HALOZYME THERAPEUTICS INC
Form 10-Q
May 10, 2018

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 March 31, 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 x No ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "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 (Do not check if a smaller reporting company) | Smaller reporting company | Emerging growth company |
|---|---|---|---|---|
| x | ¨ | ¨ | ¨ | ¨ |

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 x

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 143,965,620 as of May 3, 2018.

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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)

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $98,012 | $ 168,740 |
| Marketable securities, available-for-sale | 335,682 | 300,474 |
| Accounts receivable, net | 26,574 | 22,133 |
| Inventories | 4,393 | 5,146 |
| Prepaid expenses and other assets | 19,809 | 13,879 |
| Total current assets | 484,470 | 510,372 |
| Property and equipment, net | 4,937 | 3,520 |
| Prepaid expenses and other assets | 5,562 | 5,553 |
| Restricted cash | 500 | 500 |
| Total assets | $495,469 | $ 519,945 |
| | | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $3,628 | $ 7,948 |
| Accrued expenses | 31,889 | 39,601 |
| Deferred revenue, current portion | 1,247 | 6,568 |
| Current portion of long-term debt, net | 82,460 | 77,211 |
| Total current liabilities | 119,224 | 131,328 |
| Deferred revenue, net of current portion | 6,006 | 54,297 |
| Long-term debt, net | 102,696 | 125,140 |
| Other long-term liabilities | 2,479 | 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; 143,886 and 142,789 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively | 144 | 143 |
| Additional paid-in capital | 744,359 | 731,044 |
| Accumulated other comprehensive loss | (870) | (450) |
| Accumulated deficit | (478,569) | (522,371) |
| Total stockholders' equity | 265,064 | 208,366 |
| Total liabilities and stockholders' equity | $495,469 | $ 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 March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Revenues: | | |
| Royalties | $20,944 | $13,982 |
| Product sales, net | 6,801 | 11,434 |
| Revenues under collaborative agreements | 3,127 | 4,152 |
| Total revenues | 30,872 | 29,568 |
| Operating expenses: | | |
| Cost of product sales | 3,052 | 7,544 |
| Research and development | 37,976 | 36,935 |
| Selling, general and administrative | 13,556 | 12,615 |
| Total operating expenses | 54,584 | 57,094 |
| Operating loss | (23,712) | (27,526) |
| Other income (expense): | | |
| Investment and other income, net | 1,668 | 287 |
| Interest expense | (5,230) | (5,448) |
| Net loss before income taxes | (27,274) | (32,687) |
| Income tax expense | 187 | 210 |
| Net loss | $(27,461) | $(32,897) |
| | | |
| Net loss per share: | | |
| Basic and diluted | $(0.19) | $(0.26) |
| | | |
| Shares used in computing net loss per share: | | |
| Basic and diluted | 142,656 | 128,615 |

See accompanying notes to condensed consolidated financial statements.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net loss | $(27,461) | $(32,897) |
| Other comprehensive income (loss): | | |
| Unrealized loss on marketable securities | (418) | (40) |
| Foreign currency translation adjustment | (2) | (4) |
| Unrealized gain on foreign currency | — | 1 |
| Total comprehensive loss | $(27,881) | $(32,940) |

See accompanying notes to condensed consolidated financial statements.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Operating activities: | | |
| Net loss | $(27,461) | $(32,897) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 8,339 | 7,315 |
| Depreciation and amortization | 566 | 602 |
| Non-cash interest expense | 1,352 | 1,453 |
| (Accretion of discounts) amortization of premiums on marketable securities, net | (565) | 16 |
| Recognition of deferred revenue | (1,834) | (1,723) |
| Deferral (recognition) of rent expense | 132 | (114) |
| Other | (2) | 39 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 15,044 | 3,228 |
| Inventories | 752 | 333 |
| Prepaid expenses and other assets | (5,939) | 4,668 |
| Accounts payable and accrued expenses | (12,561) | (5,379) |
| Net cash used in operating activities | (22,177) | (22,459) |
| Investing activities: | | |
| Purchases of marketable securities | (114,661) | (54,830) |
| Proceeds from maturities of marketable securities | 79,600 | 59,194 |
| Purchases of property and equipment | (839) | (99) |
| Net cash (used in) provided by investing activities | (35,900) | 4,265 |
| Financing activities: | | |
| Repayment of long-term debt | (17,628) | (2,989) |
| Proceeds from issuance of common stock under equity incentive plans, net of taxes paid related to net share settlement | 4,977 | (393) |
| Net cash used in financing activities | (12,651) | (3,382) |
| Net decrease in cash, cash equivalents and restricted cash | (70,728) | (21,576) |
| Cash, cash equivalents and restricted cash at beginning of period | 169,240 | 67,264 |
| Cash, cash equivalents and restricted cash at end of period | $98,512 | $45,688 |

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 complex carbohydrate that is a major component of the extracellular matrix in tissues throughout the body such as skin and cartilage. We believe this temporary degradation creates an opportunistic window for the improved subcutaneous delivery of injectable biologics, such as monoclonal antibodies and other large therapeutic molecules, as well as small molecules and fluids. We refer to the application of rHuPH20 to facilitate the delivery of other drugs or fluids as our ENHANZE® Technology. 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 ("PEGPH20", PEGylated recombinant human hyaluronidase), 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 higher 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

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cancer (HALO 107-101), in Phase 1b/2 clinical testing for PEGPH20 with HALAVEN® (eribulin) in patients treated with up to two lines of prior therapy for HER2-negative metastatic breast cancer, 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 March 31, 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 March 31, 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 is recorded as research and development expense. All direct manufacturing costs incurred after receiving 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, 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 March 31, 2018 and December 31, 2017, inventories consisted of $2.9 million of Hylenex recombinant inventory, net and $1.5 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 months ended March 31, 2017 and 2018 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 a 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 record a true-up in the following quarter if necessary, when final royalty reports are received.

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. Similar to our sales of Hylenex recombinant, we use a contract manufacturer to produce bulk rHuPH20 and we concluded we are the principal in the sales to collaboration partners. Transaction price for each purchase order represents the amounts we bill for the shipment of bulk rHuPH20 which are fixed based on the cost of production plus a contractual markup, and are not subject to adjustments. Allocation of the transaction price to individual quantities of the product is usually not required because the entire order is shipped in a single shipment.

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.

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 and bulk rHuPH20 that has alternative future use 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 that has alternative future use and for use in our partners' approved collaboration products. Cost of product sales also consists of the write-down of excess, dated and obsolete inventories and the write-off of inventories that do not meet certain product specifications, if any. Prior to bulk rHuPH20 having alternative future use, all costs related to the manufacturing were charged to research and development expenses in the periods such costs were incurred. There were no costs of bulk rHuPH20 product sales for the three months ended March 31, 2018 that were previously expensed as research and development. Of the bulk rHuPH20 that has alternative future use on hand as of March 31, 2018, approximately $2.7 million in manufacturing costs were previously recorded as research and development expenses. We expect to sell this inventory by the end of 2019.

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 product, 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 March 31, 2018, the Company has not implemented any new material planning items and believes that its disclosures in its financial statements as of December 31, 2017 are still reasonably accurate.

Net Loss Per Share

Basic loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Outstanding stock options, unvested RSAs, unvested RSUs and unvested PRSUs are considered common stock equivalents and are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. For the three months ended March 31, 2018 and 2017, approximately 14.6 million and 16.4 million shares, respectively, of outstanding stock options, unvested RSAs, unvested RSUs and unvested PRSUs were excluded from the calculation of diluted net loss per common share because a net loss was reported in each of these periods and therefore their effect was anti-dilutive.

Segment Information

We operate our business in one segment, which includes all activities related to the research, development and commercialization of our proprietary enzymes. This segment also includes revenues and expenses related to (i) research and development and bulk rHuPH20 manufacturing activities conducted under our collaborative agreements with third parties and (ii) product sales of Hylenex recombinant. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment. Our long-lived assets located in foreign countries had minimal book value as of March 31, 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. |
| 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. | 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. | January 1, 2018. | 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. |

| Standard | Description | Effective Date | Effect on the Financial Statements or Other Significant Matters |
|---|---|---|---|
| In February 2016, the FASB issued ASU 2016-02, Leases. | The new guidance requires lessees to recognize assets and liabilities for most leases and provides enhanced disclosures. | January 1, 2019. Early adoption is permitted. | We plan to implement the guidance on January 1, 2019. We are currently evaluating the effect the updated standard will have on our consolidated financial statements and related disclosures. We anticipate recognition of additional assets and corresponding liabilities related to our leases on our consolidated balance sheet. This standard will have a material impact on our consolidated financial statements. |

3. Fair Value Measurement

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

| | March 31, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Asset-backed securities | $8,957 | $ — | $ (9) | $8,948 |
| Corporate debt securities | 121,341 | — | (478) | 120,863 |
| U.S. Treasury securities | 99,265 | — | (367) | 98,898 |
| Commercial paper | 106,973 | — | — | 106,973 |
| | $336,536 | $ — | $ (854) | $335,682 |

| | 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 March 31, 2018, 30 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 March 31, 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.

Contractual maturities of available-for-sale debt securities are as follows (in thousands):

| | March 31, 2018 Estimated Fair Value |
|---|---|
| Due within one year | $301,637 |
| After one but within five years | 34,045 |
| | $335,682 |

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):

| | March 31, 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 | $75,621 | $— | $75,621 | $142,091 | $— | $142,091 |
| Commercial paper | — | 8,000 | 8,000 | — | 15,700 | 15,700 |
| Available-for-sale marketable securities: | | | | | | |
| Asset-backed securities | — | 8,948 | 8,948 | — | — | — |
| Corporate debt securities | — | 120,863 | 120,863 | — | 117,192 | 117,192 |
| U.S. Treasury securities | 98,898 | — | 98,898 | 66,400 | — | 66,400 |
| Commercial paper | — | 106,973 | 106,973 | — | 116,882 | 116,882 |
| | $174,519 | $244,784 | $419,303 | $208,491 | $249,774 | $458,265 |

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

4. Revenue

Our disaggregated revenues were as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Royalties | $20,944 | $13,982 |
| | | |
| Product sales, net | | |
| Sales of bulk rHuPH20 | $3,378 | $8,229 |
| Sales of Hylenex | 3,423 | 3,205 |
| Total product sales, net | 6,801 | 11,434 |
| | | |
| Revenues under collaborative agreements: | | |
| Upfront license fees | 1,336 | 351 |
| Event-based development milestones and other fees | 1,000 | 672 |
| Research and development services | 791 | 3,129 |
| Total revenues under collaborative agreements | 3,127 | 4,152 |
| | | |
| Total revenue | $30,872 | $29,568 |

During the three months ended March 31, 2018 we recognized revenue related to licenses granted to collaboration partners in prior periods in the amount of $21.9 million. This amount represents royalties earned in the current period, in addition to the achievement of a development milestone of $1.0 million by Roche. We also recognized revenue of $1.8 million that had been included in deferred revenues at December 31, 2017. We did not recognize any adjustments to reduce sales reserves and allowances liability related to Hylenex recombinant sales in prior periods.

Revenue recognized during the three months ended March 31, 2017 was determined in accordance with the accounting rules applicable prior to the adoption of ASC 606 on January 1, 2018.

Upon the adoption of ASC 606, we recognized an adjustment to increase our accounts receivable by $19.4 million, decrease deferred revenues by $51.8 million, and decrease accumulated deficit by $71.2 million. The impact of applying the provisions of ASC 606 in the three months ended March 31, 2018 was to increase revenues by $1.1 million. Under the previously existing authoritative accounting literature, at March 31, 2018 our accounts receivable would have been $20.9 million lower, and our deferred revenue$51.4 million higher, than the amounts reported in our condensed consolidated balance sheet. ASC 606 did not have an aggregate impact on our net cash used in operating activities, but resulted in offsetting changes in net loss and certain assets and liabilities within net cash used in operating activities in the condensed consolidated statement of cash flows.

Accounts receivable, net and deferred revenues (contract liabilities) from contracts with customers, including collaboration partners, consisted of the following (in thousands):

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Accounts receivable, net | $26,574 | $ 22,133 |
| Deferred revenues | 7,253 | 60,865 |

As of March 31, 2018, the amounts included in the transaction price of our contracts with customers, including collaboration partners, and allocated to goods and services not yet provided were $7.3 million. This amount has been collected and is reported

as deferred revenues. The timing of when these goods and services will be provided is controlled by our customers. Of the total deferred revenues, $5.0 million can be used by the customers at any time through 2022 and the remaining $2.3 million at any time through 2019.

There were no contract assets related to collaborative agreements recognized during the three months ended March 31, 2018. While we may become entitled to receive additional event-based development and regulatory milestones and other fees under our collaborative agreements, which relate to intellectual property licenses granted to collaboration partners in prior periods, no amounts were probable. The following table presents amounts under our collaborative agreements included in transaction price (i.e. cumulative amounts triggered or probable) as of March 31, 2018 (in thousands):

| | Upfront (1) | Development (2) | Sales (3) | Royalty | Total |
|---|---|---|---|---|---|
| Collaboration partner and agreement date: | | | | | |
| Roche (December 2006 and September 2017) | $70,000 | $ 25,000 | $22,000 | $176,943 | $293,943 |
| Baxalta (September 2007) | 10,000 | 3,000 | 9,000 | 18,409 | 40,409 |
| Pfizer (December 2012) | 14,500 | 2,000 | — | — | 16,500 |
| Janssen (December 2014) | 15,250 | 15,000 | — | — | 30,250 |
| AbbVie (June 2015) | 23,000 | 6,000 | — | — | 29,000 |
| Lilly (December 2015) | 33,000 | — | — | — | 33,000 |
| BMS (September 2017) | 105,000 | — | — | — | 105,000 |
| Alexion (December 2017) | 40,000 | — | — | — | 40,000 |

(1) Upfront and additional target selection fees

(2) Event-based development and regulatory milestone amounts and other fees

(3) Sales-based milestone amounts

Through March 31, 2018, our collaboration partners have completed development, obtained marketing authorization approvals for certain indications and commenced commercialization of the following products:

- Roche, for Herceptin SC in the European Union (“EU”) in August 2013; and MabThera SC in the EU in March 2014 and its equivalent RITUXAN HYCELA™ in the US in June 2017;
- Baxalta, for HYQVIA in the EU and in the US in May 2013.

The remaining targets and products are currently in the process of development by the collaboration partners.

5. Certain Balance Sheet Items

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Accounts receivable from product sales to collaborators | $2,881 | $ 18,475 |
| Accounts receivable from revenues under collaborative agreements | 1,296 | 2,142 |
| Accounts receivable from royalty payments | 20,944 | — |
| Accounts receivable from other product sales | 1,950 | 2,075 |
| Subtotal | 27,071 | 22,692 |
| Allowance for distribution fees and discounts | (497) | (559) |
| Total accounts receivable, net | $26,574 | $ 22,133 |

Inventories consisted of the following (in thousands):

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 357 | $ 377 |
| Work-in-process | 2,641 | 2,131 |
| Finished goods | 1,395 | 2,638 |
| Total inventories | $ 4,393 | $ 5,146 |

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Prepaid manufacturing expenses | $ 9,085 | $ 2,337 |
| Prepaid research and development expenses | 7,488 | 7,793 |
| Other prepaid expenses | 2,150 | 2,585 |
| Other assets | 6,648 | 6,717 |
| Total prepaid expenses and other assets | 25,371 | 19,432 |
| Less long-term portion | 5,562 | 5,553 |
| Total prepaid expenses and other assets, current | $ 19,809 | $ 13,879 |

Prepaid manufacturing expenses include slot reservation fees and other amounts paid to contract manufacturing organizations. Such amounts are reclassified to work-in-process inventory once the manufacturing process has commenced.

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Research equipment | $ 11,132 | $ 10,970 |
| Computer and office equipment | 4,176 | 3,725 |
| Leasehold improvements | 4,085 | 2,715 |
| Subtotal | 19,393 | 17,410 |
| Accumulated depreciation and amortization | (14,456) | (13,890) |
| Property and equipment, net | $ 4,937 | $ 3,520 |

Depreciation and amortization expense totaled $0.6 million for the three months ended March 31, 2018 and 2017, respectively.

Accrued expenses consisted of the following (in thousands):

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Accrued outsourced research and development expenses | $ 17,863 | $ 18,757 |
| Accrued compensation and payroll taxes | 5,529 | 13,384 |
| Accrued outsourced manufacturing expenses | 2,933 | 2,504 |
| Other accrued expenses | 6,201 | 5,396 |
| Total accrued expenses | 32,526 | 40,041 |
| Less long-term portion | 637 | 440 |
| Total accrued expenses, current | $ 31,889 | $ 39,601 |

Deferred revenue consisted of the following (in thousands):

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Collaborative agreements | | |
| License fees and event-based payments: | | |
| Roche | $ — | $ 39,379 |
| Other | 2,265 | 15,999 |
| Total license fees and event-based payments | 2,265 | 55,378 |
| Product sales | 4,988 | 5,487 |
| Total deferred revenue | 7,253 | 60,865 |
| Less current portion | 1,247 | 6,568 |
| Deferred revenue, net of current portion | $ 6,006 | $ 54,297 |

6. Long-Term Debt, Net

Royalty-backed Loan

In January 2016, through our wholly-owned subsidiary Halozyme Royalty LLC (“Halozyme Royalty”), we received a $150 million loan (the “Royalty-backed Loan”) pursuant to a credit agreement (the “Credit Agreement”) with BioPharma Credit Investments IV Sub, LP and Athyrium Opportunities II Acquisition LP (the “Royalty-backed Lenders”). Under the terms of the Credit Agreement, Halozyme Therapeutics, Inc. transferred to Halozyme Royalty the right to receive royalty payments from the commercial sales of ENHANZE products owed under the Roche Collaboration and Baxalta Collaboration (“Collaboration Agreements”). The royalty payments from the Collaboration Agreements will be used to repay the principal and interest on the loan (the “Royalty Payments”). The Royalty-backed Loan bears interest at a per annum rate of 8.75% plus the three-month LIBOR rate. The three-month LIBOR rate is subject to a floor of 0.7% and a cap of 1.5%. The interest rate as of March 31, 2018 was 10.25%.

The Credit Agreement provides that none of the Royalty Payments were required to be applied to the Royalty-backed Loan prior to January 1, 2017, 50% of the Royalty Payments are required to be applied to the Royalty-backed Loan between January 1, 2017 and January 1, 2018 and thereafter all Royalty Payments must be applied to the Royalty-backed Loan. However, the amounts available to repay the Royalty-backed Loan are subject to caps of $13.75 million per quarter in 2017, $18.75 million per quarter in 2018, $21.25 million per quarter in 2019 and $22.5 million per quarter in 2020 and thereafter. Amounts available to repay the Royalty-backed Loan will be applied first to pay interest and second to repay principal on the Royalty-backed Loan. Any accrued interest that is not paid on any applicable quarterly payment date, as defined, will be capitalized and added to the principal balance

of the Royalty-backed Loan on such date. Halozyme Royalty will be entitled to receive and distribute to Halozyme any Royalty Payments that are not required to be applied to the Royalty-backed Loan or which are in excess of the foregoing caps.

Because the repayment of the term loan is contingent upon the level of Royalty Payments received, the repayment term may be shortened or extended depending on the actual level of Royalty Payments. The final maturity date of the Royalty-backed Loan will be the earlier of (i) the date when principal and interest is paid in full, (ii) the termination of Halozyme Royalty's right to receive royalties under the Collaboration Agreements, and (iii) December 31, 2050. Currently, we estimate that the loan will be repaid in the first quarter of 2020. This estimate could be adversely affected and the repayment period could be extended if future royalty amounts are less than currently expected. Under the terms of the Credit Agreement, at any time after January 1, 2019, Halozyme Royalty may, subject to certain limitations, prepay the outstanding principal of the Royalty-backed Loan in whole or in part, at a price equal to 105% of the outstanding principal on the Royalty-backed Loan, plus accrued but unpaid interest. The Royalty-backed Loan constitutes an obligation of Halozyme Royalty, and is non-recourse to Halozyme. Halozyme Royalty retains its right to the Royalty Payments following repayment of the loan.

As of March 31, 2018, we were in compliance with all covenants under the Royalty-backed Loan and there was no material adverse change in our business, operations or financial condition.

We began making principal and interest payments against the Royalty-backed Loan in the first quarter of 2017 and therefore had no capitalized interest in the three months ended March 31, 2018. In addition, we recorded accrued interest, which is included in accrued expenses, of $0.6 million and $0.7 million as of March 31, 2018 and December 31, 2017, respectively

In connection with the Royalty-backed Loan, we paid the Royalty-backed Lenders a fee of $1.5 million and incurred additional debt issuance costs totaling $0.4 million, which includes expenses that we paid on behalf of the Royalty-backed Lenders and expenses incurred directly by us. Debt issuance costs and the lender fee have been netted against the debt as of March 31, 2018, and are being amortized over the estimated term of the debt using the effective interest method. For the three months ended March 31, 2018 and 2017, the Company recognized interest expense, including amortization of the debt discount, related to the Royalty-backed Loan of $3.9 million and $4.0 million, respectively. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs requires that we make estimates that could impact the short- and long-term classification of these costs, as well as the period over which these costs will be amortized. The outstanding balance of the Royalty-backed Loan as of March 31, 2018 was $131.8 million, net of unamortized debt discount of $0.6 million.

Oxford and SVB Loan and Security Agreement

In June 2016, we entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") (collectively, the "Lenders"), providing a senior secured loan facility of up to an aggregate principal amount of $70.0 million, comprising a $55.0 million draw in June 2016 and an additional $15.0 million tranche, which we had the option to draw during the second quarter of 2017 and did not exercise. The initial proceeds carry an interest rate of 8.25% and were partially used to pay the outstanding principal and final payment of $4.25 million owed on a previous loan agreement with the Lenders. The remaining proceeds are being used for working capital and general business requirements. The repayment schedule provides for interest only payments for the first 18 months, followed by consecutive equal monthly payments of principal and interest in arrears through the maturity date of January 1, 2021. The Loan Agreement provides for a final payment equal to 5.50% of the initial $55.0 million principal amount. The final payment is due when the Loan Agreement becomes due or upon the prepayment of the facility. We have the option to prepay the outstanding balance of the Loan Agreement in full, subject to a prepayment fee of 2% in the first year and 1% in the second year of the Loan Agreement.

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

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

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

As of March 31, 2018, we were in compliance with all covenants under the Loan Agreement and there was no material adverse change in our business, operations or financial condition.

Interest expense, including amortization of the debt discount, related to the Loan Agreement totaled $1.4 million for the three months ended March 31, 2018 and 2017, respectively. Accrued interest, which is included in accrued expenses, was $0.4 million as of March 31, 2018 and December 31, 2017, respectively. The outstanding term loan balance was $53.4 million as of March 31, 2018, inclusive of $1.6 million of accretion of the final payment and net of unamortized debt discount related to offering costs of $0.4 million.

7. Share-based Compensation

Total share-based compensation expense related to share-based awards was comprised of the following (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Research and development | $3,914 | $3,274 |
| Selling, general and administrative | 4,425 | 4,041 |
| Share-based compensation expense | $8,339 | $7,315 |

Share-based compensation expense by type of share-based award (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Stock options | $4,559 | $4,749 |
| RSAs, RSUs and PRSUs | 3,780 | 2,566 |
| | $8,339 | $7,315 |

We granted stock options to purchase approximately 1.6 million and 2.2 million shares of common stock during the three months ended March 31, 2018 and 2017, respectively. The exercise price of stock options granted is equal to the closing price of the common stock on the date of grant. The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model ("Black-Scholes model"). Expected volatility is based on historical volatility of our common stock. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The dividend yield assumption is based on the expectation of no future dividend payments. The assumptions used in the Black-Scholes model were as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Expected volatility | 62.61-70.06% | 71.0-71.7% |
| Average expected term (in years) | 5.5 | 5.6 |
| Risk-free interest rate | 2.25-2.65% | 1.92-1.94% |
| Expected dividend yield | — | — |

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

| | March 31, 2018 | |
|---|---|---|
| | Unrecognized Expense | Remaining Weighted-Average Recognition Period (years) |
| Stock options | $46,233 | 2.58 |
| RSAs | $3,434 | 1.33 |
| RSUs | $36,667 | 2.70 |

8. Stockholders' Equity (Deficit)

In May 2017, we completed an underwritten public offering pursuant to which we sold 11.5 million shares of common stock, including 1.5 million shares sold pursuant to the full exercise of an option to purchase additional shares granted to the underwriters. All of the shares were offered at a public offering price of $12.50 per share, generating $134.9 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses. We intend to use the net proceeds from this offering to fund continued development of our PEGPH20 oncology program and for other general corporate purposes.

During the three months ended March 31, 2018 and 2017, we issued an aggregate of 705,856 and 74,522 shares of common stock, respectively, in connection with the exercises of stock options at a weighted average exercise price of $10.47 and $7.78 per share, respectively, for net proceeds of approximately $7.4 million and $0.6 million, respectively. For the three months ended March 31, 2018 and 2017, we issued 410,306 and 252,305 shares of common stock, respectively, upon vesting of certain RSUs for which the RSU holders surrendered 129,465 and 79,499 RSUs, respectively, to pay for minimum withholding taxes totaling approximately $2.4 million and $1.7 million, respectively. In addition, we did not cancel any shares of common stock in connection with the grants of RSAs during the three months ended March 31, 2018 and 2017, respectively. Stock options and unvested restricted units totaling approximately 14.1 million shares and 13.0 million shares of our common stock were outstanding as of March 31, 2018 and December 31, 2017, respectively.

9. Commitments and Contingencies

From time to time, we may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of our business. Any of these claims could subject us to costly legal expenses and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. We currently are not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our consolidated results of operations or financial position.

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

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

The following information should be read in conjunction with the interim unaudited condensed consolidated financial statements and Notes thereto included in Item 1 of this Quarterly Report on Form 10-Q, as well as the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2017, included in our Annual Report on Form 10-K for the year ended December 31, 2017. Past financial or operating performance is not necessarily a reliable indicator of future performance, and our historical performance should not be used to anticipate results or future period trends.

This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this report other than statements of historical fact are, or may be deemed to be, forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "ma "will," "would," "should," "continue," "potential," "likely," "opportunity," "project" and similar expressions or variations of su words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this report. Additionally, statements concerning future matters such as the anticipated timing and scope of planned clinical trials, the development or regulatory approval of new products, enhancements of existing products or technologies, timing and success of the launch of new products by us or by our collaborators, third party performance under key collaboration agreements, revenue, expense and cash burn levels and expected trends, expected repayment of the Royalty-backed Loan and trends and other statements regarding matters that are not historical are forward-looking statements. Such statements reflect management's current forecast of certain aspects of our future, are based on currently available operating, financial and competitive information and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially from those anticipated or implied in our forward-looking statements due to a number of factors including, but not limited to, those set forth below under the section entitled "Risks Factors" and elsewhere in this Quarterly Report on Form 10-Q and our most recent Annual Report on Form 10-K. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Quarterly Report.

Overview

Halozyme Therapeutics, Inc. is a biotechnology company focused on developing and commercializing novel oncology therapies. 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. Our proprietary development pipeline consists primarily of pre-clinical and clinical stage product candidates in oncology. Our lead oncology program is PEGPH20 (PEGylated recombinant human hyaluronidase), 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 higher pressure in the tumor, reducing blood flow into the tumor and with that, reduced access of cancer therapies 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 HALAVEN® (eribulin) in patients treated with up to two lines of prior therapy for HER2-negative metastatic breast cancer, 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).

We refer to the application of rHuPH20 to facilitate the delivery of other drugs or fluids as our ENHANZE® Technology. 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 first quarter of 2018 and recent highlights include:

- In January 2018, Roche initiated a Phase 1 study for an unnamed target with ENHANZE Technology, triggering a $1.0 million milestone payment.
- In January 2018, the Phase 1b portion of the study of HALAVEN (eribulin) with PEGPH20 in HER2-negative metastatic breast cancer closed enrollment. As a result of an Eisai portfolio decision, no further clinical development is planned on the Phase 2 portion of the study. Data analysis is ongoing and a submission of the results of this study to a scientific forum is expected in the second half of 2018.

Product and Product Candidates

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

Proprietary Pipeline

Hylenex Recombinant (hyaluronidase human injection)

Hylenex recombinant is a formulation of rHuPH20 that has received U.S. Food and Drug Administration (FDA) approval to facilitate subcutaneous fluid administration for achieving hydration, to increase the dispersion and absorption of other injected drugs and, in subcutaneous urography, to improve resorption of radiopaque agents. Hylenex recombinant is currently the number one prescribed branded hyaluronidase.

PEGPH20

We are developing PEGPH20 in combination with currently approved cancer therapies as a candidate for the systemic treatment of tumors that accumulate HA. 'PEG' refers to the attachment of polyethylene glycol to rHuPH20, thereby creating PEGPH20. One of the novel properties of PEGPH20 is that it lasts for an extended duration in the bloodstream and, therefore, can be administered systemically to maintain its therapeutic effect to treat disease. Cancer malignancies, including pancreatic, lung, breast, gastric, and biliary tract cancers can accumulate high levels of HA and therefore we believe that PEGPH20 has the potential to help patients with these types of cancer when used with certain currently approved cancer therapies. Among solid tumors, PDA has been reported to be associated with the highest frequency of HA accumulation. There are approximately 65,000 annual diagnoses of PDA in the United States and the European Union, and we estimate that 35-40% have high levels of HA.

The pathologic accumulation of HA, along with other matrix components, creates a unique microenvironment for the growth of tumor cells compared to normal cells. We believe that degrading the HA component of the tumor microenvironment with PEGPH20 remodels the tumor microenvironment, resulting in tumor growth inhibition in animal models. Removal of HA from the tumor microenvironment results in expansion of previously constricted blood vessels allowing increased blood flow, potentially increasing the access of activated immune cells and factors in the blood into the tumor microenvironment. If PEGPH20 is

administered in conjunction with other anti-cancer therapies, the increase in blood flow may allow anti-cancer therapies to have greater access to the tumor, which may enhance the treatment effect of therapeutic modalities like chemotherapies, monoclonal antibodies and other agents.

We are developing PEGPH20 as a targeted therapy, for patients who have tumors with high levels of HA. We have a collaboration with Ventana Medical Systems Inc. (Ventana), a member of the Roche Group, to develop, and for Ventana to ultimately commercialize, a companion diagnostic assay for use with PEGPH20. The companion diagnostic assay is being used to identify high levels of HA in tumor biopsies, and may be the first diagnostic to target tumor-associated HA and possibly the first companion diagnostic assay in pancreatic cancer.

Pancreatic cancer indications:

HALO 109-201:

In January 2015, we presented the final results from HALO 109-201, a multi-center, international open label dose escalation Phase 1b clinical study of PEGPH20 in combination with gemcitabine for the treatment of patients with stage IV PDA at the 2015 Gastrointestinal Cancers Symposium (also known as ASCO-GI meeting). This study enrolled 28 patients with previously untreated stage IV PDA. Patients were treated with one of three doses of PEGPH20 (1.0, 1.6 and 3.0 μg/kg twice weekly for four weeks, then weekly thereafter) in combination with gemcitabine 1000 mg/m2 administered intravenously. In this study, the confirmed overall response rate (complete response + partial response confirmed on a second scan as assessed by an independent radiology review) was 29 percent (7 of 24 patients) for those treated at therapeutic dose levels of PEGPH20 (1.6 and 3.0 μg/kg). Median progression-free survival (PFS) was 154 days (95% CI, 50-166) in the efficacy-evaluable population (n = 24). Among efficacy-evaluable patients with baseline tumor HA staining (n = 17), the median PFS in patients with high baseline tumor HA staining (6/17 patients) was substantially longer, 219 days, than in the patients with low baseline tumor HA staining (11/17 patients), 108 days. Median overall survival (OS) was 200 days (95% CI, 123-370) in the efficacy-evaluable population (n = 24). Among efficacy-evaluable patients with baseline tumor HA staining (n = 17), the median OS in patients with high baseline tumor HA staining (6/17 patients) was substantially longer, 395 days, than in the patients with low baseline tumor HA staining (11/17 patients), 174 days. The most common treatment-emergent adverse events (occurring in ≥ 15% of patients) were peripheral edema, muscle spasms, thrombocytopenia, fatigue, myalgia, anemia, and nausea. Thromboembolic (TE) events were reported in 8 patients (28.6%) and musculoskeletal events were reported in 21 patients (75%) which were generally grade 1/2 in severity.

HALO 109-202:

In the second quarter of 2013, we initiated HALO 109-202 (HALO-202), a Phase 2 multicenter randomized clinical trial evaluating PEGPH20 as a first-line therapy for patients with stage IV PDA. The study was designed to enroll patients who would receive gemcitabine and nab-paclitaxel (ABRAXANE®) either with or without PEGPH20. The primary endpoint is to measure the improvement in PFS in patients receiving PEGPH20 plus gemcitabine and ABRAXANE (PAG arm) compared to those who are receiving gemcitabine and ABRAXANE alone (AG arm). In April 2014, after 146 patients had been enrolled, the trial was put on clinical hold by Halozyme and the FDA to assess a question raised by the Data Monitoring Committee regarding a possible difference in the TE events rate between the group of patients treated in the PAG arm versus the group of patients treated in the AG arm. This portion of the study and patients in this portion are now referred to as Stage 1. At the time of the clinical hold all patients remaining in the study continued on gemcitabine and ABRAXANE. In July 2014, HALO-202 was reinitiated (Stage 2) under a revised protocol, which excludes patients that are expected to be at a greater risk for TE events. The revised protocol provides for thromboembolism prophylaxis of all patients in both arms of the study with low molecular weight heparin, and adds evaluation of the TE events rate in Stage 2 PEGPH20-treated patients as a co-primary end point. Stage 2 of HALO-202 enrolled an additional 133 patients, to add to the 146 patients already in the clinical trial, with a 2:1 randomization for the PAG arm compared to the AG arm.

In March 2016, our partner Ventana received approval for an investigational device exemption (IDE) application from the FDA for our companion diagnostic test to enable patient selection in our Phase 3 Study HALO-301 of PEGPH20 in HA-High patients. Based on the cutpoint for the Ventana diagnostic, we expect approximately 35 to 40 percent of stage IV PDA patients to

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have HA-High tumors, similar to the previously reported interim results from Stage 1 of Study HALO-202 using the Halozyme prototype assay.

In January 2017, we announced topline results from the combined analysis of Stage 1 and Stage 2, and Stage 2 alone, based on a December 2016 data cutoff. The combined analysis included 135 treated patients in Stage 1, of whom a total of 45 patients (24 in the PAG arm and 21 in the AG arm) were determined to have high HA, and 125 treated patients in Stage 2, of whom a total of 35 patients (24 in the PAG arm and 11 in the AG arm) were determined to have high HA. This analysis of secondary and exploratory endpoints was conducted using the Ventana companion diagnostic to prospectively identify high levels of HA. The key results showed in the combined Stage 1 and Stage 2 dataset:

- The primary endpoint of PFS in the efficacy evaluable population (total of 231 patients) was met with statistical significance with a median PFS of 6.0 months in the PAG arm compared to 5.3 months in the AG arm, hazard ratio (HR) with a 95% confidence interval (CI): 0.73 (0.53, 1.00); p=0.048;
- The secondary endpoint of PFS in the HA-High intent to treat population (total of 84 HA-High patients) was met with statistical significance with a median PFS of 9.2 months in the PAG arm compared to 5.2 months in the AG arm, HR 0.51 (95% CI: 0.26, 1.00); p=0.048;
- The exploratory analysis of median OS was 11.5 months vs. 8.5 months in the PAG vs. AG arms, respectively. Factors potentially having an impact on these results include less aggressive disease among patients in the AG arm within the Stage 1 patient population, and 9 of the 24 patients in the PAG arm (approximately 40 percent) discontinued PEGPH20 treatment at the time of the clinical hold, resulting in many patients receiving AG alone in both arms.

In the Stage 2 cohort population, in a total of 35 HA-High patients, the key results showed:

- Median PFS was 8.6 months in the PAG arm compared to 4.5 months in the AG arm, hazard ratio of 0.63 (95% CI: 0.21, 1.93);
- Median overall survival (OS) was 11.7 months in the PAG arm compared to 7.8 months in the AG arm, hazard ratio of 0.52 (95% CI: 0.22, 1.23);
- The primary safety endpoint of decreasing the rate of TE events in Stage 2 was also met with the rate of TE events reducing from 43 percent to 10 percent in the PAG arm and from 25 percent to 6 percent in the AG arm, following a protocol amendment that excluded patients at high risk of TE events and with the introduction of prophylaxis with low molecular weight heparin (enoxaparin) in Stage 2 of the study with the current 1mg/kg/day dose of enoxaparin prophylaxis given in both treatment arms of the study.

In June 2017, results from Study HALO-202 were presented at the ESMO World Congress of Gastrointestinal Cancer and the Annual Meeting of the American Society of Clinical Oncology (ASCO). HALO-202 is an ongoing study with an open database, and has completed enrollment. We continue to collect and receive data on both Stage 1 and Stage 2 patients. When the database is considered complete and locked, an updated analysis and Final Study Report will be generated.

HALO 109-301:

In March 2015, we met with the FDA to discuss both the interim efficacy and safety data from HALO-202, which included the potential risk profile including TE event rate. Based on the feedback from that meeting, we proceeded with HALO 109-301 (HALO-301), a Phase 3 clinical study of PEGPH20 in patients with stage IV PDA, using a design allowing for potential marketing application based on PFS (accelerated approval pathway) or OS. The study will enroll patients whose tumors accumulate high levels of HA measured using the Ventana companion diagnostic test. The FDA provided feedback on the current companion diagnostic approach and confirmed that an approved IDE is required for the Phase 3 study.

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