HALOZYME THERAPEUTICS INC
Form 10-Q
November 10, 2014

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

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

For the quarterly period ended September 30, 2014
OR

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

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

_____

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

_____

Delaware (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)	92121 (Zip Code)

(858) 794-8889
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

See accompanying notes to condensed consolidated financial statements.

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

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

See accompanying notes to condensed consolidated financial statements.

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

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

See accompanying notes to condensed consolidated financial statements.

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

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

See accompanying notes to condensed consolidated financial statements.

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

1. Organization and Business

Halozyme Therapeutics, Inc. is a science-driven, biopharmaceutical company committed to making molecules into medicines for patients in need. Our research focuses primarily on human enzymes that alter the extracellular matrix. The extracellular matrix is a complex matrix of proteins and carbohydrates surrounding the cell that provides structural support in tissues and orchestrates many important biological activities, including cell migration, signaling and survival. Over many years, we have developed unique technology and scientific expertise enabling us to pursue this target-rich environment for the development of therapies.

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

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

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”) and with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for a complete set of financial statements. These interim unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on February 28, 2014. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented, with such adjustments consisting only of normal recurring adjustments. Operating results for interim periods are not necessarily indicative of the operating results for an entire fiscal year.

The accompanying condensed consolidated financial statements include the accounts of Halozyme Therapeutics, Inc. and its wholly owned subsidiary, Halozyme, Inc., and Halozyme, Inc.'s wholly owned subsidiary, Halozyme Holdings Ltd. All intercompany accounts and transactions have been eliminated.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management’s estimates.

Pending Adoption of Recent Accounting Pronouncements

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

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

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

Cash Equivalents and Marketable Securities

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

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

Restricted Cash

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

Fair Value of Financial Instruments

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

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

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

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

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

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

Inventories

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

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

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

Revenue Recognition

We generate revenues from product sales and collaborative agreements. Payments received under collaborative agreements may include nonrefundable fees at the inception of the agreements, license fees, milestone payments for specific achievements designated in the collaborative agreements, reimbursements of research and development services and supply of bulk rHuPH20, and/or royalties on sales of products resulting from collaborative arrangements. We recognize revenues in accordance with the authoritative guidance for revenue recognition. We recognize revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

Product Sales, Net

Hylenex Recombinant

In December 2011, we reintroduced Hylenex recombinant to the market. We sell Hylenex recombinant in the U.S. to wholesale pharmaceutical distributors, who sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although we offer discounts to certain group purchasing organizations ("GPOs"), hospitals and government programs. The wholesalers take the title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales.

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

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

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

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

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

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

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

Bulk rHuPH20

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

Revenues under Collaborative Agreements

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

In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The deliverables under our collaborative agreements include (i) the license to our rHuPH20 technology, (ii) at the collaborator's request, research and development services which are reimbursed at contractually determined rates, and (iii) at the collaborator's request, supply of bulk rHuPH20 which is reimbursed at our cost plus a margin. A delivered item is considered a separate unit of accounting when the delivered item has value to the collaborator on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the collaborator and the availability of research expertise in this field in the general marketplace.

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

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

The terms of our collaborative agreements provide for milestone payments upon achievement of certain development and regulatory events and/or specified sales volumes of commercialized products by the collaborator. We account for milestone payments in accordance with the provisions of ASU No. 2010-17, Revenue Recognition - Milestone Method. We recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

1. The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone,
2. The consideration relates solely to past performance, and
3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

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

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is reasonably assured. Revenue from the manufacture of bulk rHuPH20 is recognized when the materials have met all specifications required for the collaborator's acceptance and title and risk of loss have transferred to the collaborator. We do not directly control when any collaborator will request research and development services or supply of bulk rHuPH20; therefore, we cannot predict when we will recognize revenues in connection with research and development services and supply of bulk rHuPH20.

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

The collaborative agreements typically provide the collaborators the right to terminate such agreement in whole or on a product-by-product or target-by-target basis at any time upon 30 to 90 days prior written notice to us. There are no performance, cancellation, termination or refund provisions in any of our collaborative agreements that contain material financial consequences to us.

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

Cost of Product Sales

Cost of product sales consists primarily of raw materials, third-party manufacturing costs, fill and finish costs, freight costs, internal costs and manufacturing overhead associated with the production of Hylenex recombinant and bulk rHuPH20 for use in approved collaboration products. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories and the write-off of any inventories that do not meet certain product specifications, if any.

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

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

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

Research and Development Expenses

Research and development expenses include salaries and benefits, facilities and other overhead expenses, external clinical trial expenses, research related manufacturing services, contract services and other outside expenses. Research and development expenses are charged to operations as incurred when these expenditures relate to our research and development efforts and have no alternative future uses. After receiving approval from the FDA or comparable regulatory agencies in foreign countries for a product, costs related to purchases and manufacturing of bulk rHuPH20 for product are capitalized as inventory. The manufacturing costs of bulk rHuPH20 for the collaboration products, Herceptin SC, MabThera SC and HYQVIA, incurred after the receipt of the European marketing approvals are capitalized as inventory.

In accordance with certain research and development agreements, we are obligated to make certain upfront payments upon execution of the agreement. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts will be recognized as an expense as the related goods are delivered or the related services are performed or such time when we do not expect the goods to be delivered or services to be performed.

Milestone payments that we make in connection with in-licensed technology for a particular research and development project that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are expensed as research and development costs at the time the costs are incurred. We have no in-licensed technologies that have alternative future uses in research and development projects or otherwise.

Clinical Trial Expenses

Payments in connection with our clinical trials are often made under contracts with multiple contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. Payments under these contracts depend on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on our estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we modify our accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain. Historically, we have had no material changes in clinical trial expense accruals that had a material impact on our consolidated results of operations or financial position.

Share-Based Compensation

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

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

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

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

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

Net Loss Per Share

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

Segment Information

We operate our business in one segment, which includes all activities related to the research, development and commercialization of our proprietary enzymes that can be used to facilitate the delivery of injected drugs and fluids, thus enhancing the efficacy and the convenience of other drugs or to alter abnormal tissue structures for clinical benefit. This segment also includes revenues and expenses related to (i) research and development and bulk rHuPH20 manufacturing activities conducted under our collaborative agreements with third parties and (ii) product sales of Hylenex recombinant. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

3. Marketable Securities

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

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

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

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

4. Collaborative Agreements

Roche Collaboration

In December 2006, we and Roche entered into a license and collaborative agreement under which Roche obtained a worldwide, exclusive license to develop and commercialize product combinations of rHuPH20 and up to thirteen Roche target compounds (the “Roche Collaboration”). As of September 30, 2014, Roche has elected a total of five exclusive targets and retains the option to develop and commercialize rHuPH20 with three additional targets, provided that Roche continues to pay annual maintenance fees to us. Roche received European marketing approval in August 2013 for its collaboration product, Herceptin SC, for the treatment of patients with HER2-positive breast cancer and launched Herceptin SC in the European Union (“EU”) in September 2013.

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

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

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

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

For the three months ended September 30, 2014 and 2013, we recognized approximately $0.8 million and