

**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): August 6, 2019

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number 001-32335

Delaware

(State or other jurisdiction of incorporation or organization)

11388 Sorrento Valley Road

San Diego

California

(Address of principal executive offices)

88-0488686

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

92121

(Zip Code)

(858) 794-8889

(Registrant's telephone number, including area code)

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))

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

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

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.

Item 2.02 Results of Operations and Financial Condition.

On August 6, 2019 , Halozyme Therapeutics, Inc. issued a press release to report its financial results for the second quarter end June 30, 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>
99.1	Press release dated August 6, 2019



HALOZYME REPORTS SECOND QUARTER 2019 RESULTS

- Total Revenues Increase 11% to \$39.1 million Compared to \$35.2 million in Prior-year Period -

- ENHANZE[®] Partner Janssen Submits Regulatory Applications for Subcutaneous Formulation of DARZALEX[®] in the U.S. and EU -

- Pivotal Phase 3 Trial Results from HALO-301 Evaluating PEGPH20 in Metastatic Pancreas Cancer Expected by December 2019 -

SAN DIEGO, August 6, 2019 - Halozyyme Therapeutics, Inc. (NASDAQ: HALO), a biotechnology company developing novel oncology and drug-delivery therapies, today reported financial results for the second quarter ended June 30, 2019 and provided an update on recent corporate activities.

“We are very pleased with the strong progress in both pillars of our business in 2019,” said Dr. Helen Torley, president and chief executive officer. “ENHANZE[®] progress included Janssen recently submitting regulatory applications to the U.S. Food and Drug Administration and the European Medicines Agency, and our most recently announced partner, argenx, initiating its first phase 1 study utilizing the ENHANZE[®] drug delivery technology. In addition, we remain focused on PEGPH20, where our HALO-301 pivotal phase 3 trial in metastatic front-line pancreas cancer is on track for the announcement of topline results by December 2019.”

Second Quarter 2019 and Recent Highlights Include:

- In July 2019, ENHANZE[®] collaborator Janssen Biotech, Inc. (Janssen) submitted a Biologics License Application to the U.S. Food and Drug Administration and an extension application to the European Medicines Agency for the subcutaneous delivery of DARZALEX[®] (daratumumab) for patients with multiple myeloma. Janssen’s regulatory submissions followed the announcement and subsequent presentation of positive results from its phase 3 COLUMBA study at the American Society of Clinical Oncology Annual Meeting in June 2019. The COLUMBA study investigated subcutaneously administered DARZALEX[®] in comparison to intravenous DARZALEX[®] in patients with relapsed or refractory multiple myeloma.
 - In July 2019, argenx dosed the first subject in a phase 1 clinical trial evaluating the safety, pharmacokinetics and pharmacodynamics of efgartigimod (ARGX-113), using Halozyyme's proprietary ENHANZE[®] drug delivery technology, triggering a \$5 million payment to Halozyyme. Additionally, in May 2019, argenx nominated a second target to be studied using ENHANZE[®] technology, a human complement factor C2 associated with the product
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candidate ARGX-117, which is being developed to treat severe autoimmune diseases, triggering a \$10 million payment to Halozyme.

- In June 2019, the target number of 330 overall survival events in the HALO-301 clinical trial was reached. The company plans to conduct the final overall survival analysis upon data maturity which will occur when all patients enrolled in the study have been followed for at least 8.5 months. Accordingly, data maturity is projected to be achieved in mid-September 2019. Based on this timing of data maturity, the company expects to announce topline results for the HALO-301 clinical trial by December 2019.
- In June 2019, a Cooperative Research and Development Agreement (CRADA) was announced with the National Institute of Allergy and Infectious Diseases' Vaccine Research Center (VRC), part of the National Institute of Health, enabling the VRC's use of ENHANZE[®] technology to develop subcutaneous formulations of broadly neutralizing antibodies (bnAbs) against HIV for HIV treatment.

Second Quarter 2019 Financial Highlights

- Revenue for the second quarter was \$39.1 million compared to \$35.2 million for the second quarter of 2018. The year-over-year increase was primarily driven by higher ENHANZE[®] license payments. Revenue for the quarter included \$18.1 million in royalties and \$5.8 million in product sales, which compared to \$20.0 million and \$4.5 million, respectively, in the prior year period. The decrease in royalties was mainly driven by lower sales of Herceptin[®] SC by Roche, partially offset by higher sales of RITUXAN HYCELA[™] in the U.S. by Roche and higher sales of HyQvia by Takeda.
- Research and development expenses for the second quarter were \$33.9 million, compared to \$40.1 million for the second 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 second quarter were \$17.3 million, compared to \$14.4 million for the second quarter of 2018. The increase is related to an increase in personnel expenses as well as preparations for the potential commercial launch of PEGPH20.
- Net loss for the second quarter was \$14.6 million, or \$0.10 per share, compared to a net loss in the second quarter of 2018 of \$22.9 million, or \$0.16 per share.
- Cash, cash equivalents and marketable securities were \$287.5 million at June 30, 2019, compared to \$354.5 million at December 31, 2018.

Financial Outlook for 2019

Halozyme is updating its 2019 financial guidance ranges:

- Total revenues unchanged from prior guidance of \$205 million to \$215 million, including revenue from royalties of \$72 million to \$74 million;
 - Operating expenses of \$255 million to \$265 million, down from prior guidance of \$265 million to \$275 million, or operating expenses excluding cost of goods sold \$215 million to \$225;
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million, down from prior guidance of \$225 million to \$235 million

- Operating cash burn of \$40 million to \$50 million, down from prior guidance of \$45 million to \$55 million;
- Debt repayment of approximately \$90 million; the company now expects to pay off the remainder of the royalty-backed debt by the end of the second quarter of 2020;
- Year-end cash, cash equivalents and marketable securities balance of \$220 million to \$230 million, up from prior guidance of \$210 million to \$220 million.

This guidance continues to exclude revenue from any potential, new ENHANZE[®] global collaboration and licensing agreements.

Webcast and Conference Call

Halozyme will webcast its Quarterly Update Conference Call for the second quarter of 2019 today, Tuesday, August 6, 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 approximately fifteen minutes prior to the call to register, download and install any necessary audio software. The call may also be accessed by dialing (877) 824-0907 (domestic callers) or (647) 689-5655 (international callers). A telephone replay will be available after the call by dialing (800) 585-8367 (domestic callers) or (416) 621-4642 (international callers) using replay ID number 5549627.

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 pegvorhialuronidase 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[®] drug delivery technology. Halozyme is headquartered in San Diego. For more information visit www.halozyme.com.

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 August 6, 2019 .

Contact:

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Royalties	\$ 18,107	\$ 19,989	\$ 36,060	\$ 40,933
Product sales, net	5,760	4,483	14,150	11,284
Revenues under collaborative agreements	15,281	10,730	45,887	13,857
Total revenues	<u>39,148</u>	<u>35,202</u>	<u>96,097</u>	<u>66,074</u>
Operating expenses:				
Cost of product sales	1,877	836	6,526	3,888
Research and development	33,910	40,086	65,238	78,062
Selling, general and administrative	17,338	14,353	35,344	27,909
Total operating expenses	<u>53,125</u>	<u>55,275</u>	<u>107,108</u>	<u>109,859</u>
Operating loss	(13,977)	(20,073)	(11,011)	(43,785)
Other income (expense):				
Investment and other income, net	1,983	1,983	4,040	3,651
Interest expense	(2,613)	(4,770)	(5,818)	(10,000)
Net loss before income taxes	(14,607)	(22,860)	(12,789)	(50,134)
Income tax expense	17	33	39	220
Net loss	<u>\$ (14,624)</u>	<u>\$ (22,893)</u>	<u>\$ (12,828)</u>	<u>\$ (50,354)</u>
Net loss per share:				
Basic and diluted	\$ (0.10)	\$ (0.16)	\$ (0.09)	\$ (0.35)
Shares used in computing net loss per share:				
Basic and diluted	145,411	143,568	145,051	143,114

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

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,041	\$ 57,936
Marketable securities, available-for-sale	220,424	296,590
Accounts receivable, net and other contract assets	32,219	30,005
Inventories	43,900	22,625
Prepaid expenses and other assets	28,122	20,693
Total current assets	391,706	427,849
Property and equipment, net	15,079	7,465
Prepaid expenses and other assets	10,545	4,434
Restricted cash	500	500
Total assets	\$ 417,830	\$ 440,248
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 12,467	\$ 4,079
Accrued expenses	45,561	49,529
Deferred revenue, current portion	6,511	4,247
Current portion of long-term debt, net	70,878	91,506
Total current liabilities	135,417	149,361
Deferred revenue, net of current portion	1,746	5,008
Long-term debt, net	14,083	34,874
Other long-term liabilities	6,532	2,118
Stockholders' equity:		
Common stock	146	145
Additional paid-in capital	803,782	780,457
Accumulated other comprehensive income (loss)	390	(277)
Accumulated deficit	(544,266)	(531,438)
Total stockholders' equity	260,052	248,887
Total liabilities and stockholders' equity	\$ 417,830	\$ 440,248

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