

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): November 12, 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 November 12, 2019, Halozyme Therapeutics, Inc. issued a press release to report its financial results for the third quarter end September 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>
<a href="#">99.1</a>	Press release dated November 12, 2019
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HALOZYME THERAPEUTICS, INC.

November 12, 2019

By: /s/ Harry J. Leonhardt, Esq.

Name: Harry J. Leonhardt, Esq.

Title: Senior Vice President, General Counsel and Corporate Secretary



## HALOZYME REPORTS THIRD QUARTER 2019 RESULTS

- *Total Revenues Increase 81% to \$46.2 million Compared to \$25.6 million in Prior-year Period -*
- *First Quarter of Sustainable Profitability Expected in Second Quarter of 2020 -*
- *Board Authorizes Initiation of Capital Return with Share Repurchase Program -*

**SAN DIEGO, November 12, 2019** - Halozyyme Therapeutics, Inc. (NASDAQ: HALO) today reported financial results for the third quarter ended September 30, 2019 and provided an update on its recent corporate activities and outlook.

“We have transitioned our strategy to focus solely on our high-growth, high-margin ENHANZE® drug delivery technology,” said Dr. Helen Torley, president and chief executive officer. “With profitability anticipated in the second quarter of 2020 and a long runway for growth with ENHANZE®, we are in a strong position to build value and return capital to investors.”

### Third Quarter 2019 and Recent Highlights Include:

- In November 2019, the Company announced strategic actions to reposition the Company with a focus solely on its ENHANZE® drug delivery technology following the announcement that the HALO-301 Phase 3 study did not meet its primary endpoint. In order to implement this strategic shift, the Company initiated an organizational restructuring to close its oncology operations. Headcount will be reduced by approximately 55%, or approximately 160 positions, with over 80% of the reduction completed in early January 2020. Upon completion of the restructuring and after booking all related one-time charges, Halozyyme anticipates becoming a sustainably profitable company beginning in the second quarter of 2020.
  - In November 2019, the Company announced that the Board of Directors has authorized the initiation of a capital return program to repurchase up to \$350 million of the Company's outstanding common stock over the next three years. The Board will regularly review this capital return program in connection with a balanced capital allocation strategy.
  - In October 2019, collaboration partner Roche nominated one new undisclosed target to be studied utilizing the ENHANZE® technology, triggering a \$10 million milestone payment to Halozyyme.
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- In October 2019, collaboration partner Bristol-Myers Squibb initiated a Phase 1 study of relatlimab in combination with nivolumab utilizing the ENHANZE® technology.
- In September 2019, Roche announced that the global Phase 3 FeDeriCa study met its primary endpoint. The FeDeriCa study investigated a fixed-dose combination of pertuzumab (Perjeta®) and trastuzumab (Herceptin®) for subcutaneous administration using Halozyme's ENHANZE® drug delivery technology in combination with intravenous chemotherapy. Additional data from the FeDeriCa study will be the subject of a presentation at the San Antonio Breast Cancer Symposium in December, followed by regulatory submissions to health authorities worldwide anticipated in early 2020.
- In September 2019, a Halozyme collaboration partner initiated a Phase 1 study in healthy volunteers for an undisclosed target utilizing the ENHANZE® technology.
- In August 2019, Roche initiated a Phase 1 study with OCREVUS® (ocrelizumab) utilizing the ENHANZE® technology in patients with multiple sclerosis.

### **Third Quarter 2019 Financial Highlights**

- Revenue for the third quarter was \$46.2 million compared to \$25.6 million for the third quarter of 2018. The year-over-year increase was primarily driven by higher product sales of bulk rHuPH20 to Janssen of \$20.1 million. Revenue for the quarter included \$16.6 million in royalties, which compared to \$18.7 million 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 third quarter were \$30.5 million, compared to \$35.5 million for the third quarter of 2018. The decline in expenses was driven by reduced clinical trial activity as the Company approached the topline results readout from HALO-301.
- Selling, general and administrative expenses for the third quarter were \$18.0 million, compared to \$14.9 million for the third quarter of 2018. The increase is due to an increase in personnel expenses related to support of the Company's oncology operations.
- Net loss for the third quarter was \$25.0 million, or \$0.17 per share, compared to a net loss in the third quarter of 2018 of \$27.9 million, or \$0.19 per share.
- Cash, cash equivalents and marketable securities were \$238.0 million at September 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 are now expected in the range of \$195 million to \$205 million, compared with prior guidance of \$205 million to \$215 million, primarily driven by the movement of a planned Phase 3 trial start from 2019 to 2020, offset in part, by a new unplanned target nomination. Included in that total, royalties are expected in the range of \$67 million to \$69 million, compared with prior guidance of \$72 million to \$74 million;
  - Operating expenses in the range of \$255 million to \$265 million, and operating expenses
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excluding cost of product sales of \$215 million to \$225 million, both of which are unchanged from prior guidance. These guidance ranges include anticipated one-time restructuring costs of \$25 million to \$27 million that will be booked in the fourth quarter of 2019. The restructuring costs were offset by expense savings related to the closing of the Company's oncology operations;

- Operating cash burn of \$50 million to \$60 million, compared with prior guidance of \$40 million to \$50 million;
- Year-end cash, cash equivalents and marketable securities balance is unchanged at \$220 million to \$230 million.

### **Webcast and Conference Call**

Halozyme will webcast its Quarterly Update Conference Call for the third quarter of 2019 today, Tuesday, November 12, 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 (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 6597916.

### **About Halozyme**

Halozyme Therapeutics is a biotechnology company focused on novel biological and drug delivery approaches. Halozyme's proprietary enzyme rHuPH20 is used to facilitate the delivery of injected drugs and fluids and potentially reduce the treatment burden of other drugs to patients. Halozyme has licensed its rHuPH20 technology, called ENHANZE<sup>®</sup>, to leading pharmaceutical and biotechnology companies including Roche, Baxalta, Pfizer, Janssen, AbbVie, Lilly, Bristol-Myers Squibb, Alexion and argenx. Halozyme derives revenues from these collaborations in the form of milestones and royalties as the Company's partners make progress developing and commercializing their products being developed with ENHANZE<sup>®</sup>. Halozyme is headquartered in San Diego. For more information visit [www.halozyme.com](http://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 financial performance including expectations for profitability and reduced expenses, plans to implement an organizational restructuring including anticipated reductions in employee headcount, plans to focus its operations solely on its ENHANZE<sup>®</sup> drug delivery technology, and the Company's plans to initiate a share repurchase program. Forward-looking statements regarding the Company's ENHANZE<sup>®</sup> drug delivery technology may include potential growth of the ENHANZE<sup>®</sup> business, the possible activity, benefits and attributes of ENHANZE<sup>®</sup>, the possible method of action of ENHANZE<sup>®</sup>, its potential application to aid in the dispersion and absorption of other injected therapeutic drugs, the number of collaborative targets actually chosen, whether such products are ultimately developed or commercialized, whether milestones triggering milestone payments will be achieved, and statements concerning facilitating more rapid delivery of injectable medications through subcutaneous delivery that involve risk and

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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 fluctuations or changes in revenues, including revenues from collaborators, unexpected delays or results of the Company's organizational restructuring, unexpected expenditures and costs, unexpected delays in the execution of the planned share repurchase, unexpected results or delays in the growth of the Company's ENHANZE<sup>®</sup> business, unexpected results or delays in the development and regulatory review of ENHANZE<sup>®</sup> products, regulatory approval requirements, unexpected adverse events and competitive conditions.

**Contact:**

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

	Three Months Ended		Nine Months Ended	
	2019	2018	2019	2018
Revenues:				
Royalties	\$ 16,609	\$ 18,710	\$ 52,669	\$ 59,643
Product sales, net	29,205	6,269	43,355	17,553
Revenues under collaborative agreements	416	577	46,303	14,434
Total revenues	46,230	25,556	142,327	91,630
Operating expenses:				
Cost of product sales	22,333	626	28,859	4,514
Research and development	30,455	35,540	95,693	113,602
Selling, general and administrative	17,979	14,864	53,323	42,773
Total operating expenses	70,767	51,030	177,875	160,889
Operating loss	(24,537)	(25,474)	(35,548)	(69,259)
Other income (expense):				
Investment and other income, net	1,613	1,910	5,653	5,561
Interest expense	(2,078)	(4,286)	(7,896)	(14,286)
Net loss before income taxes	(25,002)	(27,850)	(37,791)	(77,984)
Income tax expense	13	—	52	220
Net loss	\$ (25,015)	\$ (27,850)	\$ (37,843)	\$ (78,204)
Net loss per share:				
Basic and diluted	\$ (0.17)	\$ (0.19)	\$ (0.26)	\$ (0.55)
Shares used in computing net loss per share:				
Basic and diluted	146,136	143,949	145,435	143,396



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

	September 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 59,202	\$ 57,936
Marketable securities, available-for-sale	178,796	296,590
Accounts receivable, net	40,744	30,005
Inventories	36,051	22,625
Prepaid expenses and other assets	27,248	20,693
Total current assets	342,041	427,849
Property and equipment, net	15,398	7,465
Prepaid expenses and other assets	12,417	4,434
Restricted cash	500	500
Total assets	\$ 370,356	\$ 440,248
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,314	\$ 4,079
Accrued expenses	45,679	49,529
Deferred revenue, current portion	3,511	4,247
Current portion of long-term debt, net	54,537	91,506
Total current liabilities	108,041	149,361
Deferred revenue, net of current portion	1,247	5,008
Long-term debt, net	9,308	34,874
Other long-term liabilities	6,407	2,118
Stockholders' equity:		
Common stock	147	145
Additional paid-in capital	814,095	780,457
Accumulated other comprehensive income (loss)	392	(277)
Accumulated deficit	(569,281)	(531,438)
Total stockholders' equity	245,353	248,887
Total liabilities and stockholders' equity	\$ 370,356	\$ 440,248