843	(21,830)
rHuPH20 platform[2]	4,681	4,205	476
Other	2,069	1,726	343
Total research and development expenses	$59,968	$75,714	$(15,746)

(1) Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, the manufacturing costs of bulk rHuPH20 for these collaboration products were capitalized as inventory.

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

Research and development expenses relating to our PEGPH20 program for the nine months ended September 30, 2014 increased by 80%, compared to the same period in 2013 primarily due to the increased clinical trial activities mostly relating to Study 202. Research and development expenses relating to Hylenex recombinant program for the nine months ended September 30, 2014 decreased by 47%, compared to the same period in 2013 mainly due to the completion of the technology transfer and validation campaign with a second manufacturer for Hylenex recombinant at the end of 2013. Research and development expenses relating to our Enhanze collaborations for the nine months ended September 30, 2014 decreased by 78%, compared to the same period in 2013 primarily due to an $11.1 million decrease resulting from capitalizing manufacturing costs for approved collaboration products in the current period and a $6.7 million decrease in other outsourced manufacturing activities to support Roche. Subsequent to the European approvals of Roche's Herceptin SC product in August 2013 and MabThera SC product in March 2014 and Baxter's HYQVIA product in May 2013, the manufacturing costs of bulk rHuPH20 for these collaboration products were capitalized as inventory.

Selling, General and Administrative – SG&A expenses were $27.6 million for the nine months ended September 30, 2014 compared to $23.0 million for the nine months ended September 30, 2013. The increase of $4.6 million, or 20%, was primarily due to a $3.4 million increase in compensation costs, including a $1.5 million increase in stock-based compensation due to a 6% increase in average headcount during the nine months ended September 30, 2014, compared to the same period in 2013. The increase was also due to a $1.0 million increase in patent expenses in the current period, compared to the same period in 2013.

Interest Expense – Interest expense was $4.2 million for the nine months ended September 30, 2014 compared to $2.5 million for the nine months ended September 30, 2013. The increase of $1.7 million was due to the $20.0 million increase in the principal balance in December 2013.

Liquidity and Capital Resources

Overview

Our principal sources of liquidity are our existing cash, cash equivalents and available-for-sale marketable securities. As of September 30, 2014, we had cash, cash equivalents and marketable securities of approximately $134.5 million and bank debt of approximately $50 million. In February 2014, we sold approximately 8.8 million shares of common stock in an underwritten public offering at a public offering price of $13.00 per share, generating approximately $107.7 million in net proceeds. 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 of our products and those of our collaborators, and the resources we devote to research and other commercialization activities.

We believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. Excluding the proceeds from the February 2014 public offering, we currently anticipate total net cash burn of approximately $45 to $55 million for the year ending December 31, 2014, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up, the achievement of various milestones and royalties under our existing collaborative agreements and our potential entry into new collaborative agreement(s). 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.

In February 2012, we filed an automatic shelf registration statement on Form S-3 (Registration No. 333-179444) with the SEC, which allows us, from time to time, to offer and sell equity, debt securities and warrants to purchase any of such securities, either individually or in units. 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, cash equivalents and marketable securities 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

Operating Activities

Net cash used in operations was $46.6 million during the nine months ended September 30, 2014 compared to $34.1 million during the nine months ended September 30, 2013. The $12.5 million increase in utilization of cash in operations was mainly due to the timing of the collection of accounts receivable and the payment of accounts payables.

Investing Activities

Net cash used in investing activities was $46.4 million during the nine months ended September 30, 2014 compared to $49.9 million during the nine months ended September 30, 2013. This decrease was primarily due to the receipt of $43.8 million in proceeds from maturities of marketable securities; offset in part by a $40.2 million increase in purchases of marketable securities during the nine months ended September 30, 2014.

Financing Activities

Net cash provided by financing activities was $112.0 million during the nine months ended September 30, 2014 compared to $2.0 million during the nine months ended September 30, 2013. This increase was due to $107.7 million in net proceeds from the sale of our common stock in February 2014 and a $2.9 million increase in net proceeds from stock option exercises in the current period, compared to the same period in 2013.

Long-Term Debt

In December 2013, we entered into an Amended and Restated Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) (collectively, the Lenders), amending and restating in its entirety our original loan agreement with the Lenders, dated December 2012. The Loan Agreement provided for an additional $20 million principal amount of new term loan, bringing the total term loan balance to $50 million. The proceeds are to be used for working capital and general business requirements. The amended term loan facility matures on January 1, 2018. The outstanding term loan was $49.8 million as of September 30, 2014, net of unamortized debt discount of $0.2 million.

Consistent with the original loan, the Loan Agreement provides for a 7.55% interest rate on the term loan and a final payment equal to 8.5% of the original principal amount, or $4.25 million, which is due when the term loan becomes due or upon the prepayment of the facility. The amended term loan repayment schedule provides for interest only payments in arrears for the first 12 months, followed by consecutive equal monthly payments of principal and interest in arrears starting in February 2015 and continuing through the maturity date. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 1% to 3% depending upon when the prepayment occurs.

The amended and restated term loan facility is secured by substantially all of the assets of the Company and Halozyme, Inc., except that the collateral does not include any equity interests in Halozyme, Inc., any intellectual property (including all licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; make payments on any subordinated debt; and enter into transactions with any of our affiliates outside of the ordinary course of business or permit our subsidiaries to do the same. In addition, subject to certain exceptions, we are required to maintain with SVB our primary deposit accounts, securities accounts and commodities, and to do the same for our domestic subsidiary.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender’s lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement, which could harm our financial condition.

Off-Balance Sheet Arrangements

As of September 30, 2014, 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.

Critical Accounting Policies and Estimates

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

The listing below is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by U.S. GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. 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, 2013 (2013 Form 10-K), which contain accounting policies and other disclosures required by U.S. GAAP. There were no material changes from those included in our 2013 Form 10-K.

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 supply of bulk rHuPH20 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.

At December 31, 2013, we had developed sufficient historical experience and data to reasonably estimate future returns and chargebacks of Hylenex recombinant. As a result, effective December 31, 2013, we began recognizing Hylenex recombinant product sales and related cost of product sales at the time title transfers to the wholesalers and providing for an estimate of future product returns and chargebacks at that time.

We believe that our estimated reserve for product returns for Hylenex recombinant requires a high degree of judgment and is subject to change based on our experience and certain quantitative and qualitative factors. We have monitored actual returns history on an individual product lot basis since product launch. We considered the dating of product at the time of shipment into the distribution channel and changes in the estimated levels of inventory within the distribution channel to estimate our exposure for returned product. Because of the shelf life of Hylenex recombinant and our lengthy return period, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. If actual results differ from our estimates, we will be required to make adjustments to this reserve in the future, which could have an effect on product sales revenue in the period of adjustments.

Refer to Note 2 for a further discussion of our revenue recognition policies for product sales and revenues under our collaborative agreements and Note 4 for a further discussion of our collaborative agreements.

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. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments. Refer to Note 2 for a further discussion of share-based payments.

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trial expenses, 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. After receiving marketing approval from the FDA or comparable regulatory agencies in foreign countries for a product, costs related to purchases or manufacturing of bulk rHuPH20 for such product are capitalized as inventory. The manufacturing costs of bulk rHuPH20 for the collaboration products, Herceptin SC, MabThera SC and HYQVIA, which were incurred after the receipt of the European marketing approvals are capitalized as inventory. Refer to Note 2 for a further discussion of research and development expenses.

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 this year as we continue with our clinical trial programs and continue to develop and manufacture our product candidates.

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 collaboration 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.

Recent Accounting Pronouncements

Refer to Note 2, Summary of Significant Accounting Policies – Pending Adoption of Recent Accounting Pronouncements, of our 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, royalties, licensing fees, milestone payments, bulk rHuPH20 supply 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, royalties, licensing fees, research reimbursements, bulk rHuPH20 supply payments 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 September 30, 2014, we have incurred aggregate net losses of approximately $445.2 million.
If our 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 or equivalent health authorities is necessary to manufacture and market pharmaceutical products in the U.S. 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, risky 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 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 collaborators 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 when we or our collaborators expect, or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs. For example, we have been in dialog with the FDA regarding the regulatory pathway and data requirements for updating the label for Hylenex recombinant for use in CSII but do not have clarity to date. However, we have learned that additional clinical data will likely be required for a label update. The lack of clarity has hampered our ability to develop and commercialize this opportunity. In addition, the approval of Baxter's HYQVIA BLA was delayed until we and Baxter provided additional preclinical data sufficient to address non-neutralizing antibodies to rHuPH20 that were detected in the registration trial. Although these antibodies have not been associated with any adverse clinical effects, and the HYQVIA BLA was approved by the FDA in September 2014, we cannot assure you that they will not arise and have an adverse impact on future development of products which include rHuPH20, future sales of Hylenex recombinant, our ability to enter into collaborations, or be raised by the FDA or other health authorities in connection with testing or approval of products including rHuPH20.
Only three of our collaboration product candidates and one of our proprietary products have been approved for commercialization. We have no proprietary product candidates currently in the regulatory approval process. We and our collaborators may not be successful in obtaining such approvals for any potential products in a timely manner, or at all. Refer to the risk factor titled “Our proprietary and collaboration product candidates may not receive regulatory approvals or their development may be delayed for a variety of reasons, including unsuccessful clinical trials, regulatory requirements or safety concerns” for additional information relating to the approval of product candidates. Additionally, even with respect to products which have been approved for commercialization, in order to continue to manufacture and market pharmaceutical products, we or our collaborators must maintain our regulatory approvals. If we or any of our collaborators are unsuccessful in maintaining our regulatory approvals, our ability to generate revenues would be adversely affected.
Use of our product candidates or those of our collaborators could be associated with side effects or adverse events.
As with most pharmaceutical products, use of our product candidates or those of our collaborators could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent).

Side effects or adverse events associated with the use of our product candidates or those of our collaborators may be observed at any time, including in clinical trials or when a product is commercialized, and any such side effects or adverse events may negatively affect our or our collaborators' ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates or those of our collaborators could require us or our collaborators to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. We or our collaborators may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our pharmaceutical product candidates which we have not planned or anticipated. Furthermore, there can be no assurance that we or our collaborators will resolve any issues related to any product related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition. For example, in April 2014, a clinical hold was placed on patient enrollment and dosing of PEGPH20 in Study 202 as a result of a possible difference in the thromboembolic event rate observed thus far in the trial between the group of patients treated with PEGPH20 versus the group of patients treated without PEGPH20. The clinical hold was lifted by FDA in June 2014, and we have resumed enrollment and dosing of PEGPH20 in Study 202 under a revised clinical protocol. We and the data monitoring committee for Study 202 continue to closely monitor the occurrence of thromboembolic events in enrolled patients after the protocol amendments. The continuation of Study 202 may be halted again if the protocol changes do not result in a reduction of thromboembolic events in accordance with event rate rules established in the protocol, or for other safety reasons.

If our contract manufacturers are unable to manufacture and supply to us bulk rHuPH20 in the quantity and quality required by us or our collaborators for use in our products and product candidates, our product development and commercialization efforts could be delayed or stopped and our collaborations could be damaged.

We have existing supply agreements with contract manufacturing organizations Avid Bioservices, Inc. (Avid) and Cook Pharmica LLC (Cook) to produce bulk rHuPH20. These manufacturers each produce bulk rHuPH20 under current cGMP for clinical uses. Avid and now Cook currently produce bulk rHuPH20 for use in Hylenex recombinant and certain other collaboration products and product candidates. In addition to supply obligations, 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 bulk rHuPH20. In addition, we have been working to scale-up, validate and qualify Cook as a manufacturer of bulk rHuPH20 for use in the product and product candidates under the Roche collaboration. To date, Cook has not been submitted to the European regulatory authorities by Roche as an approved manufacturer for Herceptin SC and MabThera SC. If Cook is unable to obtain its status as an approved manufacturing facility, or if either Avid or Cook: (i) is unable to retain its status as an approved manufacturing facility; (ii) is unable to otherwise successfully scale up bulk rHuPH20 production; or (iii) fails to manufacture and supply bulk rHuPH20 in the quantity and quality required by us or our collaborators for use in our proprietary and collaboration products and product candidates for any other reason, our business will be adversely affected. In addition, a significant change in such parties' business or financial condition could adversely affect their abilities to fulfill their contractual obligations to us. We have not established, and may not be able to establish, favorable arrangements with additional bulk rHuPH20 manufacturers and suppliers of the ingredients necessary to manufacture bulk rHuPH20 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 bulk rHuPH20 inventory where possible, 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 bulk rHuPH20 on a timely basis could: (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of proprietary or collaboration product candidates; (ii) delay or prevent the effective commercialization of proprietary or collaboration products; and/or (iii) cause us to breach contractual obligations to deliver bulk rHuPH20 to our collaborators. Such delays would likely damage our relationship with our collaborators under our key collaboration agreements, and they would have a material adverse effect on our business and financial condition.

If we or any party to a key collaboration agreement 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 milestone payments, target designation fees, maintenance fees and royalties. We are dependent on our collaborators to develop and commercialize product candidates subject to our collaborations in order for us to realize any financial benefits from these collaborations. Our collaborators may not devote the attention and resources to such efforts that we would to such efforts ourselves, change their promotional efforts or simultaneously develop and commercialize products in competition to those products we have licensed to them. Any of these actions could not be visible to us immediately and could negatively impact the benefits and revenue we receive from such collaboration. In addition, 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. Specifically, the termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators 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 collaboration products and product candidates rely on the rHuPH20 enzyme, and any adverse development regarding rHuPH20 could substantially impact multiple areas of our business, including current and potential collaborations, as well as proprietary programs.

rHuPH20 is a key technological component of Enhanze technology and our most advanced proprietary and collaboration products and product candidates, including the product candidates under our Roche, Pfizer and Baxter collaborations, our PEGPH20 program, our ultrafast insulin program and Hylenex recombinant. If there is an adverse development for rHuPH20 (e.g., an adverse regulatory determination relating to rHuPH20, if we are unable to obtain sufficient quantities of rHuPH20, if we are unable to obtain or maintain material proprietary rights to rHuPH20 or if we discover negative characteristics of rHuPH20), multiple areas of our business, including current and potential collaborations, as well as proprietary programs would be substantially impacted. For example, elevated anti-rHuPH20 antibody titers were detected in the registration trial for Baxter's HYQVIA product as well as in ViroPharma's Phase 2 clinical trial with subcutaneous Cinryze with rHuPH20, but have not been associated, in either case, with any adverse events. We monitor for antibodies to rHuPH20 in our collaboration and proprietary programs, and although we do not believe at this time that the incidence of non-neutralizing anti-rHuPH20 antibodies in either the HYQVIA program or the ViroPharma program will have a significant impact on our other proprietary and other collaboration product candidates, there can be no assurance that there will not be other such occurrences in our other programs or that concerns regarding these antibodies will not also be raised by the FDA or other health authorities in the future, which could result in delays or discontinuations of our development or commercialization activities or deter entry into additional collaborations with third parties.

Our proprietary and collaboration product candidates may not receive regulatory approvals or their development may be delayed for a variety of reasons, including unsuccessful clinical trials, regulatory requirements or safety concerns.

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 and nonclinical studies or clinical trial results are promising, we or our collaborators may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not, or our collaborators may not, obtain applicable regulatory approval for a variety of other reasons. Preclinical, nonclinical, and clinical trials for any of our proprietary or collaboration product candidates could be unsuccessful, which would delay or prohibit regulatory approval and commercialization of the product candidates. In the U.S. 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; for example, in April 2013, a clinical hold was placed on patient enrollment and dosing of PEGPH20 in Study 202 as a result of a possible difference in the thromboembolic event rate observed thus far in the trial between the group of patients treated with PEGPH20 versus the group of patients treated without PEGPH20. The clinical hold was lifted by FDA in June 2014, and we have resumed enrollment and dosing of PEGPH20 in Study 202 under a revised clinical protocol;
- 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;
- regulatory authorities may require that we change our studies or conduct additional studies which may significantly delay or make continued pursuit of approval commercially unattractive; for example, we are currently in dialog but do not have clarity from the FDA regarding the data that we will need for a label change for Hylenex recombinant to be used in CSII;
- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;
- the cost of clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product;
- a regulatory agency may not approve our manufacturing processes or facilities, or the processes or facilities of our collaborators, 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 collaborators, 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 collaboration 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 collaboration product candidates and/or our ability to successfully acquire other products and technologies. There can be no assurances that any proprietary or collaboration product candidate will receive regulatory approval in a timely manner, or at all. For example, we are in dialog but have not reached agreement with the FDA regarding the requirements for updating the Hylenex recombinant label for use in CSII. There can be no assurance that we will be able to gain clarity as to the FDA's requirements or that the requirements may be satisfied in a commercially feasible way, in which case our ability to enter into collaborations with third parties or explore other strategic alternatives to exploit this opportunity will be limited or may not be possible.

We anticipate that certain proprietary and collaboration 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 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 third party collaborators are responsible for providing certain proprietary materials that are essential components of our collaboration products and product candidates, and any failure to supply these materials could delay the development and commercialization efforts for these collaboration products and product candidates and/or damage our collaborations.

Our development and commercialization collaborators are responsible for providing certain proprietary materials that are essential components of our collaboration products and product candidates. For example, Roche is responsible for producing the Herceptin and MabThera required for its subcutaneous products and Baxter is responsible for producing the GAMMAGARD LIQUID for its product HYQVIA. If a collaborator, or any applicable third party service provider of a collaborator, encounters difficulties in the manufacture, storage, delivery, fill, finish or packaging of the collaboration product or product candidate or component of such product or product candidate, such difficulties could (i) cause the delay of clinical trials or otherwise delay or prevent the regulatory approval of collaboration product candidates; and/or (ii) delay or prevent the effective commercialization of collaboration products. Such delays could have a material adverse effect on our business and financial condition.

We rely on third parties to prepare, fill, finish and package our products and product candidates, and if such third parties should fail to perform, 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 bulk rHuPH20 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. 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 until December 31, 2015, subject to further extensions in accordance with the terms and conditions of the agreement. In June 2011, we entered into a services agreement with a third party manufacturer for the technology transfer and manufacture, fill, finish or packaging of Hylenex recombinant. The FDA approved the new contract manufacturing facilities used in the production of Hylenex recombinant in October 2014.

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 approved product, Hylenex recombinant, 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 collaborators 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 collaboration agreement for the marketing rights of Hylenex recombinant and the associated agreements.

If we or our collaborators fail to comply with regulatory requirements applicable to promotion, sale and manufacturing of approved products, 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, state and foreign regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We, our collaborators and our respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising, promotion and sales of drug products, required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies. We, our collaborators and our respective contractors, suppliers and vendors, may be slow to adapt or may not be able to adapt to these changes or new requirements.

In particular, 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. Likewise, if we, our collaborators and our respective contractors, suppliers and vendors involved in sales and promotion of our products do not comply with applicable laws and regulations, for example off-label or false or misleading promotion, this could materially harm our business and financial condition.

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;
- injunctions; or
- 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 reserves and expected revenues during the next few years may not be sufficient for us to continue the development of our proprietary product candidates, to fund general operations and conduct our business at the level desired. In addition, if we engage in acquisitions of companies, products or technologies in order to execute our business strategy, we may need to raise additional capital. We may raise additional capital in the future through one or more financing vehicles that may be available to us including (i) the public or private issuance of securities; (ii) new collaborative agreements; and/or (iii) expansions or revisions to existing collaborative relationships.

In view of our stage of development, business prospects, 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 raise capital on adverse terms or significantly reduce operating expenses through the restructuring of our operations. If we raise additional capital, a substantial number of additional shares may be issued, and these shares will dilute the ownership interest of our current investors.

We currently have significant debt and failure by us to fulfill our obligations under the applicable loan agreements may cause the repayment obligations to accelerate.

In December 2013, we entered into an Amended and Restated Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC (Oxford) and Silicon Valley Bank (SVB) (collectively, the Lenders), amending and restating in its entirety our original loan agreement with the Lenders, dated December 2012. The Loan Agreement provided for an additional $20 million principal amount of new term loan, bringing the total term loan balance to $50 million. The proceeds are to be used for working capital and general business requirements. The amended term loan facility matures on January 1, 2018. The amended and restated term loan facility is secured by substantially all of the assets of the Company and its subsidiary, Halozyme, Inc., except that the collateral does not include any equity interests in Halozyme, Inc., any intellectual property (including all licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The Loan Agreement contains customary representations, warranties and covenants by us, which covenants limit our ability to convey, sell, lease, transfer, assign or otherwise dispose of certain of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay dividends and make certain other restricted payments; make certain investments; make payments on any subordinated debt; and enter into transactions with any of our affiliates outside of the ordinary course of business or permit our subsidiaries to do the same. In addition, subject to certain exceptions, we are required to maintain with SVB our primary deposit accounts, securities accounts and commodities, and to do the same for our domestic subsidiary. Complying with these covenants may make it more difficult for us to successfully execute our business strategy.

The Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain of our obligations under the Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in our business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender’s lien in the collateral or in the value of such collateral. In the event of default by us under the Loan Agreement, the Lenders would be entitled to exercise their remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan Agreement which could harm our financial condition.

If proprietary or collaboration product candidates are approved for marketing 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 collaboration product candidates obtain the necessary regulatory approvals for commercial sale, 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 relative to other therapies for the same or similar treatments;
- our ability to fund our sales and marketing efforts and the ability and willingness of our collaborators 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 collaborators;
- the introduction of generic competitors; and

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- the extent to which reimbursement for our products and related treatments will be available from third party payors including government insurance programs (Medicare and Medicaid) and private insurers.

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 collaboration product candidates will be restricted to the labels approved by FDA and applicable regulatory bodies, and these restrictions may limit the marketing and promotion of the ultimate products. If the approved labels are restrictive, the sales and marketing efforts for these products may be negatively affected.

Developing and marketing pharmaceutical products for human use involves significant 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 the liabilities may exceed the limits of our insurance policy, or 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 higher insurance requirements could impose additional costs on us. In addition, since many of our collaboration 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 relevant experience. For example, in order to pursue our current business strategy, we will need to recruit and retain personnel experience in oncology drug development which is a highly competitive market for talent. We depend substantially on our ability to hire, train, motivate and retain high quality personnel, especially our scientists and management team. Particularly in view of the small number of employees on our staff to cover our numerous programs and key functions, 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 collaborators.

Furthermore, if we were to lose key management personnel, 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. 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.

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 four buildings in San Diego, California. We depend on our facilities and on our collaborators, 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 collaborators, 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 may suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs.

If we or our collaborators do not achieve projected development, clinical, regulatory or sales 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, and we may face lawsuits relating to such declines.

From time to time, we or our collaborators may 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, our stock price may decline rapidly. For example, the announcement of the temporary halting of our Phase 2 clinical trial for PEGPH20 caused a rapid decline in our stock price. Stock price declines may also trigger direct or derivative shareholder lawsuits. As with any litigation proceeding, the eventual outcome of any legal action is difficult to predict. If any such lawsuits occur, we will incur expenses in connection with the defense of these lawsuits, and we may have to pay substantial damages or settlement costs in connection with any resolution thereof. Although we have insurance coverage against which we may claim recovery against some of these expenses and costs, the amount of coverage may not be adequate to cover the full amount or certain expenses and costs may be outside the scope of the policies we maintain. In the event of an adverse outcome or outcomes, our business could be materially harmed from depletion of cash resources, negative impact on our reputation, or restrictions or changes to our governance or other processes that may result from any final disposition of the lawsuit. Moreover, responding to and defending pending litigation significantly diverts management's attention from our operations.

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 collaborators 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;
- we may take on liabilities from the acquired company such as debt, legal liabilities or business risk which could be significant;
- 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. There is no assurance 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.

Security breaches may disrupt our operations and harm our operating results.

The wrongful use, theft, deliberate sabotage or any other type of security breach with respect to any of our information technology storage and access systems could result in disclosure or dissemination of our proprietary and confidential information that is electronically stored, including research or clinical data, resulting in a material adverse impact on our business, operating results and financial condition. Our security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our electronic storage systems. Furthermore, any physical break-in or trespass of our facilities could result in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data or damage to our research and development equipment and assets. Such adverse effects could be material and irrevocable to our business, operating results and financial condition.

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 September 30, 2014 were $18.18 and $6.88, respectively. We expect our stock price to continue to be subject to significant volatility and, in addition to the other risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q and all other risks and uncertainties that are either not known to us at this time or which we deem to be immaterial, any of the following factors may lead to a significant drop in our stock price:

- the presence of competitive products to those being developed by us;
- failure (actual or perceived) of our collaborators to devote attention or resources to the development or commercialization of product candidates licensed to such collaborator;
- a dispute regarding our failure, or the failure of one of our third party collaborators, 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 collaboration product candidates;

- the failure, for any reason, to secure or defend our intellectual property position;
- for those products that are not yet approved for commercial sale, the failure or delay of applicable regulatory bodies to approve such products;
- identification of safety or tolerability issues;
- failure of clinical trials to meet efficacy endpoints;
- suspensions or delays in the conduct of clinical trials or securing of regulatory approvals;
- adverse regulatory action with respect to our and our collaborators' products and product candidates such as clinical holds, imposition of onerous requirements for approval or product recalls;
- our failure, or the failure of our third party collaborators, to successfully commercialize products approved by applicable regulatory bodies such as the FDA;
- our failure, or the failure of our third party collaborators, to generate product revenues anticipated by investors;
- problems with a bulk rHuPH20 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 transactions where we raise capital 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.

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.

Our rights agreement and anti-takeover provisions in our charter documents and Delaware law may make an acquisition of us more difficult.

We are party to a Rights Agreement designed to deter abusive takeover tactics and to encourage prospective acquirors to negotiate with our board of directors rather than attempt to acquire us in a manner or on terms that our board deems unacceptable, which could delay or discourage takeover attempts that stockholders may consider favorable.

In addition, anti-takeover provisions in our charter documents and Delaware law may make an acquisition of us more difficult. First, our board of directors is classified into three classes of directors. Under Delaware law, directors of a corporation with a classified board may be removed only for cause unless the corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation, as amended, does not provide otherwise. In addition, our bylaws limit who may call special meetings of stockholders, permitting only stockholders holding at least 50% of our outstanding shares to call a special meeting of stockholders. Our amended and restated certificate of incorporation, as amended, does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Finally, our bylaws establish procedures, including advance notice procedures, with regard to the nomination of candidates for election as directors and stockholder proposals.

These provisions may discourage potential takeover attempts, discourage bids for our common stock at a premium over market price or adversely affect the market price of, and the voting and other rights of the holders of, our common stock. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors other than the candidates nominated by our board of directors.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit large stockholders from consummating a merger with, or acquisition of, us.

These provisions may deter an acquisition of us that might otherwise be attractive to stockholders.

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 health regulatory agencies including the FDA (and with respect to controlled drug substances, the U.S. Drug Enforcement Administration (DEA)) and equivalent foreign regulatory agencies and state and local/regional 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. Regulatory authorities may require that we change our studies or conduct additional studies, which may significantly delay or make continued pursuit of approval commercially unattractive. We are currently in dialog but do not have clarity from the FDA regarding the path for a labeling update to include key efficacy and safety data prior to initiating Hylenex recombinant for use in CSII. There can be no assurance that we will be able to gain clarity as to the FDA's requirements. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators' 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 subject, directly or indirectly, to various broad federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.
Our business operations and activities may be directly, or indirectly, subject to various broad federal and state healthcare laws, including without limitation, anti-kickback laws, false claims laws, civil monetary penalty laws, data privacy and security laws, tracing and tracking laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as sales, marketing and education programs. Many states have similar healthcare fraud and abuse laws, some of which may be broader in scope and may not be limited to items or services for which payment is made by a government health care program.
Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While we have adopted a healthcare corporate compliance program, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.
In addition, any sales of products outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.
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:

- we will be able to obtain patent protection for our products and technologies;
- the scope of any of our issued patents will be sufficient to provide commercially significant exclusivity for our products and technologies;
- others will not independently develop similar or alternative technologies or duplicate our technologies and obtain patent protection before we do; and
- any of our issued patents, or patent pending applications that result in issued patents, will be held valid, enforceable and infringed in the event the patents are asserted against others.

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. Any weaknesses or 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 (e.g. Hylenex recombinant). We may not be able to obtain trademark protection for any proposed product names we select. In addition, product names for pharmaceutical products must be approved by health regulatory authorities such as the FDA in addition to meeting the legal standards required for trademark protection and product names we propose may not be timely approved by regulatory agencies which may delay product launch. In addition, our 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. If we become involved in any intellectual property litigation, we may be required to pay substantial damages, including but not limited to treble damages, attorneys' fees and costs, 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 changes, 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 patentable subject matter requirement and 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.

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 and recent court decisions concerning patentability of isolated genes may lead to narrower patent protection, or narrower claim interpretation, for isolated 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 U.S., 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 collaboration 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 U.S., 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 U.S. adopted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the Healthcare Reform Act). This law substantially changes the way healthcare 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 may negatively affect our revenues in the future. For example, the Healthcare Reform Act imposes a non-deductible 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 U.S.

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 collaboration products under development.

Our proprietary and collaboration products have numerous competitors in the U.S. 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 include, but are not limited to, Valeant Pharmaceuticals International, Inc. and Amphastar Pharmaceuticals, Inc. For our ultrafast insulin 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 collaboration 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

There have been no material changes in our market risks during the quarter ended September 30, 2014.

As of September 30, 2014, our cash equivalents and marketable securities consisted of investments in money market funds, corporate debt obligations and commercial paper. These investments were made in accordance with our investment policy which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments that we invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments 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 that security will probably decline. As of September 30, 2014, based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and marketable securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash, cash equivalents and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our cash equivalents and marketable securities are recorded at fair market value.

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.

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Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2014 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 the risks and uncertainties regarding the regulatory approval of proprietary and collaboration product candidates. We do not believe the updates have materially changed the type or magnitude of 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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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	Composite Certificate of Incorporation (2)
3.2	Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock (1)
3.3	Bylaws, as amended (3)
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.INS	Instance Document
101.SCH	Taxonomy Extension Schema Document
101.CAL	Taxonomy Extension Calculation Linkbase Document
101.DEF	Taxonomy Extension Definition Linkbase Document
101.LAB	Taxonomy Extension Label Linkbase Document
101.PRE	Taxonomy Extension Presentation Linkbase Document

(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 Quarterly Report on Form 10-Q, filed August 7, 2013 (File No. 001-32335).

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

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:	November 10, 2014	/s/ Helen I. Torley, M.B. Ch.B., M.R.C.P. Helen I. Torley, M.B. Ch.B., M.R.C.P. President and Chief Executive Officer (Principal Executive Officer)
Dated:	November 10, 2014	/s/ David A. Ramsay David A. Ramsay Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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