

HALOZYME THERAPEUTICS INC
Form 10-Q
November 06, 2018

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, 2018
OR

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

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

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

Delaware 88-0488686
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

11388 Sorrento Valley Road, San Diego, CA 92121
(Address of principal executive offices) (Zip Code)
(858) 794-8889
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company
x

(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 144,557,543 as of October 30, 2018.

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 amounts)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,019	\$ 168,740
Marketable securities, available-for-sale	309,347	300,474
Accounts receivable, net and other contract assets	27,656	22,133
Inventories	18,285	5,146
Prepaid expenses and other assets	19,619	13,879
Total current assets	429,926	510,372
Property and equipment, net	6,790	3,520
Prepaid expenses and other assets	7,291	5,553
Restricted cash	500	500
Total assets	\$ 444,507	\$ 519,945
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,331	\$ 7,948
Accrued expenses	43,020	39,601
Deferred revenue, current portion	4,247	6,568
Current portion of long-term debt, net	88,521	77,211
Total current liabilities	139,119	131,328
Deferred revenue, net of current portion	5,507	54,297
Long-term debt, net	57,940	125,140
Other long-term liabilities	2,203	814
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; 144,522 and 142,789 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	145	143
Additional paid-in capital	769,382	731,044
Accumulated other comprehensive loss	(478) (450)
Accumulated deficit	(529,311) (522,371)
Total stockholders' equity	239,738	208,366
Total liabilities and stockholders' equity	\$ 444,507	\$ 519,945

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,	
	2018	2017	2018	2017
Revenues:				
Royalties	\$18,710	\$17,119	\$59,643	\$45,839
Product sales, net	6,269	13,589	17,553	37,803
Revenues under collaborative agreements	577	33,023	14,434	43,407
Total revenues	25,556	63,731	91,630	127,049
Operating expenses:				
Cost of product sales	626	8,332	4,514	23,664
Research and development	35,540	33,993	113,602	109,267
Selling, general and administrative	14,864	13,329	42,773	39,045
Total operating expenses	51,030	55,654	160,889	171,976
Operating (loss) income	(25,474)	8,077	(69,259)	(44,927)
Other income (expense):				
Investment and other income, net	1,910	790	5,561	1,512
Interest expense	(4,286)	(5,538)	(14,286)	(16,526)
Net (loss) income before income taxes	(27,850)	3,329	(77,984)	(59,941)
Income tax expense	—	580	220	970
Net (loss) income	\$(27,850)	\$2,749	\$(78,204)	\$(60,911)
Net (loss) income per share:				
Basic	\$(0.19)	\$0.02	\$(0.55)	\$(0.45)
Diluted	\$(0.19)	\$0.02	\$(0.55)	\$(0.45)
Shares used in computing net (loss) income per share:				
Basic	143,949	141,190	143,396	134,633
Diluted	143,949	143,236	143,396	134,633

See accompanying notes to condensed consolidated financial statements.

HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net (loss) income	\$(27,850)	\$2,749	\$(78,204)	\$(60,911)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	256	24	(17)	(40)
Foreign currency translation adjustment	2	1	(11)	(6)
Unrealized loss on foreign currency	—	(17)	—	(1)
Total comprehensive (loss) income	\$(27,592)	\$2,757	\$(78,232)	\$(60,958)

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,	
	2018	2017
Operating activities:		
Net loss	\$(78,204)	\$(60,911)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	26,684	23,268
Depreciation and amortization	1,798	1,668
Non-cash interest expense	2,000	2,378
Accretion of discounts on marketable securities, net	(2,166)	(94)
Deferral of unearned revenue	3,000	422
Recognition of deferred revenue	(2,333)	(4,192)
Deferral (recognition) of rent expense	78	(125)
Other	(10)	38
Changes in operating assets and liabilities:		
Accounts receivable, net and other contract assets	13,962	985
Inventories	(13,139)	5,292
Prepaid expenses and other assets	(7,477)	8,998
Accounts payable and accrued expenses	(4,155)	3,077
Net cash used in operating activities	(59,962)	(19,196)
Investing activities:		
Purchases of marketable securities	(272,643)	(198,748)
Proceeds from maturities of marketable securities	265,917	184,494
Purchases of property and equipment	(1,590)	(490)
Net cash used in investing activities	(8,316)	(14,744)
Financing activities:		
Proceeds from issuance of common stock, net	—	134,875
Repayment of long-term debt	(57,099)	(10,988)
Proceeds from issuance of common stock under equity incentive plans, net of taxes paid related to net share settlement	11,656	7,686
Net cash (used in) provided by financing activities	(45,443)	131,573
Net (decrease) increase in cash, cash equivalents and restricted cash	(113,721)	97,633
Cash, cash equivalents and restricted cash at beginning of period	169,240	67,264
Cash, cash equivalents and restricted cash at end of period	\$55,519	\$164,897
Supplemental disclosure of non-cash investing and financing activities:		
Amounts accrued for purchases of property and equipment	\$2,345	\$266
Leasehold improvements paid by lessor	\$1,322	\$—
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 exploit our technology and expertise using a two pillar strategy that we believe enables us to manage risk and cost 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 that 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 is the active ingredient in our first commercially approved product, Hylenex[®] recombinant, and it works by temporarily breaking down hyaluronan (or "HA"), a naturally occurring 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 our ENHANZE[®] Drug Delivery Technology ("ENHANZE"). We license the ENHANZE technology to form collaborations with biopharmaceutical companies that develop or market drugs requiring or benefiting from injection via the subcutaneous route of administration.

We currently have ENHANZE collaborations with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. ("Roche"), Baxalta US Inc. and Baxalta GmbH (Baxalta Incorporated was acquired by Shire plc in June 2016) ("Baxalta"), Pfizer Inc. ("Pfizer"), Janssen Biotech, Inc. ("Janssen"), AbbVie, Inc. ("AbbVie"), Eli Lilly and Company ("Lilly"), Bristol-Myers Squibb Company ("BMS") and Alexion Pharma Holding ("Alexion"). We receive royalties from two of these collaborations, including royalties from sales of one product from the Baxalta collaboration and two products from the Roche collaboration. Future potential revenues from the sales and/or royalties of our approved products, product candidates, and ENHANZE collaborations will depend on the ability of Halozyme and our collaborators to develop, manufacture, secure and maintain regulatory approvals for approved products and product candidates and commercialize product candidates.

Our proprietary development pipeline consists primarily of pre-clinical and clinical stage product candidates in oncology. Our lead oncology program is Pegvorhyaluronidase alfa (PVHA), also referred to as PEGylated recombinant human hyaluronidase ("PEGPH20"), a molecular entity we are developing in combination with currently approved cancer therapies as a candidate for the systemic treatment of tumors that accumulate HA. We have demonstrated that when HA accumulates in a tumor, it can cause increased pressure in the tumor, reducing blood flow into the tumor and with that, reduced access of cancer therapies to the tumor. PEGPH20 has been demonstrated in animal models to work by temporarily degrading HA surrounding cancer cells resulting in reduced pressure and increased blood flow to the tumor thereby enabling increased amounts of anticancer treatments administered concomitantly gaining access to the tumor. Through our efforts and efforts of our partners and collaborators, we are currently in Phase 3 clinical testing for PEGPH20 with ABRAXANE[®] (nab-paclitaxel) and gemcitabine in stage IV pancreatic ductal adenocarcinoma ("PDA") (HALO 109-301), in Phase 1b clinical testing for PEGPH20 with KEYTRUDA[®] (pembrolizumab) in

non-small cell lung cancer and gastric cancer (HALO 107-101), in Phase 1b/2 clinical testing for PEGPH20 with Tecentriq® (atezolizumab) in patients with previously treated metastatic PDA, in Phase 1b/2 clinical testing for PEGPH20 with Tecentriq in patients with gastric cancer and in Phase 1b/2 clinical testing for PEGPH20 with Tecentriq in patients with cholangiocarcinoma and gall bladder cancer (HALO 110-101/MATRIX).

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 subsidiaries, Halozyme Holdings Ltd., Halozyme Royalty LLC, Halozyme Switzerland GmbH and Halozyme Switzerland Holdings GmbH.

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, 2017, filed with the SEC on February 20, 2018. 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. Certain reclassifications have been made to the prior period condensed consolidated statement of cash flows within operating activities to conform to the current period presentation. There was no change to net cash used in operating activities. 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 our wholly owned subsidiary, Halozyme, Inc., and Halozyme, Inc.’s wholly owned subsidiaries, Halozyme Holdings Ltd., Halozyme Royalty LLC, Halozyme Switzerland GmbH and Halozyme Switzerland Holdings GmbH. All intercompany accounts and transactions have been eliminated.

Use of Estimates

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.

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. As of September 30, 2018, our cash equivalents consisted of money market funds and commercial paper.

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 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 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, 2018 and December 31, 2017, 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 and other assets, 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 and other assets, 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. Based on Level 3 inputs and 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 asset-backed securities, corporate debt securities, U.S. Treasury securities and commercial paper, and are measured at fair value using Level 1 and 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 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.

Inventories

Inventories are stated at lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Inventories are reviewed periodically for potential excess, dated or obsolete status. We evaluate 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.

We capitalize inventory costs associated with our drug candidates prior to receipt of regulatory approval, based on management's judgment of probable future commercialization. We would be required to expense these capitalized costs upon a change in such judgment, due to, among other factors, a decision denying approval of the drug candidate by regulatory agencies.

Bulk rHuPH20 formulations manufactured for partner use prior to our partner receiving marketing approval from the U.S. Food and Drug Administration (“FDA”) or comparable regulatory agencies in foreign countries and with no alternative future use are recorded as research and development expense. All direct manufacturing costs incurred after the partner receives marketing approval are capitalized as inventory. Bulk rHuPH20 formulations manufactured for general partner and internal use, which can potentially be used by any collaboration partner or by us in any stage of development or in commercial product, and ENHANZE drug product used by our partners in clinical trials, is considered to have alternative future use and all manufacturing costs are capitalized as inventory. Inventories used in our clinical trials are expensed at the time the inventories are packaged for the clinical trials.

As of September 30, 2018 and December 31, 2017, inventories consisted of \$2.4 million and \$2.9 million, respectively, of Hylenex recombinant inventory, net and \$15.9 million and \$2.2 million, respectively, of bulk rHuPH20.

Revenue Recognition

We generate revenues from payments received under collaborative agreements and product sales. As of January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers (ASC 606) which affects how we recognize revenues in these arrangements. We applied the provisions of ASC 606 using the modified retrospective approach, with the cumulative effect of the adoption recognized as of January 1, 2018, to all contracts that had not been completed as of that date. Under ASC 606, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform the following five steps: (i) identify the promised goods or services in the contract; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations. Amounts reported in prior periods have not been adjusted. Accordingly, the reported revenue amounts for the three and nine months ended September 30, 2018 and 2017 are based on different accounting policies.

Prior to the ASC 606 adoption, revenue was recognized when all of the following criteria were 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. Differences between the revenue recognition policies applicable prior to the adoption and ASC 606 are described in the following sections and in Note 4.

Revenues under Collaborative Agreements - as reported under ASC 606 beginning January 1, 2018

Under these agreements, we grant the collaboration partner a worldwide license to develop and commercialize products using our ENHANZE technology to combine our patented rHuPH20 enzyme with their proprietary biologics directed at up to a specified number of targets. Targets are usually licensed on an exclusive, global basis. Targets selected subsequent to inception of the arrangement require payment of an additional license fee. The collaboration partner is responsible for all development, manufacturing, clinical, regulatory, sales and marketing costs for any products developed under the agreement. We are responsible for supply of bulk rHuPH20 based on the collaboration partner’s purchase orders, and may also be separately engaged to perform research and development services.

We collect an upfront license payment from the collaboration partner, and are also entitled to receive event-based payments subject to the collaboration partner’s achievement of specified development, regulatory and sales-based milestones. In several agreements, collaboration partners pay us annual fees to maintain their exclusive license rights if they are unable to advance product development to specified stages. We earn separate fees for bulk rHuPH20 supplies and research and development services. In addition, the collaboration partner will pay us royalties at an on average mid-single digit percent rate of their sales if products under the collaboration are commercialized. All amounts owed to us are noncancelable after the underlying triggering event occurs,

and nonrefundable once paid. Unless terminated earlier in accordance with its terms, the 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, which is determined separately for each country. In the event such valid claims expire prior to the last to expire royalty term, the royalty rate is reduced for the remaining royalty term following such expiration. The collaboration partner may terminate the agreement prior to expiration for any reason in its entirety or on a target-by-target basis generally upon 90 days prior written notice to us. Upon any such termination, the license granted to the collaboration partner (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. Although these agreements are in form structured as collaborative agreements, we concluded for accounting purposes they represent contracts with customers, and are not subject to accounting literature on collaborative arrangements. This is because we grant to collaboration partners licenses to our intellectual property, and provide supply of bulk rHuPH20 and research and development services which are all outputs of our ongoing activities, in exchange for consideration. We do not develop assets jointly with collaboration partners, and do not share in significant risks of their development or commercialization activities. Accordingly, we concluded our collaborative agreements must be accounted for pursuant to ASC Topic 606, Revenue from Contracts with Customers.

Under all of our collaborative agreements, we have identified licenses to use functional intellectual property as the only performance obligation. The intellectual property underlying the license is our proprietary ENHANZE[®] technology which represents application of rHuPH20 to facilitate delivery of drugs or fluids. The license grants the collaboration partners right to use our intellectual property as it exists on the effective date of the license, because there is no ongoing development of the ENHANZE technology required. Therefore, we recognize revenue from licenses at the point when the license becomes effective and the collaboration partner has received access to our intellectual property, usually at the inception of the agreement.

When collaboration partners can select additional targets to add to the licenses granted, we consider these rights to be options. We evaluate whether such options contain material rights, i.e. have exercise prices that are discounted compared to what we would charge for a similar license to a new collaboration partner. The exercise price of these options includes a combination of the target selection fees, event-based milestone payments and royalties. When these amounts in aggregate are not offered at a discount that exceeds discounts available to other customers, we conclude the option does not contain a material right, and we consider grants of additional licensing rights upon option exercises to be separate contracts (target selection contracts).

We provide standard indemnification and protection of licensed intellectual property for our customers. These provisions are part of assurance that the licenses meet the agreements representations and are not obligations to provide goods or services.

We also fulfill purchase orders for supply of bulk rHuPH20 and perform research and development services pursuant to projects authorization forms for our collaboration partners, which represent separate contracts. Additionally, we price our supply of bulk rHuPH20 and research and development services at our regular selling prices, called standalone selling price or SSP. Therefore, our collaboration partners do not have material rights to order these items at prices not reflective of SSP. Refer to the discussion below regarding recognition of revenue for these separate contracts.

Transaction price for a contract represents the amount to which we are entitled in exchange for providing goods and services to the customer. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment (or target selection fees in the target selection contracts), all other fees we may earn under our collaborative agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining marketing authorization approvals

and successful completion of clinical trials. With respect to other development milestones, e.g. dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. We do not include any amounts subject to uncertainties into the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

When target exchange rights are held by collaboration partners, and the amounts attributed to these rights are not refundable, they are included in the transaction price. However, they are recorded as deferred revenues because we have a potential performance obligation to provide a new target if the exchange right is exercised. These amounts are recognized in revenue when the right of exchange expires or is exercised.

Because our agreements only have one type of performance obligation (licenses) which are typically all transferred at the same time at agreement inception, allocation of transaction price often is not required. However, allocation is required when licenses for some of the individual targets are subject to rights of exchange, because revenue associated with these targets cannot be recognized. We perform an allocation of the upfront amount based on relative SSP of licenses for individual targets. We determine license SSP using income-based valuation approach utilizing risk-adjusted discounted cash flow projections of the estimated return a licensor would receive. When amounts subject to uncertainties, such as milestones and royalties, are included in the transaction price, we attribute them to the specific individual target licenses which generate such milestone or royalty amounts.

We also estimate SSP of bulk rHuPH20 and research and development services, to determine that our collaboration partners do not have material rights to order them at discounted prices. For supplies of bulk rHuPH20, because we effectively act as a contract manufacturer to our collaboration partners, we estimate and charge SSP based on the typical contract manufacturer margins consistently with all of our collaborative partners. We determine SSP of research and development services based on a fully-burdened labor rate. Our rates are comparable to those we observe in other collaborative agreements. We also have a history of charging similar rates to all of our collaboration partners. Upfront amounts allocated to licenses to individual targets are recognized as revenue when the license is transferred to the collaboration partner, as discussed above, if the license is not subject to exchange rights, or when the exchange right expires or is exercised. Development milestones and other fees are recognized in revenue when they are included in the transaction price, because by that time we have already transferred the related license to the collaboration partner.

Sales-based milestones and royalties cannot be recognized until the underlying sales occur. We do not receive final royalty reports from our collaboration partners until after we complete our financial statements for a prior quarter. Therefore, we recognize revenue based on estimates of the royalty earned, which are based on preliminary reports provided by our collaboration partners. We will record a true-up in the following quarter if necessary, when final royalty reports are received. To date, we have not recorded any material true-ups.

In contracts to provide research and development services, such services represent the only performance obligation. The fees are charged based on hours worked by our employees and the fixed contractual rate per hour, plus third-party pass-through costs, on a monthly basis. We recognize revenues as the related services are performed based on the amounts billed, as the collaboration partner consumes the benefit of research and development work simultaneously as we perform these services, and the amounts billed reflect the value of these services to the customer.

Refer to Note 4 Revenue, for further discussion on our collaborative arrangements.

Prior to the adoption of ASC 606 on January 1, 2018, we recognized upfront amounts received under two of our collaborative agreements straight-line over the contract term in accordance with the accounting standards that were in effect in 2006-2007, when these collaborative agreements were entered into. In addition, we recognized royalty revenue in the period when we received final

royalty reports from the collaboration partners, in the quarter following the quarter in which the corresponding sales occurred. There were no other differences in revenue to be recognized under the previously existing authoritative accounting literature and ASC 606 applied to our collaborative agreements.

Product Sales, Net - as reported under ASC 606 beginning January 1, 2018

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 are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual packages of Hylenex recombinant represent performance obligations under each purchase order. We use a contract manufacturer to produce Hylenex recombinant and a third-party logistics (3PL) vendor to process and fulfill orders. We concluded we are the principal in the sales to wholesalers because we control access to services rendered by both vendors and direct their activities. We have no significant obligations to wholesalers to generate pull-through sales.

Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when wholesalers sell Hylenex recombinant at negotiated discounted prices to members of certain group purchasing organizations (“GPOs”) and government programs. We also pay quarterly distribution fees to certain wholesalers for inventory reporting and chargeback processing, and to GPOs for access to GPO members. We concluded the benefits received in exchange for these fees are not distinct from our sales of Hylenex recombinant, and accordingly we apply these amounts to reduce revenues. Wholesalers also have rights to return unsold product nearing or past the expiration date. 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.

We estimate the transaction price when we receive each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler arising from all of the above factors. We have compiled historical experience and data to estimate future returns and chargebacks of Hylenex recombinant and the impact of the other discounts and fees we pay. When estimating these adjustments to the transaction price, we reduce it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

Each purchase order contains only one type of product, and is usually shipped to the wholesaler in a single shipment. Therefore, allocation of the transaction price to individual packages is not required.

We recognize revenue from Hylenex recombinant product sales and related cost of sales upon product delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership, and have an enforceable obligation to pay us. They also have the ability to direct sales of product to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, we do not believe they have a significant incentive to return the product to us.

Upon recognition of revenue from product sales of Hylenex recombinant, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, and GPO fees are included in sales reserves, accrued liabilities and net of accounts receivable. We monitor actual product returns, chargebacks, discounts and fees subsequent to the sale. If these amounts differ from our estimates, we make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustments.

In connection with the orders placed by wholesalers, we incur costs such as commissions to our sales representatives. However, as revenue from product sales is recognized upon delivery to the wholesaler, which occurs shortly after we receive a purchase order, we do not capitalize these commissions and other costs, based on application of a practical expedient allowed in ASC 606.

Bulk rHuPH20

We sell bulk rHuPH20 to collaboration partners for use in research and development; subsequent to receiving marketing approval, we sell it for use in collaboration commercial products. Sales are made pursuant to purchase orders subject to the terms of the collaborative agreement, and delivery of units of bulk rHuPH20 represent performance obligations under each purchase order. We provide a standard warranty that the product conforms to specifications. We use a contract manufacturer to produce bulk rHuPH20 and have concluded we are the principal in the sales to collaboration partners. The transaction price for each purchase order of bulk rHuPH20 is fixed based on the cost of production plus a contractual markup, and is not subject to adjustments. Allocation of the transaction price to individual quantities of the product is usually not required because each order contains only one type of product. We recognize revenue from bulk rHuPH20 formulations as product sales and related cost of sales upon transfer of title to our partners. At that time, the partners take control of the product, bear the risk of loss of ownership, and have an enforceable obligation to pay us.

There were no differences in how the previously existing authoritative accounting literature applied to our product sales transactions.

ENHANZE Drug Product

We sell ENHANZE drug product to collaboration partners for use in research and development in early phase clinical studies. Sales are made pursuant to purchase orders subject to the terms of the collaborative agreement, and delivery of units of ENHANZE drug product represent performance obligations under each purchase order. We provide a standard warranty that the product conforms to specifications. We use a contract manufacturer to produce ENHANZE drug product and we concluded we are the principal in the sales to collaboration partners. The transaction price for each purchase order of ENHANZE drug product is fixed based on the cost of production plus a contractual markup, and is not subject to adjustments. Allocation of the transaction price to individual quantities of the product is usually not required because each order contains only one type of product.

We recognize revenue from ENHANZE drug product as product sales and related cost of sales upon transfer of title to our partners. At that time, the partners take control of the product, bear the risk of loss of ownership, and have an enforceable obligation to pay us.

There were no differences in how the previously existing authoritative accounting literature applied to our product sales transactions.

Revenue Presentation

In our statements of operations, we report as revenues under collaborative agreements the upfront payments, event-based development and regulatory milestones and sales milestones. We also include in this category revenues from separate research and development contracts pursuant to project authorization forms and sales of bulk rHuPH20 that has no alternative future use. We report royalties received from collaboration partners as a separate line in our statements of operations.

Revenues from sales of Hylenex recombinant, bulk rHuPH20 that has alternative future use and ENHANZE drug product are included in product sales, net.

In footnotes to our financial statements, we provide disaggregated revenue information by type of arrangement (product sales, net, collaborative agreements and research and development services), and additionally, by type of payment stream received under collaborative agreements (upfront amounts, event-based development and regulatory milestones and other fees, sales milestones and royalties).

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 and ENHANZE drug product that has alternative future use. 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. Prior to bulk rHuPH20 and ENHANZE drug product having alternative future use, all costs related to the manufacturing of those products were charged to research and development expenses in the periods such costs were incurred. During the three and nine months ended September 30, 2018, sales of bulk rHuPH20 and ENHANZE drug product included \$1.7 million and \$2.3 million, respectively, of cost of sales that were previously expensed as research and development. Of the bulk rHuPH20 and ENHANZE drug product that has alternative future use on hand as of September 30, 2018, approximately \$2.0 million in manufacturing costs were previously recorded as research and development expenses. We expect to sell this inventory by the end of 2020.

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 operating expenses as incurred when these expenditures relate to our research and development efforts and have no alternative future uses. When bulk rHuPH20 is manufactured for use in research and development by us or our partners and the product cannot be redirected for alternative use due to formulation and manufacturing specifications, the manufacturing costs are recorded as research and development expense. Bulk rHuPH20 that is manufactured for partner use prior to our partner receiving marketing approval from the FDA or comparable regulatory agencies in foreign countries and meet these specifications is recorded as research and development expenses. The manufacturing costs of bulk rHuPH20 for the approved collaboration products, Herceptin SC, MabThera SC (RITUXAN HYCELA™ in the U.S.) and HYQVIA, incurred after the receipt of marketing approvals are capitalized as inventory. Bulk rHuPH20 formulations manufactured for general partner and internal use, which can potentially be used by any collaboration partner or by us in any stage of development or in commercial products, is considered to have alternative future use and all manufacturing costs are capitalized as inventory. Inventories used in our clinical trials are expensed at the time the inventories are packaged for the clinical trials. 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. 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

We make payments in connection with our clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. 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. A portion of our obligation to make payments under these contracts depends 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 amounts we are obligated to pay under our clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we adjust our accruals accordingly on a prospective basis. Revisions to our contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

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 over the requisite service period of the award. 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. Forfeitures are recognized as a reduction of share-based compensation expense as they occur.

Income Taxes

We provide for income taxes using the liability method. Under this method, deferred income tax assets and liabilities are determined based on the differences between the financial statement carrying amounts of existing assets and liabilities at each year end and their respective tax bases and are measured using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Significant judgment is required by management to determine our provision for income taxes, our deferred tax assets and liabilities, and the valuation allowance to record against our net deferred tax assets, which are based on complex and evolving tax regulations throughout the world. Deferred tax assets and other tax benefits are recorded when it is more likely than not that the position will be sustained upon audit. While we have begun to utilize certain of our net operating losses, we have not yet established a track record of profitability. Accordingly, valuation allowances have been recorded to reduce our net deferred tax assets to zero, with the exception of the alternative minimum tax (“AMT”) credit carryover of \$5.5 million. Under the Tax Cuts and Jobs Act (the “Act”) enacted in December 2017, the AMT credit carryover will either be utilized, or if unutilized fully refunded in 2022. For all other deferred tax assets the valuation allowance will reduce the net value to zero until such time as we can demonstrate an ability to realize them.

The Act reduces the U.S. federal corporate tax rate from 35% to 21%. As a result, the Company evaluated and adjusted its deferred tax assets to reflect the new corporate tax rates as of December 31, 2017. The Company is still evaluating other potential impacts and planning opportunities related to tax reform. As of September 30, 2018, the Company believes that its disclosures in its financial statements as of December 31, 2017 are still reasonably accurate.

Net (Loss) Income Per Share

Basic net (loss) income per common share is computed by dividing net (loss) income 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, 2018, approximately 13.8 million shares of outstanding stock options, unvested RSAs, unvested RSUs 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. Outstanding common stock equivalents totaling approximately 7.8 million and 14.3 million, respectively, were excluded from the calculation of diluted net (loss) income per common share for the three and nine months ended September 30, 2017, respectively, because their effect was anti-dilutive. A reconciliation of the numerators

and the denominators of the basic and diluted net (loss) income per common share computations is as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net (loss) income	\$(27,850)	\$ 2,749	\$(78,204)	\$(60,911)
Denominator:				
Weighted average common shares outstanding for basic net (loss) income per share	143,949	141,190	143,396	134,633
Net effect of dilutive common stock equivalents	—	2,046	—	—
Weighted average common shares outstanding for diluted net (loss) income per share	143,949	143,236	143,396	134,633
Net (loss) income per share:				
Basic	\$(0.19)	\$ 0.02	\$(0.55)	\$(0.45)
Diluted	\$(0.19)	\$ 0.02	\$(0.55)	\$(0.45)

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. Our long-lived assets located in foreign countries had minimal book value as of September 30, 2018 and December 31, 2017.

Adoption and Pending Adoption of Recent Accounting Pronouncements

The following table provides a brief description of recently issued accounting standards, those adopted in the current period and those not yet adopted:

Standard	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters
In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall; Recognition and Measurement of Financial Assets and Financial Liabilities.	The new guidance supersedes the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and requires equity securities to be measured at fair value with changes in the fair value recognized through net income. The new guidance requires public business entities that are required to disclose fair value of financial instruments measured at amortized cost on the balance sheet to measure that fair value using the exit price notion consistent with Topic 820, Fair Value Measurement.	January 1, 2018	We currently do not hold equity securities. The adoption did not have a material impact on our condensed consolidated financial position or results of operations.
In October 2016, the FASB issued ASU 2016-16, Income Taxes; Intra-Entity Transfers of Assets Other Than Inventory.	The new guidance removes the current requirement to defer the income tax effects of intercompany transfers of assets other than inventory (e.g., intangible assets) until the asset has been sold to an outside party. As a result, the income tax consequences of an intercompany transfer of assets other than inventory will be recognized in the current period income statement rather than being deferred until the assets leave the consolidated entity.	January 1, 2018	We adopted the new guidance on January 1, 2018. The adoption did not have a material impact on our condensed consolidated financial position or results of operations.

Standard	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters
<p>In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). In March, April, May and December 2016, the FASB issued additional guidance related to Topic 606.</p>	<p>The new standard superseded nearly all existing revenue recognition guidance. Under Topic 606, an entity is required to recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration to be received in exchange for those goods or services. Topic 606 defines a five-step process in order to achieve this core principle, which may require the use of judgment and estimates, and also requires expanded qualitative and quantitative disclosures relating to the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers, including significant judgments and estimates used. The new standard also defines accounting for certain costs related to origination and fulfillment of contracts with customers, including whether such costs should be capitalized.</p>	<p>January 1, 2018</p>	<p>We adopted the new guidance on January 1, 2018 using the modified retrospective approach. Refer to Notes 2 “Revenue Recognition” and 4 for additional detail regarding the impact of this adoption.</p>

Standard	Description	Effective Date	Effect on the Financial Statements or Other Significant Matters
<p>In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). In July 2018, the FASB issued additional guidance related to Topic 842.</p>	<p>The new guidance requires lessees to recognize assets and liabilities for most leases and provides enhanced disclosures.</p>	<p>January 1, 2019. Early adoption is permitted.</p>	<p>We plan to implement the guidance on January 1, 2019 using a modified retrospective transition basis for leases existing as of the period of adoption. In order to adopt the new standard, we will be using available practical expedients and newly implemented processes and internal controls for lease accounting. The practical expedients allow us to carry forward our historical assessment of whether existing agreements are or contain a lease and the classification of our existing lease arrangements. We expect all of our real-estate and automobile operating lease commitments will be recognized as lease liabilities with corresponding right-of-use assets upon adoption, resulting in an increase in the assets and liabilities of the consolidated balance sheet. We anticipate that the adoption will have a material impact on our consolidated financial statements.</p>
<p>In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820).</p>	<p>The new guidance removes, modifies and adds to certain disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement.</p>	<p>January 1, 2020</p>	<p>We plan to adopt the new guidance on January 1, 2020. We do not anticipate the adoption will have a material impact on our condensed consolidated financial position or results of operations.</p>

3. Fair Value Measurement

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

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Asset-backed securities	\$39,721	\$	—\$ (24)	\$39,697
Corporate debt securities	74,699	—	(181)	74,518
U.S. Treasury securities	99,716	—	(248)	99,468
Commercial paper	95,664	—	—	95,664
	\$309,800	\$	—\$ (453)	\$309,347
	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$117,427	\$	—\$ (235)	\$117,192
U.S. Treasury securities	66,601	—	(201)	66,400
Commercial paper	116,882	—	—	116,882
	\$300,910	\$	—\$ (436)	\$300,474

As of September 30, 2018, all of our available-for-sale debt securities were scheduled to mature within the next 12 months and 27 available-for-sale marketable securities were in a gross unrealized loss position, all of which had been in such position for less than 12 months. Based on our review of these marketable securities, we believe we had no other than-temporary impairments on these securities as of September 30, 2018, because we do not intend to sell these securities and it is not more-likely-than-not that we will be required to sell these securities before the recovery of their amortized cost basis.

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

	September 30, 2018			December 31, 2017		
	Level 1	Level 2	Total estimated fair value	Level 1	Level 2	Total estimated fair value
Cash equivalents:						
Money market funds	\$55,271	\$—	\$55,271	\$142,091	\$—	\$142,091
Commercial paper	—	—	—	—	15,700	15,700
Available-for-sale marketable securities:						
Asset-backed securities	—	39,697	39,697	—	—	—
Corporate debt securities	—	74,518	74,518	—	117,192	117,192
U.S. Treasury securities	99,468	—	99,468	66,400	—	66,400
Commercial paper	—	95,664	95,664	—	116,882	116,882
	\$154,739	\$209,879	\$364,618	\$208,491	\$249,774	\$458,265

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the nine months ended September 30, 2018. We had no instruments that were classified within Level 3 as of September 30, 2018 and December 31, 2017.

4. Revenue

Our disaggregated revenues were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Royalties	\$18,710	\$17,119	\$59,643	\$45,839
Product sales, net				
Sales of bulk rHuPH20	\$2,402	\$9,748	\$6,350	\$26,825
Sales of ENHANZE drug product	186	—	322	—
Sales of Hylenex	3,681	3,841	10,881	10,978
Total product sales, net	6,269	13,589	17,553	37,803

Revenues under collaborative agreements: