HALOZYME THERAPEUTICS INC
Form 10-Q
November 08, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

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 and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 103,691,643 as of November 2, 2011.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2011 (Unaudited)	December 31, 2010 (Note)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,329,358	$ 83,255,848
Accounts receivable	6,237,904	2,328,268
Inventory	103,443	193,422
Prepaid expenses and other assets	4,297,814	3,720,896
Total current assets	76,968,519	89,498,434
Property and equipment, net	1,274,753	1,846,899
Total Assets	$ 78,243,272	$ 91,345,333
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,219,905	$ 3,820,368
Accrued expenses	8,864,705	8,605,569
Deferred revenue	3,707,795	2,917,129
Total current liabilities	13,792,405	15,343,066
Deferred revenue, net of current portion	36,667,445	55,176,422
Deferred rent, net of current portion	728,259	474,389
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock $0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding	-	-
Common stock $0.001 par value; 150,000,000 shares authorized; 103,647,930 and 100,580,849 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	103,648	100,581
Additional paid-in capital	253,557,547	245,502,670
Accumulated deficit	(226,606,032)	(225,251,795)
Total stockholders equity	27,055,163	20,351,456
Total Liabilities and Stockholders Equity	$ 78,243,272	$ 91,345,333

Note: The condensed consolidated balance sheet at December 31, 2010 has been derived from audited financial statements at that date. It does not include, however, all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product sales	$ 1,156,903	$ 98,100	$ 1,487,822	$ 695,440
Revenues under collaborative agreements	21,785,525	3,298,407	52,187,447	9,356,151
Total revenues	22,942,428	3,396,507	53,675,269	10,051,591
Operating expenses:				
Cost of product sales	11,723	7,214	201,675	96,413
Research and development	13,514,352	12,448,865	42,647,265	35,840,475
Selling, general and administrative	4,263,520	3,374,069	12,237,152	10,488,568
Total operating expenses	17,789,595	15,830,148	55,086,092	46,425,456
Operating income (loss)	5,152,833	(12,433,641)	(1,410,823)	(36,373,865)
Interest and other income, net	12,360	24,065	56,586	25,889
Net income (loss)	$ 5,165,193	$ (12,409,576)	$ (1,354,237)	$ (36,347,976)
Net income (loss) per share:				
Basic	$ 0.05	$ (0.13)	$ (0.01)	$ (0.39)
Diluted	$ 0.05	$ (0.13)	$ (0.01)	$ (0.39)
Shares used in computing net income (loss) per share:				
Basic	103,223,352	93,626,893	102,282,904	92,342,665
Diluted	105,009,189	93,626,893	102,282,904	92,342,665

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended September 30,	
	2011	**2010**
Operating activities:		
Net loss	$ (1,354,237)	$ (36,347,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,916,329	3,745,976
Depreciation and amortization	851,613	1,164,162
(Gain) loss on disposal of equipment	(992)	8,431
Changes in operating assets and liabilities:		
Accounts receivable	(3,909,636)	1,621,833
Inventory	89,979	82,971
Prepaid expenses and other assets	(576,918)	(3,317,779)
Accounts payable and accrued expenses	(2,183,864)	(2,184,007)
Deferred rent	89,453	(226,699)
Deferred revenue	(17,718,311)	(2,557,349)
Net cash used in operating activities	(20,796,584)	(38,010,437)
Investing activities:		
Purchases of property and equipment	(271,521)	(315,807)
Net cash used in investing activities	(271,521)	(315,807)
Financing activities:		
Proceeds from exercises of stock options	4,141,615	737,267
Proceeds from issuance of common stock, net	-	59,965,059
Net cash provided by financing activities	4,141,615	60,702,326
Net (decrease) increase in cash and cash equivalents	(16,926,490)	22,376,082
Cash and cash equivalents at beginning of period	83,255,848	67,464,506
Cash and cash equivalents at end of period	$ 66,329,358	$ 89,840,588
Supplemental disclosure of non-cash investing and financing activities:		
Accounts payable for purchases of property and equipment	$ 6,954	$ 109,705

See accompanying notes to condensed consolidated financial statements.

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HALOZYME THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization and Business

Halozyme Therapeutics, Inc. (Halozyme or the Company) is a biopharmaceutical company dedicated to the development and commercialization of recombinant human enzymes that either transiently modify tissue under the skin to facilitate injection of other therapies or correct diseased tissue structures for clinical benefit. The Company s existing products and its products under development are based primarily on intellectual property covering the family of human enzymes known as hyaluronidases.

The Company s operations to date have involved: (i) organizing and staffing its operating subsidiary, Halozyme, Inc.; (ii) acquiring, developing and securing its technology; (iii) undertaking product development for its existing products and a limited number of product candidates; and (iv) supporting the development of partnered product candidates. The Company currently has multiple proprietary programs in various stages of research and development. In addition, the Company has collaborative partnerships with F. Hoffmann-La Roche, Ltd. and Hoffmann-La Roche, Inc. (Roche), Baxter Healthcare Corporation (Baxter), ViroPharma Incorporated (ViroPharma) and Intrexon Corporation (Intrexon) to apply th Company s proprietary EnhanzTechnology to the partners biological therapeutic compounds. The Company also had a partnership with Baxter, under which Baxter had worldwide marketing rights for the Company s marketed product, *Hylenex*® recombinant (hyaluronidase human injection), (the Hylenex Partnership). *Hylenex* recombinant is a human recombinant formulation of hyaluronidase that has received approval from the U.S. Food and Drug Administration (FDA) to facilitate subcutaneous fluid administration for achieving hydration; to increase the dispersion and absorption of other injected drugs; and in subcutaneous urography for improving resorption of radiopaque agents. In January 2011, the Company and Baxter mutually agreed to terminate the Hylenex Partnership. The Company s technology is also being used in ICSI Cumulase®, a third party s marketed product used for *in vitro* fertilization (IVF). Currently, the Company has received only limited revenue from the sales of active pharmaceutical ingredients (API) to the third party that produces ICSI Cumulase, in addition to other revenues from its collaborative partnerships.

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 the Company s Annual Report on Form 10-K for the year ended December 31, 2010, filed with the SEC on March 11, 2011. The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented, with such adjustments consisting only of normal recurring adjustments. Operating results for interim periods are not necessarily indicative of the operating results for an entire fiscal year.

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

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the Company s consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management

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believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management s estimates.

Adoption of Recent Accounting Pronouncements

Effective January 1, 2011, the Company adopted on a prospective basis Financial Accounting Standards Board s (FASB) Accounting Standards Update (ASU) No. 2010-17, Revenue Recognition (Topic 605): *Milestone Method of Revenue Recognition* (Milestone Method). ASU No. 2010-17 states that the Milestone Method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Milestone Method is not required and is not the only acceptable method of revenue recognition for milestone payments. The adoption of ASU No. 2010-17 did not have a material impact on the Company s consolidated financial position or results of operations.

Effective January 1, 2011, the Company adopted on a prospective basis FASB s ASU No. 2009-13, Revenue Recognition (Topic 605): *Multiple-Deliverable Revenue Arrangements*. ASU No. 2009-13 requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. ASU No. 2009-13 eliminates the use of the residual method of allocation and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue for an arrangement with multiple deliverables subject to Accounting Standards Code 605-25. The Company accounted for the collaborative arrangements with ViroPharma and Intrexon under the provisions of ASU No. 2009-13, which resulted in revenue recognition patterns that are materially different from those recognized for the Company s existing multiple-element arrangements.

Pending Adoption of Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income*. In ASU No. 2011-05, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in ASU No. 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company does not expect the adoption of ASU No. 2011-05 to have a material impact on its consolidated financial position or results of operations.

Revenue Recognition

The Company generates revenues from product sales and collaborative agreements. The Company recognizes revenues in accordance with the authoritative guidance for revenue recognition. The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller s price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured.

Product Sales Revenue from the sales of API for ICSI Cumulase is recognized when the transfer of ownership occurs, which is upon shipment to the Company s distributor. The Company is obligated to accept returns for product that does not meet product specifications. Historically, the Company has not had any product returns as a result of not meeting product specifications.

Prior to the termination of the Hylenex Partnership with Baxter in January 2011, the Company supplied Baxter with API for *Hylenex* recombinant at its fully burdened cost plus a margin. Baxter filled and finished *Hylenex* recombinant and held it for subsequent distribution, at which time the Company ensured it met product specifications and released it as available for sale. Because of the Company s continued involvement in the

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development and production process of *Hylenex* recombinant, the earnings process was not considered to be complete. Accordingly, the Company deferred the revenue and related product costs on the API for *Hylenex* recombinant until the product was filled, finished, packaged and released. Baxter could only return the API for *Hylenex* recombinant to the Company if it did not conform to the specified criteria set forth in the Hylenex Partnership or upon termination of such agreement. In addition, the Company received product-based payments upon the sale of *Hylenex* recombinant by Baxter, in accordance with the terms of the Hylenex Partnership. Product-based revenues were recognized as the Company earned such revenues based on Baxter s shipments of *Hylenex* recombinant to its distributors when such amounts could be reasonably estimated. Effective January 7, 2011, the Company and Baxter mutually agreed to terminate the Hylenex Partnership and the associated agreements. See Note 7, *Deferred Revenue*, for further discussion.

Revenues under Collaborative Agreements The Company entered into license and collaboration agreements under which the collaborative partners obtained worldwide exclusive rights for the use of the Company s proprietary recombinant human PH20 enzyme (rHuPH20) in the development and commercialization of the collaborators biologic compounds. The collaborative agreements contain multiple elements including nonrefundable payments at the inception of the arrangement, license fees, exclusivity fees, payments based on achievement of specific milestones designated in the collaborative agreements, reimbursements of research and development services, payments for supply of rHuPH20 API for the collaborator and/or royalties on sales of products resulting from collaborative agreements. The Company analyzes each element of its collaborative agreements and considers a variety of factors in determining the appropriate method of revenue recognition of each element.

Prior to the adoption of ASU No. 2009-13 on January 1, 2011, in order for a delivered item to be accounted for separately from other deliverables in a multiple-element arrangement, the following three criteria had to be met: (i) the delivered item had standalone value to the customer, (ii) there was objective and reliable evidence of fair value of the undelivered items and (iii) if the arrangement included a general right of return relative to the delivered item, delivery or performance of the undelivered items was considered probable and substantially in the control of the vendor. For the collaborative agreements entered into prior to January 1, 2011, there was no objective and reliable evidence of fair value of the undelivered items. Thus, the delivered licenses did not meet all of the required criteria to be accounted for separately from undelivered items. Therefore, the Company recognizes revenue on nonrefundable upfront payments and lice COLSPAN=1 STYLE="text-align: center">June 5, 2014*

Paul Keglevic Director June 5, 2014*

William C. Repko Director June 5, 2014

*Signed by Robert T. Ladd pursuant to a power of attorney signed by each individual on December 4, 2013.