

HALOZYME THERAPEUTICS INC  
Form 10-Q  
November 09, 2015

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

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

For the quarterly period ended September 30, 2015  
OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-32335

HALOZYME THERAPEUTICS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

88-0488686  
(I.R.S. Employer Identification No.)

11388 Sorrento Valley Road, San Diego, CA  
(Address of principal executive offices)  
(858) 794-8889  
(Registrant's telephone number, including area code)

92121  
(Zip Code)

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

Indicate by check mark whether the registrant 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  No

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

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

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 128,014,034 as of November 2, 2015.



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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 amounts)

	September 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$71,514	\$61,389
Marketable securities, available-for-sale	52,204	74,234
Accounts receivable, net	8,392	9,149
Inventories	11,101	6,406
Prepaid expenses and other assets	9,879	10,143
Total current assets	153,090	161,321
Property and equipment, net	2,686	2,951
Prepaid expenses and other assets	2,458	1,205
Restricted cash	500	500
Total assets	\$158,734	\$165,977
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$4,437	\$3,003
Accrued expenses	18,926	13,961
Deferred revenue, current portion	5,789	7,367
Current portion of long-term debt, net	15,699	—
Total current liabilities	44,851	24,331
Deferred revenue, net of current portion	44,244	47,267
Long-term debt, net	34,094	49,860
Other long-term liabilities	3,746	3,167
Commitments and contingencies (Note 9)		
Stockholders' equity:		
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; 127,811 and 125,721 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	128	126
Additional paid-in capital	518,647	491,694
Accumulated other comprehensive loss	—	(41 )
Accumulated deficit	(486,976 )	(450,427 )
Total stockholders' equity	31,799	41,352
Total liabilities and stockholders' equity	\$158,734	\$165,977
See accompanying notes to condensed consolidated financial statements.		

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	\$10,301	\$9,617	\$32,503	\$27,679
Royalties	8,274	2,895	21,431	5,382
Revenues under collaborative agreements	2,205	2,094	28,896	11,896
Total revenues	20,780	14,606	82,830	44,957
Operating expenses:				
Cost of product sales	6,180	5,141	20,818	16,585
Research and development	27,611	19,904	65,490	59,968
Selling, general and administrative	10,226	8,587	29,439	27,589
Total operating expenses	44,017	33,632	115,747	104,142
Operating loss	(23,237 )	(19,026 )	(32,917 )	(59,185 )
Other income (expense):				
Investment and other income, net	78	122	267	287
Interest expense	(1,301 )	(1,376 )	(3,899 )	(4,203 )
Net loss	\$(24,460 )	\$(20,280 )	\$(36,549 )	\$(63,101 )
Net loss per share:				
Basic and diluted	\$(0.19 )	\$(0.16 )	\$(0.29 )	\$(0.52 )
Shares used in computing net loss per share:				
Basic and diluted	126,921	124,041	126,127	122,157

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net loss	\$(24,460 )	\$(20,280 )	\$(36,549 )	\$(63,101 )
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	40	(49 )	41	(63 )
Total comprehensive loss	\$(24,420 )	\$(20,329 )	\$(36,508 )	\$(63,164 )

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,	
	2015	2014
Operating activities:		
Net loss	\$(36,549	) \$(63,101
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	15,588	11,065
Depreciation and amortization	1,218	1,304
Non-cash interest expense	885	1,610
Amortization of premiums on marketable securities, net	699	1,062
Changes in operating assets and liabilities:		
Accounts receivable, net	757	822
Inventories	(4,695	) (746
Prepaid expenses and other assets	(1,000	) 98
Accounts payable and accrued expenses	6,011	1,693
Deferred revenue	(4,600	) (418
Other liabilities	(200	) 32
Net cash used in operating activities	(21,886	) (46,579
Investing activities:		
Purchases of marketable securities	(46,360	) (89,117
Proceeds from maturities of marketable securities	67,730	43,816
Purchases of property and equipment	(726	) (1,132
Net cash provided by (used in) investing activities	20,644	(46,433
Financing activities:		
Proceeds from issuance of common stock under equity incentive plans, net	11,367	4,317
Proceeds from issuance of common stock, net	—	107,713
Net cash provided by financing activities	11,367	112,030
Net increase in cash and cash equivalents	10,125	19,018
Cash and cash equivalents at beginning of period	61,389	27,357
Cash and cash equivalents at end of period	\$71,514	\$46,375
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 biotechnology company focused on developing and commercializing novel oncology therapies. We are seeking to translate our unique knowledge of the tumor microenvironment to create therapies that have the potential to improve cancer patient survival. Our research primarily focuses on human enzymes that alter the extracellular matrix and tumor microenvironment. 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 are used to facilitate the delivery of injected drugs and fluids, potentially enhancing the efficacy and the convenience of other drugs or can be used to alter tissue structures for potential 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, with a focus on oncology, 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 hyaluronan (or "HA"), a naturally occurring complex carbohydrate 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 commercially approved product, Hylenex® recombinant.

Our proprietary development pipeline consists primarily of clinical stage product candidates in oncology. 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. When HA accumulates in a tumor, it can cause higher pressure in the tumor, reducing blood flow into the tumor and with that, reduced access of cancer therapies to the tumor. PEGPH20 works by temporarily degrading HA surrounding cancer cells resulting in reduced pressure and increased blood flow to the cancer with increased amounts of anticancer treatments administered concomitantly gaining access to the tumor. We are currently in Phase 2 clinical testing for PEGPH20 in metastatic pancreatic cancer (Study 109-202), in Phase 1b clinical testing in non-small cell lung cancer (Study 107-201), and in Phase 1b clinical testing in non-small cell lung cancer and gastric cancer (Study 107-101).

Regarding Enhanze, we currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. ("Roche"), Baxter Healthcare Corporation (predecessor to Baxalta Incorporated) ("Baxalta"), Pfizer Inc. ("Pfizer"), Janssen Biotech, Inc. ("Janssen"), and AbbVie, Inc. ("AbbVie"), 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.

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, 2014, filed with the SEC on March 2, 2015. 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.

### Adoption and 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 eliminates the diversity in practice in the presentation of unrecognized tax benefits but does not alter the way in which entities assess deferred tax assets for realizability. ASU 2013-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2014. ASU 2013-11 is applied prospectively to unrecognized tax benefits that exist at the effective date. The adoption of ASU 2013-11 did 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 U.S. 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 our annual reporting beginning on January 1, 2018. 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 is not expected to have a material impact on our consolidated financial position or results of operations.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from that debt liability, consistent with the presentation of a debt discount. The recognition and measurement guidance for debt issuance costs is not affected by ASU 2015-03. ASU 2015-03 is effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early application is permitted. The adoption of ASU 2015-03 is not expected to have a material impact on our consolidated financial position or results of operations.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory (“ASU 2015-11”). ASU 2015-11 requires that for entities that measure inventory using the first-in, first-out method, inventory should be measured at the lower of cost and net realizable value. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of ASU 2015-11 is not expected to 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 the 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. 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 condensed 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 condensed 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, 2015 and December 31, 2014, 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 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 financial instruments from our investment manager, who obtains these fair values from a third-party pricing source. 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 financial instrument 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, 2015			December 31, 2014		
	Level 1	Level 2	Total estimated fair value	Level 1	Level 2	Total estimated fair value
Cash equivalents:						
Money market funds	\$67,561	\$—	\$67,561	\$42,685	\$—	\$42,685
Available-for-sale marketable securities:						
Corporate debt securities	—	52,204	52,204	—	74,234	74,234
	\$67,561	\$52,204	\$119,765	\$42,685	\$74,234	\$116,919

There were no transfers between Level 1 and Level 2 of the fair value hierarchy in the three and nine months ended September 30, 2015. We have no financial instruments that were classified within Level 3 as of September 30, 2015 and December 31, 2014.

#### 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 used in 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, 2015 and December 31, 2014, inventories consisted of \$1.7 million and \$3.0 million of Hylenex recombinant inventory, respectively, and \$9.4 million and \$3.4 million of bulk rHuPH20 inventory, respectively.

#### Revenue Recognition

We generate revenues from product sales and payments received under collaborative agreements. Collaborative agreement payments may include nonrefundable fees at the inception of the agreements, license fees, milestone and event-based 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 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

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 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.

We have developed sufficient historical experience and data to reasonably estimate future returns and chargebacks of Hylenex recombinant. As a result, we recognize 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 takes 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 in the wholesale channel. We have monitored actual return history on an individual product lot basis since product launch. We consider 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 to returned product. We also consider historical chargebacks activity and current contract prices to estimate our exposure to 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 receipt of FDA approval of Baxalta's HYQVIA<sup>®</sup> in September 2014 and European marketing approvals of Roche's Herceptin SC product in August 2013 and MabThera<sup>®</sup> SC product in March 2014 and Baxalta's HYQVIA product in May 2013, revenue from the sales of bulk rHuPH20 for these collaboration products has been recognized as product sales. For the three months ended September 30, 2015 and 2014, we recognized product sales of bulk rHuPH20 for Roche collaboration products in the amount of \$4.7 million and \$5.8 million, respectively, and for Baxalta collaboration products in the amount of \$1.6 million and zero, respectively. For the nine months ended September 30, 2015 and 2014, we recognized product sales of bulk rHuPH20 for Roche

collaboration products in the amount of \$17.0 million and \$17.7 million, respectively, and for Baxalta collaboration products in the amount of \$3.1 million and zero, respectively.

#### 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 or events designated in the collaborative agreements, annual maintenance fees, reimbursements of research and development services, payments for supply of bulk rHuPH20 by 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.

Consideration we receive under collaboration agreements 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 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 the timing of 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 (i) 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, (ii) the relative selling price allocation of the license is equal to or exceeds the upfront license fee, (iii) persuasive evidence of an arrangement exists, (iv) our price to the collaborator is fixed or determinable and (v) 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.

Certain of our collaborative agreements provide for milestone payments upon achievement of 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 (“Milestone Method of Accounting”). 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:

The consideration is commensurate with either the entity’s performance to achieve the milestone or the enhancement

1. 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 is 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 inventories that do not meet certain product specifications, if any.

#### 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 such 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 marketing approvals are capitalized as inventory.

We are obligated to make upfront payments upon execution of certain research and development agreements. 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 are recognized as 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 value are expensed as research and development costs at the time the costs are incurred. We currently 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 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, restricted stock awards (“RSAs”), restricted stock units (“RSUs”), and RSUs with performance conditions (“PRSUs”) 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. Share-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed. Share-based compensation expense recognition is based on awards ultimately expected to vest and is reduced for estimated forfeitures. The authoritative guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

### 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. Outstanding stock options, unvested RSAs, unvested RSUs and unvested PRSUs are considered common stock equivalents and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. For the three and nine months ended September 30, 2015 and 2014, approximately 9.6 million and 9.8 million shares, respectively, of outstanding stock options, unvested RSAs, unvested RSUs and unvested PRSUs were excluded from the calculation of diluted net loss per common share because a net loss was reported in each of these periods and therefore their effect was 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. 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, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$52,204	\$16	\$(16)	) \$52,204
	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$74,275	\$2	\$(43)	) \$74,234

As of September 30, 2015, \$43.1 million of our available-for-sale marketable securities were scheduled to mature within the next 12 months. As of September 30, 2015, we had 11 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 there were no other-than-temporary impairments on these marketable securities as of September 30, 2015 because we do not intend to sell these marketable securities prior to maturity 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 collaboration and license 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, 2015, Roche has elected a total of five targets, two of which are exclusive, and retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual maintenance fees to us. In August 2013, Roche received European marketing approval 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.

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 supplying 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 to us with respect to each product commercialized 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 Roche 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, 2015, we have received \$78.3 million from Roche, excluding royalties and reimbursements for providing research and development services and supplying bulk rHuPH20. The amounts received consisted of a \$20.0 million upfront license fee payment for the application of rHuPH20 to the initial three Roche exclusive targets, \$22.3 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 amortized over the remaining term of the Roche Collaboration.

For the three months ended September 30, 2015 and 2014, we recognized approximately \$0.9 million and \$0.8 million of Roche deferred revenues as revenues under collaborative agreements. For the nine months ended September 30, 2015 and 2014, we recognized approximately \$2.5 million and \$7.3 million, respectively, of Roche deferred revenues as revenues under collaborative agreements. Roche deferred revenues were approximately \$40.3 million and \$42.7 million as of September 30, 2015 and December 31, 2014, respectively.

#### Baxalta Collaboration

In September 2007, we and Baxalta entered into a collaboration and license agreement, under which Baxalta obtained a worldwide, exclusive license to develop and commercialize HYQVIA, a combination of Baxalta's current product GAMMAGARD LIQUID™ and our patented rHuPH20 enzyme (the "Baxalta Collaboration"). In May 2013, the European Commission granted Baxalta 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. Baxalta launched HYQVIA in the EU in July 2013. In September 2014, the FDA approved HYQVIA for treatment of adult patients with primary immunodeficiency. In October 2014, Baxalta announced the launch and first shipments of HYQVIA in the U.S. The Baxalta Collaboration is applicable to both kit and formulation combinations. Baxalta assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the Baxalta 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 Baxalta, and are reimbursed by Baxalta under the terms of the Baxalta Collaboration. In addition, Baxalta has certain product development and commercialization obligations in major markets identified in the Baxalta Collaboration.

Unless terminated earlier in accordance with its terms, the Baxalta Collaboration continues in effect until the expiration of Baxalta's obligation to pay royalties to us. Baxalta has the obligation to pay royalties, with respect to each product commercialized 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 Baxalta 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, 2015, we have received \$17.0 million under the Baxalta Collaboration, excluding royalties and reimbursements for providing research and development services and supplying bulk rHuPH20. The amounts received consisted of a \$10.0 million upfront license fee payment, a \$3.0 million regulatory milestone payment and a \$4.0 million sales-based payment. Baxalta 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 license fee and sales-based payments were deferred and are being recognized over the term of the Baxalta Collaboration.

For both the three months ended September 30, 2015 and 2014, we recognized approximately \$0.2 million of Baxalta deferred revenues as revenues under collaborative agreements. For both the nine months ended September 30, 2015 and 2014, we recognized approximately \$0.6 million of Baxalta deferred revenues as revenues under collaborative agreements. For the three and nine months ended September 30, 2015, we recognized approximately \$0.6 million and \$1.2 million, respectively, of deferred revenues relating to manufacturing prepayments received from Baxalta. No such deferred revenues were recognized in the corresponding periods in 2014. Baxalta deferred revenues related to collaborative agreements and manufacturing prepayments totaled approximately \$9.7 million and \$10.9 million as of September 30, 2015 and December 31, 2014, respectively.

#### Other Collaborations

In June 2015, we and AbbVie, Inc. ("AbbVie") entered into a collaboration and license agreement, under which AbbVie has the worldwide license to develop and commercialize products combining our patented rHuPH20 enzyme with AbbVie proprietary biologics directed at up to nine targets (the "AbbVie Collaboration"). Targets, once selected, will be on an exclusive, global basis. As of September 30, 2015, we have received a \$23.0 million payment for the license fee of one specified exclusive target, TNF alpha. AbbVie has announced plans to develop rHuPH20 with HUMIRA® (adalimumab) which may allow reduced number of induction injections and deliver additional performance benefits. AbbVie has the right to elect up to eight additional targets for additional fees. The upfront license payment may be followed by event-based payments subject to AbbVie's achievement of specified development, regulatory and sales-based milestones. In addition, AbbVie will pay tiered royalties if products under the collaboration are commercialized. Unless terminated earlier in accordance with its terms, the AbbVie 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

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the AbbVie 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. AbbVie may terminate the agreement prior to expiration for any reason in its entirety or on a target-by-target basis upon 90 days prior written notice to us. Upon any such termination, the license granted to AbbVie (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. In December 2014, we and Janssen entered into a collaboration and license agreement, under which Janssen has the worldwide license to develop and commercialize products combining our patented rHuPH20 enzyme with Janssen proprietary biologics directed at up to five targets (the “Janssen Collaboration”). Targets, once selected, will be on an exclusive, global basis. As of September 30, 2015, we have received a \$15.0 million payment for the license fee of one specified exclusive target, CD38. Janssen has the right to elect four additional targets in the future upon payment of additional fees. Unless terminated earlier in accordance with its terms, the Janssen 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 Janssen 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. Janssen may terminate the agreement prior to expiration for any reason in its entirety or on a target-by-target basis upon 90 days prior written notice to us. Upon any such termination, the license granted to Janssen (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. In November 2015, Janssen initiated dosing in a Phase 1b clinical trial of a subcutaneous formulation of rHuPH20 and daratumumab, a human monoclonal antibody that targets CD38 on the surface of multiple myeloma cells.

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 our patented 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, 2015, we have received \$11.0 million in upfront and license fee payments for the licenses to four specified exclusive targets. One of the targets is proprotein convertase subtilisin/kexin type 9, also known as PCSK9. Pfizer is also developing Rivipansel directed to another target under the collaboration to treat vaso-occlusive crisis in individuals with sickle cell disease. Pfizer has the right to elect two additional targets 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. In October 2015, Pfizer initiated dosing in a Phase 1 clinical trial for a subcutaneous formulation of Rivipansel, triggering a \$1.0 million milestone payment. At the inception of the Pfizer, Janssen and AbbVie arrangements, we identified the deliverables in each arrangement to include the license, research and development services and supply of bulk rHuPH20. We have determined that the license, research and development services and supply of bulk rHuPH20 individually represent separate units of

accounting, because each deliverable has standalone value. The estimated selling prices for these units of accounting were determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotech industry and entity-

specific factors such as the terms of our previous collaborative agreements, our pricing practices and pricing objectives. The arrangement consideration was allocated to the deliverables based on the relative selling price method and the nature of the research and development services to be performed for the collaborator.

The amount allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions (non-contingent amount). As such, we excluded from the allocable arrangement consideration the event-based payments, milestone payments, annual exclusivity fees and royalties regardless of the probability of receipt. Based on the results of our analysis, we allocated the \$11.0 million license fees from Pfizer, the \$15.0 million upfront license fee from Janssen and the \$23.0 million upfront license fee from AbbVie to the license fee deliverable under each of the arrangements. We determined that the upfront payments were earned upon the granting of the worldwide, exclusive right to our technology to the collaborators in these arrangements. As a result, we recognized the \$11.0 million license fees under the Pfizer Collaboration, the \$15.0 million upfront license fee under the Janssen Collaboration and the \$23.0 million upfront license fee under the AbbVie Collaboration as revenues under collaborative agreements in the period when such license fees were earned. There were no revenues recognized related to event-based payments or milestone payments under these collaborations for the three and nine months ended September 30, 2015 and 2014.

The collaborators are each solely responsible for the development, manufacturing and marketing of any products resulting from their respective collaborations. We are entitled to receive payments for research and development services and supply of bulk rHuPH20 to these collaborators if requested by such collaborator. We recognize amounts allocated to research and development services as revenues under collaborative agreements as the related services are performed. We recognize amounts allocated to the sales of bulk rHuPH20 as revenues under collaborative agreements when such bulk rHuPH20 has met all required specifications by the collaborators and the related title and risk of loss and damages have passed to the collaborators. We cannot predict the timing of delivery of research and development services and bulk rHuPH20 as they are at the collaborators' requests.

Pursuant to the terms of our collaboration agreements with Roche and Pfizer, certain future payments meet the definition of a milestone in accordance with the Milestone Method of Accounting. 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, 2015	December 31, 2014
Accounts receivable from product sales to collaborators	\$5,463	\$6,361
Accounts receivable from other product sales	2,433	2,133
Accounts receivable from revenues under collaborative agreements	1,230	1,266
Subtotal	9,126	9,760
Allowance for distribution fees and discounts	(734            )	(611            )
Total accounts receivable, net	\$8,392	\$9,149

Inventories consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw materials	\$467	\$553
Work-in-process	9,494	5,207
Finished goods	1,140	646
Total inventories	\$11,101	\$6,406

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

	September 30, 2015	December 31, 2014
Prepaid manufacturing expenses	\$7,181	\$6,339
Prepaid research and development expenses	3,120	2,380
Other prepaid expenses	1,516	1,094
Other assets	520	1,535
Total prepaid expenses and other assets	12,337	11,348
Less long-term portion	2,458	1,205
Total prepaid expenses and other assets, current	\$9,879	\$10,143



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

	September 30, 2015		December 31, 2014
Research equipment	\$9,142		\$8,474
Computer and office equipment	1,973		2,178
Leasehold improvements	1,554		1,518
Subtotal	12,669		12,170
Accumulated depreciation and amortization	(9,983	)	(9,219
Property and equipment, net	\$2,686		\$2,951

Depreciation and amortization expense totaled approximately \$0.4 million for both of the three months ended September 30, 2015 and 2014, and approximately \$1.2 million and \$1.3 million for the nine months ended September 30, 2015 and 2014, respectively.

Accrued expenses consisted of the following (in thousands):

	September 30, 2015		December 31, 2014
Accrued outsourced research and development expenses	\$7,017		\$4,383
Accrued compensation and payroll taxes	5,614		5,923
Accrued outsourced manufacturing expenses	3,914		2,112
Other accrued expenses	3,060		2,023
Total accrued expenses	19,605		14,441
Less long-term accrued outsourced research and development expenses	679		480
Total accrued expenses, current	\$18,926		\$13,961

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, 2015		December 31, 2014
Collaborative agreements	\$49,455		\$53,479
Product sales	578		1,155
Total deferred revenue	50,033		54,634
Less current portion	5,789		7,367
Deferred revenue, net of current portion	\$44,244		\$47,267

## 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.

In January 2015, we entered into the second amendment to the Loan Agreement with the Lenders, amending and restating the loan repayment schedules of the Loan Agreement. The amended and restated term loan repayment schedule provides for interest only payments through January 2016, followed by consecutive equal monthly payments of principal and interest in arrears starting in February 2016 and continuing through the previously established maturity date of 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 interest 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. 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, Halozyne, Inc., except that the collateral does not include any equity interests in Halozyne, Inc., any of our 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 subsidiary, Halozyne, Inc.

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, 2015, 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 \$1.3 million and \$1.4 million for the three months ended September 30, 2015 and 2014, respectively. Interest expense, including amortization of the debt discount, related to the long-term debt totaled approximately \$3.9 million and \$4.2 million for the nine months ended September 30, 2015 and 2014, respectively. Accrued interest, which is included in accrued expenses and other long-term liabilities, was \$2.9 million and \$2.0 million as of September 30, 2015 and December 31, 2014, respectively.



## 7. Share-based Compensation

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,	
	2015	2014	2015	2014
Research and development	\$2,269	\$2,295	\$7,268	\$5,735
Selling, general and administrative	3,284	1,881	8,320	5,330
Share-based compensation expense	\$5,553	\$4,176	\$15,588	\$11,065
Share-based compensation expense from type of share-based award (in thousands):				

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Stock options	\$3,281	\$1,896	\$7,905	\$5,954
RSAs, RSUs and PRSUs	2,272	2,280	7,683	5,111
	\$5,553	\$4,176	\$15,588	\$11,065

Since we have a net operating loss carryforward as of September 30, 2015, 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, 2015.

The Company granted stock options to purchase approximately 0.8 million and 0.1 million shares of the Company's common stock during the three months ended September 30, 2015 and 2014, respectively, and 3.3 million and 2.1 million shares of the Company's common stock during the nine months ended September 30, 2015 and 2014, respectively. The exercise price of the stock options granted during the three and nine months ended September 30, 2015 and 2014 was equal to the closing price of the Company's common stock on the date of grant. The estimated fair value of each stock option granted was estimated on the date of grant using the Black-Scholes-Merton option pricing model ("Black-Scholes model") that used assumptions noted in the following table. Expected volatility is based on historical volatility of our common stock. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The dividend yield assumption is based on the expectation of no future dividend payments by us. The weighted-average assumptions used in the Black-Scholes model were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2015	2014	2015	2014	
Expected volatility	66.8	% 69.6	% 66.7	% 71.0	%
Average expected term (in years)	5.6	5.7	5.6	5.7	
Risk-free interest rate	1.8	% 1.9	% 1.6	% 1.9	%
Expected dividend yield	—	% —	% —	% —	%

Total unrecognized estimated compensation cost related to by type of award and the weighted-average remaining requisite service period over which such expense is expected to be recognized (in thousands, unless otherwise noted):

	September 30, 2015	
	Unrecognized Expense	Remaining Weighted-Average Recognition Period (years)
Stock options	\$29,697	3.0
RSAs	\$6,780	2.5
RSUs	\$5,249	2.8
PRSUs	\$258	1.0

#### 8. Stockholders' Equity

During the nine months ended September 30, 2015 and 2014, we issued an aggregate of 1,626,091 and 1,078,748 shares of common stock, respectively, in connection with the exercises of stock options at a weighted average exercise price of \$7.43 and \$4.87 per share, respectively, for net proceeds of approximately \$12.1 million and \$5.2 million, respectively. For the nine months ended September 30, 2015 and 2014, we issued 134,088 and 176,743 shares of common stock, respectively, upon vesting of certain RSUs for which the RSU holders surrendered 52,019 and 67,704 RSUs, respectively, to pay for minimum withholding taxes totaling approximately \$0.7 million and \$0.9 million, respectively. In addition, we issued 515,695 and 978,972 shares of common stock in connection with the grants of RSAs during the nine months ended September 30, 2015 and 2014, respectively. Stock options, unvested RSUs, and PRSUs totaling approximately 8.8 million shares and 8.4 million shares of our common stock were outstanding as of September 30, 2015 and December 31, 2014, 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.

#### 9. 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.

#### 10. Restructuring Expense

In November 2014, we completed a corporate reorganization to focus our resources on advancing our PEGPH20 oncology proprietary program and Enhance collaborations. This reorganization resulted in a reduction in the workforce of approximately 13%, primarily in research and development.

As of December 31, 2014, the restructuring liability was approximately \$0.5 million and was included in current accrued expenses. The restructuring liability was paid in full during the three months ended March 31, 2015.

## 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," and "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, 2014, included in our Annual Report on Form 10-K for the year ended December 31, 2014. 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," "may," "will," "would," "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this report. Additionally, statements concerning future matters such as the anticipated timing and scope of planned clinical trials, 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, expense and cash burn levels and trends 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 this Quarterly Report.

### Overview

Halozyme Therapeutics, Inc. is a biotechnology company focused on developing and commercializing novel oncology therapies. We are seeking to translate our unique knowledge of the tumor microenvironment to create therapies that can improve cancer survival. Our research primarily focuses on human enzymes that alter the extracellular matrix and tumor microenvironment. 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 are used to facilitate the delivery of injected drugs and fluids, potentially enhancing the efficacy and the convenience of other drugs or to alter tissue structures for potential 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, with a focus on oncology, 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 hyaluronan (or 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 Enhance™ technology. rHuPH20 is also the active ingredient in our first commercially approved product, Hylenex® recombinant.

Regarding Enhance, we currently have collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Baxalta Healthcare Corporation (Baxalta), Pfizer Inc. (Pfizer), Janssen Biotech, Inc. (Janssen), and AbbVie, Inc. (AbbVie), 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.

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.

Our proprietary development pipeline consists of a clinical stage product candidate in oncology and research-stage oncology projects. 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. When HA accumulates in a tumor, it can cause higher pressure in the tumor, reducing blood flow into the tumor and with that, reduced access of cancer therapies to the tumor. PEGPH20 works by temporarily degrading HA surrounding cancer cells resulting in reduced pressure and increased blood flow to the cancer with increased amounts of anticancer treatments administered concomitantly gaining access to the tumor. We are currently in Phase 2 clinical testing for PEGPH20 in metastatic pancreatic cancer (Study 109-202), in Phase 1b clinical testing in non-small cell lung cancer (Study 107-201) and in Phase 1b clinical testing in non-small cell lung cancer and gastric cancer (Study 107-101).

Our receipt of Fast Track and Orphan Drug designations for PEGPH20, new pre-clinical data further supporting the pan-tumor potential for PEGPH20 and investigator interest in both our pancreatic and lung cancer trials have confirmed PEGPH20 as our priority product candidate for investment.

Our key accomplishments for the third quarter of 2015 include:

In July 2015, we entered into a clinical collaboration agreement with Eisai Co. Ltd. (Eisai) to evaluate Eisai's agent eribulin mesylate (brand name: Halaven®, eribulin) in combination with PEGPH20 in first line HER2-negative HA-high metastatic breast cancer patients. The companies will jointly share the costs of a phase 1b/2 clinical trial to assess whether or not eribulin, in combination with PEGPH20, can improve overall response rate (ORR) -- the proportion of patients that have a predefined reduction in tumor burden -- as compared with eribulin alone as a therapy in patients with advanced breast cancer.

Since the submission of the Halozyme Study 301 protocol to the FDA we have identified strong interest to participate in the global study. This Phase 3 study of PEGPH20 in previously untreated metastatic pancreatic cancer patients is planned for initiation by the end of first quarter 2016.

We continue to enroll patients in Halozyme Study 202 and plan to complete our target enrollment of 114 patients by the end of 2015 and present results of the study in the second half of 2016.

#### Product and Product Candidates

We have one marketed proprietary product and one proprietary product candidate targeting several indications in various stages of development. The following table summarizes our proprietary product and product candidate 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. 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 in combination with currently approved cancer therapies. '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 (half-life of one to two days) and, therefore, can be used to maintain therapeutic effect to treat systemic disease.



Cancer malignancies, including pancreatic, lung, breast, gastric, colon and prostate cancers can accumulate high levels of HA and therefore we believe that PEGPH20 has the potential to help patients with these types of cancer when used with currently approved cancer therapies. Among solid tumors, pancreatic ductal adenocarcinoma has been reported to be associated with the highest frequency of HA accumulation.

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 in animal models. Removal of HA from the tumor microenvironment results in expansion of previously constricted blood vessels allowing increased blood flow, increasing the access of activated immune cells and factors in the blood into the tumor microenvironment. 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.

#### Study Halo 109-201:

In January 2015, we presented the final results from Study 109-201, a multi-center, international open label dose escalation Phase 1b clinical study of PEGPH20 in combination with gemcitabine for the treatment of patients with stage IV metastatic pancreatic cancer at the 2015 Gastrointestinal Cancers Symposium (also known as ASCO-GI 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  $\mu\text{g}/\text{kg}$  twice weekly for four weeks, then weekly thereafter) in combination with gemcitabine 1000 mg/m<sup>2</sup> administered intravenously. In this study, the confirmed overall response rate (complete response + partial response confirmed on a second scan as assessed by an independent radiology review) was 29 percent (7 of 24 patients) for those treated at therapeutic dose levels of PEGPH20 (1.6 and 3.0  $\mu\text{g}/\text{kg}$ ). Median progression free survival (PFS) was 154 days (95% CI, 50-166) in the efficacy-evaluable population (n = 24). Among efficacy-evaluable patients with baseline tumor HA staining (n = 17), the median PFS in patients with high baseline tumor HA staining (6/17 patients) was substantially longer, 219 days, than in the patients with low baseline tumor HA staining (11/17 patients), 108 days. Median overall survival (OS) was 200 days (95% CI, 123-370) in the efficacy-evaluable population (n = 24). Among efficacy-evaluable patients with baseline tumor HA staining (n = 17), the median OS in patients with high baseline tumor HA staining (6/17 patients) was substantially longer, 395 days, than in the patients with low baseline tumor HA staining (11/17 patients), 174 days. The most common treatment-emergent adverse events (occurring in  $\geq 15\%$  of patients) were peripheral edema, muscle spasms, thrombocytopenia, fatigue, myalgia, anemia, and nausea. Thromboembolic events were reported in 8 patients (28.6%) and musculoskeletal events were reported in 21 patients (75%) which were generally grade 1/2 in severity.

#### Study Halo 109-202:

In the second quarter of 2013, we initiated Study 109-202, 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 patients who would receive gemcitabine and nab-paclitaxel (ABRAXANE<sup>®</sup>) either with or without PEGPH20. The primary endpoint is to measure the improvement in PFS in patients receiving PEGPH20 plus gemcitabine and nab-paclitaxel compared to those who are receiving gemcitabine and nab-paclitaxel alone. In April 2014, after 146 patients had been enrolled, the trial was put on clinical hold by Halozyme and the FDA to assess a question raised by the Data Monitoring Committee regarding a possible difference in the thromboembolic event rate between the group of patients treated with PEGPH20, nab-paclitaxel and gemcitabine (PAG arm) versus the group of patients treated with nab-paclitaxel and gemcitabine without PEGPH20 (AG arm). This portion of the study and patients in this portion are now referred to as Stage 1. It should be noted that at the time of the clinical hold all patients remaining in the study continued on gemcitabine and nab-paclitaxel. In July 2014, the Study 109-202 was reinitiated (Stage 2) under a revised protocol, which excludes patients that are expected to be at a greater risk for thromboembolic events, provides for venous thromboembolism prophylaxis of all patients in both arms of the study with low molecular weight heparin, and adds evaluation of the thromboembolic event rate in Stage 2 PEGPH20-treated patients compared with

Stage 1 as a co-primary end point. Stage

29

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2 of Study 109-202 is designed to enroll an additional 114 patients, to add to the 146 patients already accrued in the clinical trial, with a 2:1 randomization for PAG compared to AG.

In May 2015, interim findings from the ongoing Phase 2 clinical study of PEGPH20 for the potential treatment of patients with metastatic pancreatic cancer were presented at the American Society of Clinical Oncology annual meeting in an oral presentation by Principal Investigator Sunil Hingorani, M.D., Ph.D., Associate Member of the Fred Hutchinson Cancer Research Center and Associate Professor at University of Washington School of Medicine. The trial included 135 treated patients in Stage 1, of whom a total of 44 patients -- 23 receiving PEGPH20 in combination with ABRAXANE® and gemcitabine (PAG treatment arm) and 21 receiving ABRAXANE and gemcitabine alone (AG treatment arm) -- had available biopsies that were determined in a retrospective analysis to have high levels of hyaluronan. PEGPH20 targets HA to help improve cancer therapy access to tumor cells. Results reported include:

• A more than doubling of median PFS of 9.2 months versus 4.3 months in high HA patients treated with PAG vs. AG (hazard ratio of 0.39; p-value of 0.05);

• A more than doubling of overall response rate of 52 percent versus 24 percent (p-value of 0.038) and a duration of response of 8.1 months compared to 3.7 months in high HA patients treated with PAG versus AG;

In the 30 high HA patients (15 PAG treatment arm versus 15 AG treatment arm) who were evaluated for response prior to the April 2014 clinical hold and subsequent PEGPH20 treatment discontinuation, the overall response rate was 73 percent versus 27 percent (p-value of 0.01), respectively, consistent with findings presented in January;

• A trend toward improvement in median overall survival of 12 months compared to 9 months in high HA patients treated with PAG versus AG (hazard ratio of 0.62) despite discontinuation of PEGPH20 in more than half of the PAG-treated patients at the time of the clinical hold in April 2014.

Data was also presented on the rate of thromboembolic (TE) events in 55 patients treated in Stage 2 of the trial, which is currently randomizing patients at a 2:1 ratio of PAG versus AG. As noted above, Stage 2 began after a protocol amendment in July 2014, excluding patients at high risk of TE events and adding prophylaxis with low molecular weight heparin (enoxaparin) to all patients in both treatment arms. Reported results included a TE event rate of 13 percent in 38 patients treated with PAG versus 18 percent in 17 patients receiving AG.

We and the Data Monitoring Committee for Study 109-202 continue to closely monitor the occurrence of thromboembolic events in enrolled patients after the revision to the protocol. The revised protocol includes pre-specified analyses to evaluate the rate of thromboembolic events, and Study 109-202 may be halted again if the protocol changes do not result in a reduction of thromboembolic events in accordance with the pre-specified analyses in the protocol.

In March 2015, we met with the FDA to discuss both the interim efficacy and safety data from Study 109-202, which included the potential risk profile including thromboembolic event rate. Based on the feedback from that meeting, we plan to proceed with a Phase 3 clinical study (Study 109-301) of PEGPH20 in patients with metastatic pancreatic cancer, using a design allowing for potential marketing application based on either PFS or overall survival. The study will enroll patients whose tumors accumulate high levels of hyaluronan using a companion diagnostic test. The FDA provided feedback on the current companion diagnostic approach and confirmed that an approved companion diagnostic strategy is required prior to Phase 3 study initiation.

The use of PFS as the basis for marketing approval will be subject to the overall benefit and risk associated with PEGPH20 combined with nab-paclitaxel (ABRAXANE®) and gemcitabine therapy, including the:

• Magnitude of the PFS treatment effect observed;

• Toxicity profile; and

• Interim overall survival data.

In June 2015, we received scientific advice/protocol assistance from the European Medicines Agency (EMA) regarding our planned Phase 3 study. The EMA agreed to the patient population, and the use of both PFS and OS as co-primary endpoints stating that OS is the preferred endpoint and that ultimate approval would require an overall positive benefit:risk balance.

SWOG Study S1313:

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 in some of their study centers, examining 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). This study was also placed on clinical hold temporarily at the time of the hold on Study 109-202. 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 continuing. The Phase 2 portion of the study, where up to 172 patients are planned to be enrolled began in June 2015. As with Study 109-202, the occurrence of thromboembolic events will be closely monitored in enrolled patients, 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.

Other indications outside of pancreatic cancer:

Study HALO 107-201, PRIMAL Study: In December 2014, we initiated 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 this 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 into the Phase 2 portion of the study to evaluate the safety and efficacy of PEGPH20 in second line HA-high NSCLC patients in combination with docetaxel.

Study HALO 107-101, the immuno-oncology trial: We recently initiated a Phase 1b study exploring the combination of PEGPH20 and KEYTRUDA®, an immuno-oncology agent in relapsed NSCLC and gastric cancer. We expect to evaluate and identify the dose and safety of PEGPH20 plus KEYTRUDA prior to embarking on expansion into larger trials and into additional tumor types.

Halozyne Eisai Clinical Collaboration: In the first quarter of 2016 we plan to initiate a Phase 1b/2 study exploring the combination of PEGPH20 and eribulin in first line HER2-negative HA-high metastatic breast cancer. Halozyne is partnering with Eisai to conduct this global study.

Regulatory:

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 Office of Orphan Products Development'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 December 2014, the European Committee for Orphan Medicinal Products of the EMA designated PEGPH20 an orphan medicinal product for the treatment of pancreatic cancer.

In March 2015, we met with the FDA to discuss both the interim efficacy and safety data from Study 109-202 and to discuss the Phase 3 Study 109-301 as a potential registration seeking study in stage IV metastatic pancreatic cancer patients whose tumors are determined to have high levels of HA accumulation. In June 2015, we received scientific advice/protocol assistance from the EMA regarding our planned Phase 3 study. In addition, we will continue our dialog with the FDA regarding the development of a companion diagnostic agent for detection and qualification of hyaluronan in the tumor tissue of cancer patients.

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.

## Collaborations

### Roche Collaboration

In December 2006, we and Roche entered into a collaboration and license 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). 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, 2015, Roche has elected a total of five targets, two of which are exclusive, 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 patented Enhance technology 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 reported to be a particularly aggressive form of breast cancer.

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 Enhance 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. Roche has also announced that it filed MabThera SC in Europe for previously untreated chronic lymphocytic leukemia in the fourth quarter of 2014. Additional information about the Phase 3 Herceptin SC and Phase 3 MabThera SC clinical trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.roche-trials.com](http://www.roche-trials.com). Information available on these websites is not incorporated into this report.

### Baxalta Collaboration

In September 2007, we and Baxalta entered into a collaboration and license agreement under which Baxalta obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 with GAMMAGARD LIQUID (HYQVIA) (the Baxalta Collaboration). GAMMAGARD LIQUID is a current Baxalta product that is indicated for the treatment of primary immunodeficiency disorders associated with defects in the immune system.

In October 2014, Baxalta announced the launch and first shipments of Baxalta'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 immune globulin (IG) treatment approved for adult 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 in most patients, 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 Baxalta 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. Baxalta 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 our 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 and initiated dosing in a Phase 1 clinical trial in October 2015.

#### Janssen Collaboration

In December 2014, we and Janssen entered into a collaboration and license agreement, under which Janssen has the worldwide license to develop and commercialize products combining our rHuPH20 enzyme with Janssen proprietary biologics directed to up to five targets. Targets may be selected on an exclusive basis. Janssen has elected CD38 as the first target on an exclusive basis. In November 2015, Janssen initiated dosing in a Phase 1b clinical trial of a subcutaneous formulation of rHuPH20 and daratumumab, a human monoclonal antibody that targets CD38 on the surface of multiple myeloma cells.

#### AbbVie Collaboration

In June 2015, we and AbbVie entered into a collaboration and license agreement, under which AbbVie has the worldwide license to develop and commercialize products combining our rHuPH20 enzyme with AbbVie proprietary biologics directed to up to nine targets. Targets may be selected on an exclusive basis. AbbVie has elected TNF alpha as the first target on an exclusive basis. AbbVie has announced plans to develop rHuPH20 with HUMIRA® (adalimumab) which may allow a reduced number of induction injections and deliver additional performance benefits. 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, 2015 Compared to Three Months Ended September 30, 2014

Product Sales, Net – Product sales, net were \$10.3 million for the three months ended September 30, 2015 compared to \$9.6 million for the three months ended September 30, 2014. The increase of \$0.7 million was primarily due to an increase in Hylenex recombinant product sales to \$3.9 million for the three months ended September 30, 2015 from \$3.6 million for the same period in 2014, and to the sale of bulk rHuPH20 to Baxalta of \$1.6 million for the three months ended September 30, 2015, compared to no sales in the same period in 2014, partially offset by a decrease in the sale of bulk rHuPH20 to Roche to \$4.7 million for the three months ended September 30, 2015 from \$5.8 million for the three months ended September 30, 2014.



Royalties – Royalty revenue was \$8.3 million for the three months ended September 30, 2015 compared to \$2.9 million for the three months ended September 30, 2014. This increase relates primarily to increased sales of Herceptin SC by Roche. We recognize royalties on sales of the collaboration products by the collaborators in the quarter following the quarter in which the corresponding sales occurred. In general, we expect royalty revenue to increase in future periods reflecting expected increases in the sales of products under collaborations, although there may be quarters with flat or declining royalty revenues as sales of products under collaborations vary.

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

	Three Months Ended		
	September 30,		
	2015	2014	Change
Upfront payments, license maintenance fees and amortization of deferred upfront, license fees and product-based payments:			
Roche	\$815	\$801	\$14
Baxalta	192	192	—
	1,007	993	14
Reimbursements for research and development services:			
Roche, Janssen, Baxalta, other	1,198	1,101	97
Total revenues under collaborative agreements	\$2,205	\$2,094	\$111

Revenue from reimbursements for research and development services increased in the three months ended September 30, 2015, compared to the same period in 2014 mainly due to an increase in services provided to Janssen compared to the same period in 2014. 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 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 \$6.2 million for the three months ended September 30, 2015 compared to \$5.1 million for the three months ended September 30, 2014. The increase of \$1.1 million in cost of product sales was due to a \$1.2 million increase in bulk rHuPH20 sales to collaboration partners offset by a \$0.2 million decrease in Hylenex recombinant cost of product sales.



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	Three Months Ended		Change
	September 30, 2015	September 30, 2014	
Product Candidates:			
PEGPH20	\$22,607	\$9,996	\$12,611
Ultrafast insulin program	6	4,890	(4,884 )
Hylenex recombinant	67	1,342	(1,275 )
rHuPH20 platform <sup>(1)</sup>	3,058	1,060	1,998
Enhance collaborations	1,037	1,605	(568 )
Other	836	1,011	(175 )
Total research and development expenses	\$27,611	\$19,904	\$7,707

<sup>(1)</sup> 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, 2015 increased by 126%, compared to the same period in 2014 primarily due to increased clinical trial activities.

Research and development expenses relating to our ultrafast insulin program for the three months ended September 30, 2015 decreased by 100%, compared to the same period in 2014 primarily due to the cessation of clinical trial and manufacturing activities. Research and development expenses relating to our Hylenex recombinant program for the three months ended September 30, 2015 decreased by 95%, compared to the same period in 2014 mainly due to the completion of the technology transfer and validation campaign with a second manufacturer for Hylenex recombinant in 2014. Research and development expenses relating to our Enhance collaborations for the three months ended September 30, 2015 decreased by 35%, compared to the same period in 2014 primarily due to a decrease in manufacturing expenses related to Roche. 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 \$10.2 million for the three months ended September 30, 2015 compared to \$8.6 million for the three months ended September 30, 2014.

The increase of \$1.6 million, or 19%, was primarily due to an increase in compensation expense in the current period. We expect SG&A expenses to increase moderately in future periods as our operations expand.

Interest Expense – Interest expense remained constant at \$1.3 million for the three months ended September 30, 2015 compared to \$1.4 million for the three months ended September 30, 2014.

Nine Months Ended September 30, 2015 Compared to Nine Months Ended September 30, 2014

Product Sales, Net – Product sales, net were \$32.5 million for the nine months ended September 30, 2015 compared to \$27.7 million for the nine months ended September 30, 2014. The increase of \$4.8 million was primarily due to an increase in Hylenex recombinant product sales to \$11.8 million for the nine months ended September 30, 2015 from \$9.0 million for the same period in 2014, and due to the sale of bulk rHuPH20 to Baxalta of \$3.1 million for the nine months ended September 30, 2015, compared to no sales in the same period in 2014, partially offset by a decrease in the sale of bulk rHuPH20 to Roche to \$17.0 million for the nine months ended September 30, 2015 from \$17.7 million for the nine months ended September 30, 2014.

Royalties – Royalty revenue was \$21.4 million for the nine months ended September 30, 2015 compared to \$5.4 million for the nine months ended September 30, 2014. This increase relates primarily to increased sales of Herceptin SC by Roche. We recognize royalties on sales of the collaboration products by the collaborators in the quarter following the quarter in which the corresponding sales occurred. In general, we expect royalty revenue to increase in future periods reflecting expected increases in sales of products under collaborations, although there may be periods with flat or declining royalty revenue as sales of products under collaborations vary.

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

	Nine Months Ended		
	September 30,		
	2015	2014	Change
Upfront payments, license maintenance fees and amortization of deferred upfront, license fees and product-based payments:			
AbbVie	\$23,000	\$—	\$23,000
Roche	2,448	2,222	226
Pfizer	1,000	1,000	—
Baxalta	574	574	—
	27,022	3,796	23,226
Reimbursements for research and development services:			
Roche, Janssen, Baxalta, other	1,874	8,100	(6,226 )
Total revenues under collaborative agreements	\$28,896	\$11,896	\$17,000

Revenue from license fees in connection with the AbbVie Collaboration of \$23.0 million was recognized in the nine months ended September 30, 2015. Revenue from reimbursements for research and development services decreased in the nine months ended September 30, 2015, compared to the same period in 2014 mainly due to a reduction in services provided to Roche compared to the same period in 2014. 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 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 \$20.8 million for the nine months ended September 30, 2015 compared to \$16.6 million for the nine months ended September 30, 2014. The increase of \$4.2 million in cost of product sales was due to a \$1.3 million increase in Hylenex recombinant cost of product sales and a \$2.9 million increase in bulk rHuPH20 cost of product sales.

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		Change
	September 30, 2015	September 30, 2014	
Product Candidates:			
PEGPH20	\$52,552	\$23,968	\$28,584
Ultrafast insulin program	1,626	17,372	(15,746 )
Hylenex recombinant	1,246	4,563	(3,317 )
rHuPH20 platform <sup>(1)</sup>	5,307	4,681	626
Enhance collaborations	2,200	6,013	(3,813 )
Other	2,559	3,371	(812 )
Total research and development expenses	\$65,490	\$59,968	\$5,522

(1) 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, 2015 increased by 119%, compared to the same period in 2014 primarily due to increased clinical trial activities.

Research and development expenses relating to our ultrafast insulin program for the nine months ended September 30, 2015 decreased by 91%, compared to the same period in 2014 primarily due to decreased clinical trial and manufacturing activities. Research and development expenses relating to our Hylenex recombinant program for the nine months ended September 30, 2015 decreased by 73%, compared to the same period in 2014 mainly due to the completion of the technology transfer and validation campaign with a second manufacturer for Hylenex recombinant in 2014. Research and development expenses relating to our Enhance collaborations for the nine months ended September 30, 2015 decreased by 63%, compared to the same period in 2014 primarily due to a decrease in manufacturing expenses related to Roche. We expect research and development expenses to increase in future periods reflecting expected increases in our PEGPH20 development activities.

Selling, General and Administrative – SG&A expenses were \$29.4 million for the nine months ended September 30, 2015 compared to \$27.6 million for the nine months ended September 30, 2014. The increase of \$1.8 million, or 7%, was primarily due to an increase in compensation expense in the current period. We expect SG&A expenses to increase moderately in future periods as our operations expand.

Interest Expense – Interest expense decreased to \$3.9 million for the nine months ended September 30, 2015 compared to \$4.2 million for the nine months ended September 30, 2014.

#### 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, 2015, we had cash, cash equivalents and marketable securities of approximately \$123.7 million and bank debt of approximately \$49.8 million. We will continue to have significant cash requirements to support product development activities. The amount and timing of cash requirements will depend on the progress and success of our clinical development programs, regulatory and market acceptance, and the resources we devote to research and other commercialization activities.

We believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. We currently anticipate total net cash burn of approximately \$20 million to \$30 million for the year ending December 31, 2015, depending on the progress of various preclinical and clinical programs, the timing of our manufacturing scale up and the achievement of various milestones and royalties under our existing collaborative agreements. We expect to fund our operations going forward with existing cash resources, anticipated revenues from our existing collaborations and cash that we may raise through future transactions. We may finance future cash needs through any one of the following financing vehicles: (i) the public offering of securities; (ii) new collaborative agreements; (iii) expansions or revisions to existing collaborative relationships; (iv) private financings; and/or (v) other equity or debt financings.

We are a “well known seasoned issuer”, which allows us to file an automatically effective shelf registration statement on Form S-3 which would allow 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 \$21.9 million during the nine months ended September 30, 2015 compared to \$46.6 million during the nine months ended September 30, 2014. The \$24.7 million decrease in utilization of cash in operations was mainly due to the decrease in net loss, partially offset by an increase in inventory.

##### Investing Activities

Net cash provided by investing activities was \$20.6 million during the nine months ended September 30, 2015 compared to net cash used in investing activities of \$46.4 million during the nine months ended September 30, 2014. This change was primarily due to the \$42.8 million decrease in purchases of marketable securities and \$23.9 million increase in proceeds from the maturities of marketable securities during the nine months ended September 30, 2015.

##### Financing Activities

Net cash provided by financing activities was \$11.4 million during the nine months ended September 30, 2015 compared to \$112.0 million during the nine months ended September 30, 2014. This decrease was due to \$107.7 million in net proceeds from the sale of our common stock in February 2014 partially offset by the \$7.0 million increase in net proceeds from the issuance of common stock under equity incentive plans during the nine months ended September 30, 2015.

##### 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, 2015, net of unamortized debt discount of \$0.2 million. In January 2015, we and the Lenders entered into a second amendment to the Loan Agreement (the Amendment) amending and restating the loan repayment schedule of the Loan Agreement. The amended and restated loan repayment schedule provides for interest only payments in arrears through January 2016, followed by consecutive equal monthly payments of principal and interest in arrears starting in February 2016 and continuing through the previously established maturity date. Consistent with the original loan, the Loan Agreement provides for a 7.55% interest rate on the term loan and a final interest 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. 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 Halozyne, Inc., except that the collateral does not include any equity interests in Halozyne, 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, 2015, 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 condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our condensed 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 condensed 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, 2014 (2014 Form 10-K), which contain accounting policies and other disclosures required by U.S. GAAP. There were no material changes from those policies and disclosures included in our 2014 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.

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 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 – Adoption and 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 limited 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 limited 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, 2015, we have incurred aggregate net losses of approximately \$487.0 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 and have learned that an additional clinical study will be required. We have determined we will not invest in this additional clinical trial and to date have not identified a strategic partner who will conduct the trial. In addition, the approval of Baxalta's HYQVIA BLA was delayed until we and Baxalta provided additional preclinical data sufficient to address concerns regarding non-neutralizing antibodies to rHuPH20 that were detected in the registration trial. Although these antibodies have not been associated with any known 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 approvals for any potential products in a timely manner, or at all. Refer to the risk factor titled “Our proprietary and collaboration product candidates or companion diagnostic assays may not receive regulatory approvals or their development may be delayed for a variety of reasons, including delayed or 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 or maintain 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 commercialization 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 that had been observed at that time 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 or other raw materials 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 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. Cook has relatively limited experience manufacturing bulk rHuPH20. If either Avid or Cook: (i) is unable to retain its status as an FDA approved manufacturing facility; (ii) is unable to otherwise successfully scale up bulk rHuPH20 production to meet corporate or regulatory authority quality standards; 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’ or other third party manufacturers’ 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

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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 a potential 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 or the ability of other third party manufacturers, to supply other raw materials or ingredients necessary to produce our products 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, and they would have a material adverse effect on royalties and thus 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, 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 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 Enhance technology and our most advanced proprietary and collaboration products and product candidates, including the current and future products and product candidates under our Roche, Pfizer, Janssen, Baxalta, and AbbVie collaborations, our PEGPH20 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 Baxalta's HYQVIA product as well as in a former collaborator's product in a Phase 2 clinical trial 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 former collaborator's 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 the foregoing programs or 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.



We routinely evaluate, and may modify, our business strategy and our strategic focus to only a few fields or applications of our technology which may increase or decrease the risk for potential negative impact of adverse developments.

We routinely evaluate our business strategy, and may modify this strategy in the future in light of our assessment of unmet medical needs, growth potential, resource requirements, regulatory issues, competition, risks and other factors. As a result of these strategic evaluations, we may focus our resources and efforts on one or a few programs or fields and may suspend or reduce our efforts on other programs and fields. For example, in the third quarter of 2014, we decided to focus our resources on advancing PEGPH20 and expanding utilization of our Enhance platform. While we believe these are applications with the greatest potential value, we have reduced the diversification of our programs and increased our dependence on the success of the areas we are pursuing. By focusing on one or a few areas, we increase the potential impact on us if one of those programs or product candidates does not successfully complete clinical trials, achieves commercial acceptance or meets expectations regarding sales and revenue. Our decision to focus on one or a few programs may also reduce the value of programs that are no longer within our principal strategic focus, which could impair our ability to pursue collaborations or other strategic alternatives for those programs we are not pursuing.

Our proprietary and collaboration product candidates or companion diagnostic assays may not receive regulatory approvals or their development may be delayed for a variety of reasons, including delayed or 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, including the patient enrollment 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 or development of any collaboration companion diagnostic assays could be unsuccessful, which would delay or preclude regulatory approval and commercialization of the product candidates or companion diagnostic assays. 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 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 that had been observed at that time 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;

- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;

- a regulatory agency may approve only a narrow use of our product or may require additional safety monitoring and reporting through Risk Evaluation and Mitigation Strategies (REMS) or conditions to assure safe use program;

- 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 or companion diagnostic assay is not approved in a timely fashion or obtained on commercially viable terms, or if development of any product candidate or a companion diagnostic assay 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 would 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 or companion diagnostic assay will receive regulatory approval in a timely manner, or at all. 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 Baxalta 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 addition, we are in the early stages of scaling up our manufacturing of PEGPH20 with third party suppliers to support additional clinical trials, including a possible registration-enabling trial, and ultimately, if approved, potential commercial supply. If our contract manufacturers are unable to successfully manufacture and supply PEGPH20, the progress of our clinical trials could be delayed or halted for a



period of time.

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

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;

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- 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 need to raise additional capital in the future and there can be no assurance that we will be able to obtain such funds.

We may need to raise additional capital in the future 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 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 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. In January 2015, we entered into the Second Amendment to the Amended and Restated Loan and Security Agreement and First Amendment to Disbursement Letter (the Amendment) with the Lenders, amending and restating the loan payment schedules of the Amended and Restated Loan and Security Agreement. The amended and restated term loan repayment schedule provides for interest only payments through January 2016, followed by consecutive equal monthly payments of principal and interest in arrears starting in February 2016 and continuing through the previously established maturity date of January 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
- 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 experienced 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 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 in April 2014 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, 2015 were \$25.25 and \$7.51, 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;
- disruptions in our clinical or commercial supply chains, including disruptions caused by 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 at all; 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.

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 acquirers 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 change, our competitors may be able to develop and commercialize products based on our discoveries.

Patent protection for protein-based therapeutic products is highly uncertain and involves complex legal and factual questions. In recent years, there have been significant changes in patent law, including the legal standards that govern the scope of protein and biotechnology patents. Standards for patentability of full-length and partial genes, and their corresponding proteins, are changing. Recent court decisions have made it more difficult to obtain patents, by making it more difficult to satisfy the 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 PEGPH20 product candidate, such competitors may include major pharmaceutical and specialized biotechnology firms. 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, 2015.

As of September 30, 2015, our cash equivalents and marketable securities consisted of investments in money market funds and corporate debt obligations. 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, 2015, 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.

#### 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, 2015 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 5. Other Information

Beginning in early 2015, the Compensation Committee of the Company's Board of Directors initiated a review of the Company's severance practices for all employee levels in the event of a change in control of the Company. As a result of that review, on November 4, 2015 the Compensation Committee adopted several changes to existing severance programs and agreements applicable to employees at various levels, including amending the Company's previously disclosed "double-trigger" Change in Control Agreement (the "Amended Change in Control Agreement") to be entered into with certain executives of the Company (collectively, the "Executives"), including Laurie D. Stelzer, Senior Vice President and Chief Financial Officer and Dr. Helen Torley, President and Chief Executive Officer (the "CEO"). Generally, the Amended Change in Control Agreement provides that, if within 12 months after the occurrence of a "change in control" of the Company (as defined in the Amended Change in Control Agreement), (i) the Company terminates the Executive without "cause" (as defined in the Amended Change in Control Agreement), (ii) the Executive resigns for "good reason" (as defined in the Amended Change in Control Agreement), or (iii) the Executive's employment is terminated due to death or "disability" (as defined in the Amended Change in Control Agreement), then the Executive will be entitled to receive his or her annual base salary earned through the employment termination date and any accrued obligations (as defined in the Amended Change in Control Agreement), as well as certain severance payments and benefits.

The severance payments and benefits would include, for each Executive, subject to the timely execution by the Executive of an effective release of claims against the Company and certain affiliated persons and entities:

An amount equal to 1.5 times (or in the case of the CEO, 2.0 times) the sum of the Executive's (A) current annual (1) base salary and (B) the amount of target annual bonus opportunity (based on the target percentage of annual base salary) in respect of the year the termination of employment occurs;

An amount equal to 2.0 times the cost of 18 (or, in the case of the CEO, 24) months of monthly medical premiums (2) (including the employee and employer portions for the Executive and, if applicable, the Executive's spouse and eligible dependents), if any, under the Company's group health plans in which the Executive participated immediately prior to the employment termination date; and

100% of all equity awards (including any equity awards the vesting of which is based in whole or in part upon the achievement of performance goals) outstanding as of the employment termination date will become fully vested (3) and non-forfeitable, and otherwise exercisable in accordance with the underlying terms of the applicable equity plan and award agreement pursuant to which such awards were granted.

The Executive will also be entitled to receive the compensation and benefits described above if (i) the Company terminates the Executive without "cause" (as defined in the Amended Change in Control Agreement) or (ii) the Executive resigns for "good reason" (as defined in the Amended Change in Control Agreement) before a "change in control" of the Company, and, in either case, the Executive reasonably demonstrates that such termination was at the request of a third party who has taken steps reasonably calculated to effect the "change in control" of the Company or otherwise arose in connection with or anticipation of a "change in control" of the Company.

If a change in control occurs but the Executive's employment is not terminated, then the Amended Change in Control Agreement provides for lesser protections with respect to equity awards then held by the Executive, the vesting of which is based in whole or in part upon the achievement of performance goals. With respect to such awards, the numbers of shares or units subject to such awards shall be determined based upon the greater of target and actual performance, and, unless fully paid and settled in connection with the change in control, will remain outstanding, with the number and kind of shares or units subject to the awards adjusted to reflect the change in control in accordance with the terms of the applicable equity plan, and any applicable service-based vesting requirements will continue to apply.

The Amended Change in Control Agreement supersedes all prior agreements the Executive may have with the Company regarding compensation or benefits that may become payable in connection with a change in control of the Company, including any provision contained in any employment agreement, offer letter or change in control agreement, as well as any equity incentive plan or equity award agreement.

Pursuant to the Amended Change in Control Agreement, the Executive will be solely responsible for all federal, state, local or non-U.S. taxes due with respect to any payments received thereunder, including any excise tax imposed by Section 4999 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The Amended Change in Control Agreement also provides that the amount of severance benefits could potentially be subject to reduction to the extent that the total payments (as defined in the Amended Change in Control Agreement) constitute an "excess parachute payment" under Section 280G of the Code or become subject to the excise tax imposed under Section 4999 of the Code.

Unless a change in control termination has occurred, the Amended Change in Control Agreement will terminate on the earlier to occur of (i) the Executive's employment termination date and (ii) the first anniversary of a change in control event.

The foregoing description of the Amended Change in Control Agreement does not purport to be complete and is qualified in its entirety by reference to the complete Amended Change in Control Agreement, the form of which is attached to this Quarterly Report on Form 10-Q as Exhibit 10.1 and incorporated by reference herein.

Item 4. Mine Safety Disclosures

Not applicable.

Item 6. Exhibits

- 3.1 Composite Certificate of Incorporation (1)
- 3.2 Certificate of Designation, Preferences and Rights of the terms of the Series A Preferred Stock (2)
- 3.3 Bylaws, as amended (3)
- 4.1 Amended Rights, Agreement between Corporate Stock Transfer, as rights agent and the registrant, as amended November 12, 2007 (4)
- 10.1 Form of Amended and Restated Change in Control Agreement
- 10.2 Form of Stock Option Agreement (2011 Stock Plan)
- 10.3 Form of Restricted Stock Award Agreement (2011 Stock Plan)
- 10.4 Form of Restricted Stock Units Agreement (2011 Stock Plan)
- 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 Quarterly Report on Form 10-Q, filed August 7, 2013 (File No. 001-32335).

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

(4) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed March 14, 2008 (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 9, 2015

/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 9, 2015

/s/ Laurie D. Stelzer  
Laurie D. Stelzer  
Senior Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)