
**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): February 21, 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
(IRS 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))
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Item 2.02 Results of Operations and Financial Condition.

On February 21, 2019, Halozyme Therapeutics, Inc. issued a press release to report its financial results for the fourth quarter and year end December 31, 2018. 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 February 21, 2019

Exhibit Index

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99.1	Press release dated February 21, 2019



HALOZYME REPORTS FOURTH QUARTER AND FULL-YEAR 2018 RESULTS

- ENHANZE[®] Technology Licensed to argenx for up to Three Targets, Including Named target FcRn, Resulting in Upfront Payment of \$30 Million -

- 2019 Guidance Raised for Net Revenue and Year End Cash Balance to Reflect Latest Collaboration -

- Enrollment Completed in HALO-301 with Data Projected in Second Half of 2019 -

- Finished 2018 in Strong Financial Position with \$355 Million in Cash, Cash Equivalents and Marketable Securities -

SAN DIEGO, February 21, 2019 - Halozyyme Therapeutics, Inc. (NASDAQ: HALO), a biotechnology company developing novel oncology and drug-delivery therapies, today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided an update on recent corporate activities.

"Our latest collaboration with argenx demonstrates the broad applicability of our ENHANZE[®] drug delivery technology and is a great way to start the year," said Dr. Helen Torley, president and chief executive officer. "We anticipate multiple additional key milestones in our ENHANZE[®] business including potential approval of Herceptin[®] SC later this quarter and potential regulatory submissions for a subcutaneous formulation of Darzalex[®] in the second half of the year. With a total of nine ENHANZE[®] collaborations spanning from established products to new, innovative therapies addressing unmet needs, we remain confident in the potential for \$1 billion in royalty revenue in 2027."

"Our PEGPH20 oncology program achieved a critical milestone during the fourth quarter with the completion of enrollment in our pivotal HALO-301 pancreas cancer study with approximately 500 patients. We also reached agreement with the FDA to change the primary endpoint for HALO-301 to a single primary endpoint of overall survival (OS), which we believe incrementally de-risked the study. We look forward with excitement to topline results from HALO-301, which we currently project in the second half of 2019."

Fourth Quarter 2018 and Recent Highlights Include:

- In February 2019, Halozyme licensed its ENHANZE[®] drug delivery technology to argenx providing exclusive access to ENHANZE[®] for any product targeting the human neonatal Fc receptor FcRn, including argenx's lead asset efgartigimod (ARGX-113), and up to two additional targets. Under the terms of the agreement, argenx paid an upfront payment of \$30 million to Halozyme, and will pay Halozyme \$10 million per target for future target nominations and potential future payments of up to \$160 million per selected target subject to achievement of specified development, regulatory and sales-based milestones. Halozyme will also receive mid-single digit royalties on sales of commercialized products.
- In January 2019, the U.S. Food and Drug Administration completed its review of the submitted clinical study protocol amendment and statistical analysis plan for HALO-301, which included a change in the primary endpoint to a single primary endpoint of overall survival (OS), with no additional questions or comments.
- In December, enrollment in HALO-301, the company's Phase 3 study evaluating PEGPH20 in metastatic pancreas cancer, was completed with approximately 500 subjects enrolled. The company projects the study will achieve its target of 330 OS events between August and November of 2019. Based on achieving this timeline, the company projects topline results will be available in the second half of 2019.
- In December, Roche dosed the first patient in a Phase 1b/2 study of Tecentriq[®] (atezolizumab) with ENHANZE[®] triggering a \$5 million milestone payment to Halozyme.
- During the fourth quarter, BMS began recruitment for a Phase 1 study of OPDIVO[®] (nivolumab) with ENHANZE[®].
- ENHANZE[®] partner Janssen continued to make progress in clinical studies for a subcutaneous co-formulation of Darzalex[®] (daratumumab) with the recent initiation of two additional Phase 3 trials. Janssen is planning regulatory filings in the second half of 2019.
- In October, Halozyme expanded its collaboration with Roche by licensing its ENHANZE[®] drug-delivery technology for exclusive development of a new undisclosed clinical stage therapeutic target resulting in an upfront payment of \$25 million.

Fourth Quarter and Full Year 2018 Financial Highlights

- Revenue for the fourth quarter was \$60.2 million compared to \$189.6 million for the fourth quarter of 2017. The year-over-year decrease was driven by \$141.4 million upfront license fees for the BMS and Alexion agreements and a \$15.0 million milestone payment from Janssen recognized in 2017, compared to \$30.0 million in upfront and milestone revenue for the Roche collaboration recognized in 2018. The decrease was offset by a 9 percent growth in royalties on a reported basis from partner sales. Revenue for the fourth quarter included \$19.3 million in royalties and \$4.2 million in HYLENEX[®] recombinant (hyaluronidase human injection) product sales.

Revenue for the full year was \$151.9 million, compared to \$316.6 million in 2017.

Revenue from royalties for the full year was \$79.0 million, up 24% on an as-reported basis compared to \$63.5 million in 2017.

- Research and development expenses for the fourth quarter were \$36.7 million , compared to \$41.4 million for the fourth quarter of 2017 .

Research and development expenses for the full year were \$150.3 million, compared to \$150.6 million in 2017.

- Selling, general and administrative expenses for the fourth quarter were \$18.0 million , compared to \$14.8 million for the fourth quarter of 2017 .

Selling, general and administrative expenses for 2018 were \$60.8 million, compared to \$53.8 million in 2017.

- Net loss for the fourth quarter was \$2.1 million , or \$0.01 per share, compared to net income in the fourth quarter of 2017 of \$123.9 million , or \$0.85 per share.

Net loss for the full year was \$80.3 million, or \$0.56 per share, compared to net income of \$63.0 million in 2017, or \$0.45 per share.

- Cash, cash equivalents and marketable securities were \$354.5 million at December 31, 2018 , compared to \$469.2 million at December 31, 2017.

Financial Outlook for 2019

Halozyme updated its 2019 financial guidance, first provided on January 9, 2019, to reflect the recent argenx collaboration and license agreement:

- Net revenue of \$205 million to \$215 million, excluding revenue from any additional, new ENHANZE[®] global collaboration and licensing agreements;
- Operating expenses of \$265 million to \$275 million, or \$225 million to \$235 million excluding an expected increase in cost of goods sold. Excluding the cost of goods sold the modest increase in expenses is driven by ENHANZE partner support, and support of the potential commercialization of PEGPH20;
- 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 .

Webcast and Conference Call

Halozyme will webcast its Quarterly Update Conference Call for the fourth quarter of 2018 today, Thursday, February 21 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) 410-5657 (domestic callers) or (334) 323-7224 (international callers) using passcode 387156. A telephone replay will be available after the call by dialing (877) 919-4059 (domestic callers) or (334) 323-0140 (international callers) using replay ID number 68892505.

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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2019.

Contact:

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Revenues:				
Royalties	\$ 19,338	\$ 17,668	\$ 78,981	\$ 63,507
Product sales, net	10,681	12,593	28,234	50,396
Revenues under collaborative agreements	30,213	159,303	44,647	202,710
Total revenues	<u>60,232</u>	<u>189,564</u>	<u>151,862</u>	<u>316,613</u>
Operating expenses:				
Cost of product sales	5,622	7,488	10,136	31,152
Research and development	36,650	41,376	150,252	150,643
Selling, general and administrative	18,031	14,771	60,804	53,816
Total operating expenses	<u>60,303</u>	<u>63,635</u>	<u>221,192</u>	<u>235,611</u>
Operating (loss) income	(71)	125,929	(69,330)	81,002
Other income (expense):				
Investment and other income, net	2,017	1,080	7,578	2,592
Interest expense	(3,755)	(5,458)	(18,041)	(21,984)
Net (loss) income before income taxes	(1,809)	121,551	(79,793)	61,610
Income tax expense	317	(2,331)	537	(1,361)
Net (loss) income	<u>\$ (2,126)</u>	<u>\$ 123,882</u>	<u>\$ (80,330)</u>	<u>\$ 62,971</u>
Net (loss) income per share:				
Basic	\$ (0.01)	\$ 0.87	\$ (0.56)	\$ 0.46
Diluted	<u>\$ (0.01)</u>	<u>\$ 0.85</u>	<u>\$ (0.56)</u>	<u>\$ 0.45</u>
Shares used in computing net (loss) income per share:				
Basic	144,203	141,718	143,599	136,419
Diluted	<u>144,203</u>	<u>145,633</u>	<u>143,599</u>	<u>139,068</u>

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,936	\$ 168,740
Marketable securities, available-for-sale	296,590	300,474
Accounts receivable, net	30,005	22,133
Inventories	22,625	5,146
Prepaid expenses and other assets	20,693	13,879
Total current assets	<u>427,849</u>	<u>510,372</u>
Property and equipment, net	7,465	3,520
Prepaid expenses and other assets	4,434	5,553
Restricted cash	500	500
Total assets	<u>\$ 440,248</u>	<u>\$ 519,945</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,079	\$ 7,948
Accrued expenses	49,529	39,601
Deferred revenue, current portion	4,247	6,568
Current portion of long-term debt, net	91,506	77,211
Total current liabilities	<u>149,361</u>	<u>131,328</u>
Deferred revenue, net of current portion	5,008	54,297
Long-term debt, net	34,874	125,140
Other long-term liabilities	2,118	814
Stockholders' equity:		
Common stock	145	143
Additional paid-in capital	780,457	731,044
Accumulated other comprehensive loss	(277)	(450)
Accumulated deficit	(531,438)	(522,371)
Total stockholders' equity	<u>248,887</u>	<u>208,366</u>
Total liabilities and stockholders' equity	<u>\$ 440,248</u>	<u>\$ 519,945</u>

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