

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 7, 2019

**HALOZYME THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-32335

(Commission File Number)

88-0488686

(I.R.S. Employer Identification No.)

11388 Sorrento Valley Road, San Diego, California

(Address of principal executive offices)

92121

(Zip Code)

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

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	HALO	The Nasdaq Stock Market LLC

**Item 2.02 Results of Operations and Financial Condition.**

On May 7, 2019, Halozyme Therapeutics, Inc. issued a press release to report its financial results for the first quarter end March 31, 2019. A copy of the press release is attached as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	Press release dated May 7, 2019

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## HALOZYME REPORTS FIRST QUARTER 2019 RESULTS

*- Revenue of \$56.9 Million Compared to \$30.9 Million in Prior-year Period -*

*- ENHANZE<sup>®</sup> Partner Receives FDA Approval for Subcutaneous Formulation of Herceptin<sup>®</sup> -*

*- Positive Phase 3 Trial Results Announced for Subcutaneous Formulation of DARZALEX<sup>®</sup> -*

*- On Track for Pivotal Phase 3 Trial Results from HALO-301 in second half 2019 -*

**SAN DIEGO, May 7, 2019** - Halozyyme Therapeutics, Inc. (NASDAQ: HALO), a biotechnology company developing novel oncology and drug-delivery therapies, today reported financial results for the first quarter ended March 31, 2019 and provided an update on recent corporate activities.

“We enjoyed a strong start to 2019 as our first quarter included a new ENHANZE<sup>®</sup> collaboration with argenx, positive phase III data from Janssen’s COLUMBA study evaluating a subcutaneous formulation of DARZALEX<sup>®</sup>, and FDA approval of Herceptin Hylecta™,” said Dr. Helen Torley, president and chief executive officer. “Looking ahead in 2019, we expect this momentum to continue. On ENHANZE<sup>®</sup> we anticipate regulatory submissions by ENHANZE<sup>®</sup> partner Janssen for the subcutaneous formulation of DARZALEX<sup>®</sup>, a new phase 3 trial initiation by one of our ENHANZE<sup>®</sup> partners and multiple Phase 1 trial initiations. On PEGPH20, we project the announcement of topline results from our HALO-301 pivotal phase 3 trial in pancreas cancer in the second half of the year.”

### **First Quarter 2019 and Recent Highlights Include:**

- In February 2019, we announced that Genentech, a member of the Roche Group, received approval from the FDA for Herceptin Hylecta™, a co-formulation of trastuzumab and rHuPH20. Herceptin Hylecta™ is approved for the treatment of certain people with HER2-positive early breast cancer. Herceptin Hylecta™ is a ready-to-use formulation that can be administered in two to five minutes, compared to 30 to 90 minutes for intravenous trastuzumab. In April 2019, Roche made Herceptin Hylecta™ available in the U.S.
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- In February 2019, Janssen's development partner, Genmab, announced positive Phase 3 trial results from the COLUMBA study. The study evaluated subcutaneous DARZALEX<sup>®</sup> in comparison to DARZALEX<sup>®</sup> IV in patients with relapsed and refractory multiple myeloma. DARZALEX<sup>®</sup> SC, using ENHANZE<sup>®</sup> drug delivery technology, was found to be non-inferior to DARZALEX<sup>®</sup> IV with regard the co-primary endpoints of Overall Response Rate and Maximum Trough concentration on day 1 of the third treatment cycle. Additional data from this trial will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago at an oral presentation on Sunday, June 2, 2019.
- In February 2019, we entered into a collaboration agreement with argenx for the right to develop and commercialize one exclusive target, the human neonatal Fc receptor FcRn, which includes argenx's lead asset efgartigimod (ARGX-113), and an option to select two additional targets using our ENHANZE<sup>®</sup> technology for an upfront payment of \$30.0 million. We will receive payments of \$10.0 million per target for future target nominations and potential milestone payments of up to \$160.0 million per target, subject to the achievement of specific development, regulatory and sales-based milestones. We will receive mid-single digit royalties on sales of commercialized products.
- With regard to HALO-301, a Phase 3 study evaluating PEGPH20 in metastatic pancreas cancer, the company now expects to achieve the target number of overall survival (OS) events in the third quarter of 2019. The company plans to initiate the database lock process for final analysis after 330 OS events have been achieved with mature data. As a result, the company expects topline results will be available in the second half of 2019.

### **First Quarter 2019 Financial Highlights**

- Revenue for the first quarter was \$56.9 million compared to \$30.9 million for the first quarter of 2018. The year-over-year increase was primarily driven by \$30.0 million in upfront license fees for the argenx collaboration. Revenue for the quarter included \$18.0 million in royalties and \$8.4 million in product sales, which compared to \$20.9 million and \$6.8 million, respectively, in the prior year period. The decrease in royalties was mainly driven by lower sales of Herceptin<sup>®</sup> SC by Roche, partially offset by higher sales of RITUXAN HYCELA<sup>™</sup> in the U.S. by Roche.
  - Research and development expenses for the first quarter were \$31.3 million, compared to \$38.0 million for the first quarter of 2018. The decline in expenses was driven by reduced clinical trial activity due to the completion of enrollment in HALO-301.
  - Selling, general and administrative expenses for the first quarter were \$18.0 million, compared to \$13.6 million for the first quarter of 2018. The increase is related to an increase in personnel expenses, including stock based compensation as well as preparations for the potential commercial launch of PEGPH20.
  - Net income for the first quarter was \$1.8 million, or \$0.01 per share, compared to a net loss in the first quarter of 2018 of \$27.5 million, or \$0.19 per share.
  - Cash, cash equivalents and marketable securities were \$328.7 million at March 31, 2019, compared to \$354.5 million at December 31, 2018.
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## Financial Outlook for 2019

Halozyme reiterates its overall 2019 financial guidance while lowering the anticipated contribution from royalties and increasing the anticipated contribution from products sales related to API. For 2019, Halozyme now expects:

- Net revenue of \$205 million to \$215 million;
  - Revenue from royalties of \$72 million to \$74 million, with the decrease primarily attributable to the ongoing impact from biosimilars in Europe and updated expectations for the US launched products;
  - Product sales related to API increased to reflect additional customer orders;
- Operating expenses of \$265 million to \$275 million, or \$225 million to \$235 million excluding an expected increase in cost of goods sold;
- Operating cash burn of \$45 million to \$55 million;
- Debt repayment of approximately \$90 million, the company expects to pay off the remainder of the royalty-backed debt by the end of the first quarter of 2020;
- Year-end cash, cash equivalents and marketable securities balance of \$210 million to \$220 million.

This guidance continues to exclude revenue from any potential, new ENHANZE<sup>®</sup> global collaboration and licensing agreements.

## Webcast and Conference Call

Halozyme will webcast its Quarterly Update Conference Call for the first quarter of 2019 today, Tuesday, May 7, 2019 at 4:30 p.m. ET/1:30 p.m. PT. Dr. Torley will lead the call, which will be webcast live through the "Investors" section of Halozyme's corporate website and a replay will be available following the close of the call. To access the webcast and additional documents related to the call, please visit [halozyme.com](http://halozyme.com) approximately fifteen minutes prior to the call to register, download and install any necessary audio software. The call may also be accessed by dialing (866) 393-4306 (domestic callers) or (734) 385-2616 (international callers). A telephone replay will be available after the call by dialing (855) 859-2056 (domestic callers) or (404) 537-3406 (international callers) using replay ID number 3076769.

## About Halozyme

Halozyme Therapeutics is a biotechnology company focused on developing and commercializing novel oncology therapies that target the tumor microenvironment. Halozyme's lead proprietary program, investigational drug pegvorhyaluronidase alfa (PEGPH20), applies a unique approach to targeting solid tumors, allowing increased access of co-administered cancer drug therapies to the tumor in animal models. PEGPH20 is currently in development for the treatment of several cancers and has the potential to be used in combination with different types of cancer therapies. In addition to its proprietary product portfolio, Halozyme has established value-driving partnerships with leading pharmaceutical companies including Roche, Baxalta, Pfizer, Janssen, AbbVie, Lilly, Bristol-Myers Squibb, Alexion and argenx for its ENHANZE<sup>®</sup> drug delivery technology. Halozyme is headquartered in San Diego. For more information visit [www.halozyme.com](http://www.halozyme.com).

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## Safe Harbor Statement

In addition to historical information, the statements set forth above include forward-looking statements (including, without limitation, statements concerning the Company's future expectations and plans for future growth, revenue and milestone and other potential payments from collaboration partners, the development and commercialization of product candidates, including timing of clinical trial results announcements and future development and commercial activities of our collaboration partners, the potential benefits and attributes of such product candidates and expected financial outlook for 2019) that involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. The forward-looking statements are typically, but not always, identified through use of the words "believe," "enable," "may," "will," "could," "intends," "estimate," "anticipate," "plan," "predict," "probable," "potential," "possible," "should," "continue," and other words of similar meaning. Actual results could differ materially from the expectations contained in forward-looking statements as a result of several factors, including unexpected expenditures and costs, unexpected fluctuations or changes in revenues, including revenues from collaborators, unexpected results or delays in development of product candidates, including delays in development activities of our collaboration partners, and regulatory review, regulatory approval requirements, unexpected adverse events and competitive conditions. These and other factors that may result in differences are discussed in greater detail in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2019.

### Contact:

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**Halozyme Therapeutics, Inc.**  
**Condensed Consolidated Statements of Operations**  
(Unaudited)  
(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Royalties	\$ 17,953	\$ 20,944
Product sales, net	8,390	6,801
Revenues under collaborative agreements	30,606	3,127
Total revenues	<u>56,949</u>	<u>30,872</u>
Operating expenses:		
Cost of product sales	4,649	3,052
Research and development	31,328	37,976
Selling, general and administrative	18,006	13,556
Total operating expenses	<u>53,983</u>	<u>54,584</u>
Operating income (loss)	2,966	(23,712)
Other income (expense):		
Investment and other income, net	2,057	1,668
Interest expense	(3,205)	(5,230)
Net income (loss) before income taxes	1,818	(27,274)
Income tax expense	22	187
Net income (loss)	<u>\$ 1,796</u>	<u>\$ (27,461)</u>
Net income (loss) per share:		
Basic	\$ 0.01	\$ (0.19)
Diluted	<u>\$ 0.01</u>	<u>\$ (0.19)</u>
Shares used in computing net income (loss) per share:		
Basic	144,743	142,656
Diluted	<u>147,474</u>	<u>142,656</u>

**Halozyme Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**  
(Unaudited)  
(In thousands)

	March 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 60,595	\$ 57,936
Marketable securities, available-for-sale	268,122	296,590
Accounts receivable, net	28,164	30,005
Inventories	31,241	22,625
Prepaid expenses and other assets	20,914	20,693
Total current assets	<u>409,036</u>	<u>427,849</u>
Property and equipment, net	14,542	7,465
Prepaid expenses and other assets	5,031	4,434
Restricted cash	500	500
Total assets	<u>\$ 429,109</u>	<u>\$ 440,248</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,089	\$ 4,079
Accrued expenses	43,663	49,529
Deferred revenue, current portion	4,247	4,247
Current portion of long-term debt, net	86,663	91,506
Total current liabilities	<u>138,662</u>	<u>149,361</u>
Deferred revenue, net of current portion	4,509	5,008
Long-term debt, net	18,742	34,874
Other long-term liabilities	7,149	2,118
Stockholders' equity:		
Common stock	145	145
Additional paid-in capital	789,483	780,457
Accumulated other comprehensive income (loss)	61	(277)
Accumulated deficit	(529,642)	(531,438)
Total stockholders' equity	<u>260,047</u>	<u>248,887</u>
Total liabilities and stockholders' equity	<u>\$ 429,109</u>	<u>\$ 440,248</u>

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