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 26, 2018

HALOZYME THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-32335**	**88-0488686**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11388 Sorrento Valley Road, San Diego, California	**92121**
(Address of principal executive offices)	**(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 (see General Instruction A.2. below):

☐ 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 (§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 8.01. Other Events.

On November 26, 2018 Halozyme Therapeutics, Inc. (the "Company") issued a press release announcing that prior to data analysis, the FDA has agreed to the Company's request to change the primary endpoint of the Company's HALO-301 study to the single primary endpoint of overall survival. As a result, the previously planned interim analysis will not be conducted. The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

On November 26, 2018, the Company webcasted a conference call to discuss the HALO-301 statistical plan. The webcast was accompanied by a slide presentation a copy of which is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Please refer to the attached press release and slide presentation for a discussion of certain forward-looking statements included therein and the risks and uncertainties related thereto.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated November 26, 2018
99.2	Slide presentation dated November 26, 2018

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 26, 2018

By: /s/ Harry J. Leonhardt
Harry J. Leonhardt, Esq.
Senior Vice President, General Counsel
and Corporate Secretary

Exhibit 99.1

FOR IMMEDIATE RELEASE

HALOZYME ANNOUNCES CHANGE IN PRIMARY ENDPOINT FOR HALO-301 TO OVERALL SURVIVAL

–FDA Agrees to Company Request to Change Primary Endpoint to Overall Survival–

–Previously Planned Interim Analysis Will Not Be Conducted–

–Management to Host Webcast / Conference Call Today at 5 p.m. ET / 2 p.m. PT–

SAN DIEGO, November 26, 2018 - Halozyme Therapeutics, Inc. (NASDAQ: HALO), a biotechnology company developing novel oncology and drug-delivery therapies, today announced that prior to data analysis, the FDA has agreed to Halozyme's request to change the primary endpoint of the HALO-301 study to the single primary endpoint of overall survival (OS). As a result, the previously planned interim analysis will not be conducted. The company will host a webcast and conference call today at 5 p.m. Eastern / 2 p.m. Pacific to discuss this change in further detail.

HALO-301 is a phase 3 global, randomized, double-blind placebo controlled clinical trial evaluating investigational new drug PEGPH20 as a first-line therapy for potential treatment of patients with metastatic pancreas cancer.

Webcast and Conference Call

Halozyme will webcast a conference call today at 5 p.m. ET / 2 p.m. PT to discuss the HALO-301 statistical plan. Dr. Helen Torley, president and chief executive officer, 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 www.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 49634758.

About HALO 301

HALO 301 is a phase 3 global, randomized, double-blind placebo controlled clinical trial evaluating investigational new drug PEGPH20 as a first-line therapy for potential treatment of patients with

metastatic pancreas cancer. The trial will now be conducted at approximately 200 sites with a single primary endpoint of overall survival in patients receiving investigational new drug PEGPH20 in combination with gemcitabine and ABRAXANE ® (nab-paclitaxel) compared to gemcitabine and nab-paclitaxel alone. Secondary endpoints include progression-free survival and objective response rate. More information may be found at clinicaltrials.gov (search HALO 301 or trial identifier NCT02715804) or www.HALO301.com.

About PEGPH20

PEGPH20 is an investigational PEGylated form of Halozyme's proprietary recombinant human hyaluronidase under clinical development for the potential systemic treatment of tumors that accumulate hyaluronan. PEGPH20 is an enzyme that temporarily degrades HA, a dense component of the tumor microenvironment that can accumulate in higher concentrations around certain cancer cells, potentially constricting blood vessels and impeding the access of other therapies.

FDA granted orphan drug designation to PEGPH20 for treatment of pancreas cancer and fast track for PEGPH20 in combination with gemcitabine and nab-paclitaxel for the treatment of metastatic pancreas cancer. Additionally, the European Commission, acting on the recommendation from the Committee for Orphan Medicinal Products of the European Medicines Agency, designated investigational drug PEGPH20 an orphan medicinal product for the treatment of pancreas cancer.

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 and Alexion 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 possible activity, benefits and attributes of PEGPH20, the possible method of action of PEGPH20, its potential application to improve cancer therapies and statements concerning future actions relating to the development of PEGPH20) 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 results or delays in development, 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 most recent Annual and Quarterly Reports filed with the Securities and Exchange Commission.

Contact:

Al Kildani
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858-704-8122
akildani@halozyme.com

Exhibit 99.2

Halozyme

HALO-301 Trial Update

November 26, 2018

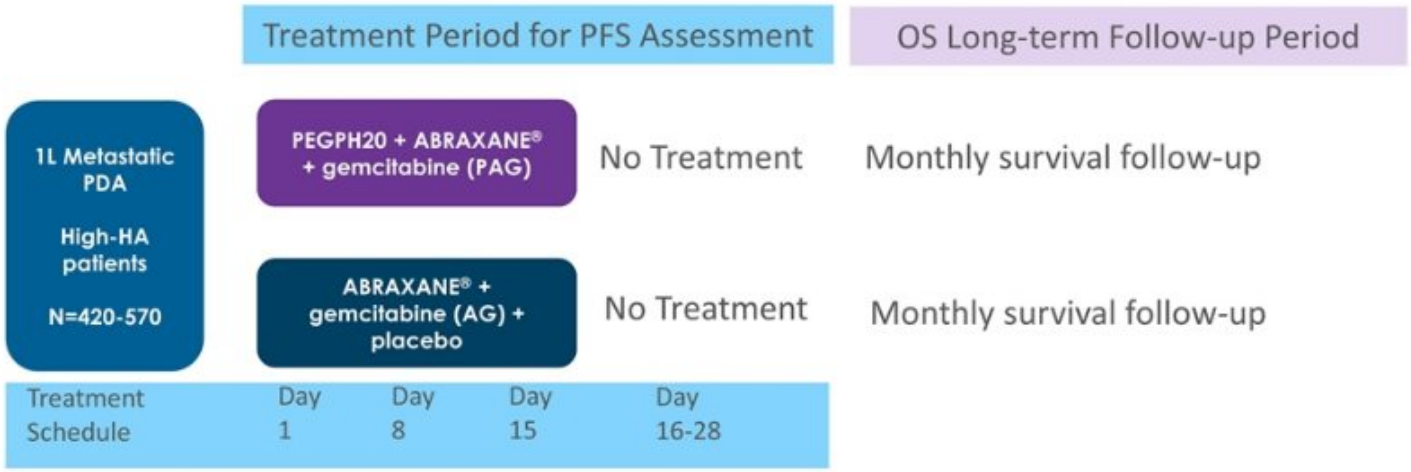
Forward-Looking Statements

All of the statements in this presentation that are not statements of historical facts constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of such statements include possible activity, benefits and attributes of PEGPH20, future product development and regulatory events and goals, anticipated clinical trial results and strategies, product collaborations, our business intentions and financial estimates and results, including projected revenue amounts. These statements are based upon management's current plans and expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from such statements. A discussion of the risks and uncertainties that can affect these statements is set forth in the Company's annual and quarterly reports filed from time to time with the Securities and Exchange Commission under the heading "Risk Factors." The Company disclaims any intention or obligation to revise or update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Summary

- Agreement reached with FDA to change the primary endpoint of HALO-301 to a **single primary endpoint**, Overall Survival (OS)
  - Company and advisors remain blinded to all efficacy data
- Additional statistical plan changes:
  - No interim analysis
  - Target number of OS events for final analysis, unchanged at 330, projected to occur August - November 2019
  - 93% power if HR (Hazard Ratio) is 0.67: corresponds to a median OS benefit of 12.7 months versus 8.5 months
    - Observed HR of 0.795 would be statistically significant, with a minimum observable Overall Survival difference of 2.2 months
  - Enrollment will be ~500 patients, assuring a mature data set
    - All patients expected to be followed for at least 8.5 months and only 9% will have less than ~13 months follow-up
  - FDA provided feedback that these details appear acceptable with a final determination pending review of amended protocol and statistical plan to be submitted in December 2018

Original Design HALO-301: Overview



- Two primary endpoints: Progression Free Survival (PFS) and Overall Survival (OS)
- Adaptive design: at time of PFS final analysis, iDMC will recommend target number of events for final OS analysis

Original Design HALO-301: Statistics and Timing Assumptions

Analysis		Sample Size Events (%)	Alpha Level (2-sided)	Significant HR (minimal observable difference in months for statistical significance)	Statistical Power	Timeline assumptions to events in March 2016
Original Design (PFS & OS as two primary endpoints; adaptive sample size increase)						
Interim Analysis	PFS (final)	226 (100%)	0.01	0.695 (2.4)	90% for HR=0.59	April 2018
Final OS Analysis	330 OS events	330 (100%)	0.04	0.787 (2.3)	92% for HR=0.67	August 2019
	Increase up to 450 OS events	450 (136%)	0.04	0.814 (1.9)	98% for HR=0.67	October 2020

16 months

FDA Provided Feedback on Original Design in Type B Meeting March 2015

- FDA feedback on PFS as an endpoint with potential to support a marketing application:

  "FDA did not object to the proposal to retain PFS as a co-primary endpoint. However, the ability of the PFS results to support a marketing application would be dependent upon the magnitude of the treatment effect observed, the toxicity profile of the drug, and the interim overall survival data."

  Excerpted from FDA minutes of Type B End Of Phase 2 Meeting March 2015

Key Timeline and Events

Earliest achievement of 226 PFS events

August 2018	September 2018	October 2018	November 2018	December 2018

Initiated statistical review in anticipation of upcoming data analysis:
- PFS events projected December 2018-February 2019

Engaged external regulatory and statistical advisers

Submitted Type C request, including questions and Briefing Book to seek FDA feedback on potential design change

Preliminary FDA feedback

Type C meeting

Type C meeting Meeting Minutes

Company and advisors remain blinded to efficacy data

Time Difference to Target PFS and OS Events Considerably Shortened, Triggering Review of Plan

Events	Original Projected Timeline	August 2018 Projected Timeline (570 to be enrolled)
Expected target 226 **PFS** events	April 2018	Dec. 2018 - Feb. 2019
Expected target 330 **OS** Events	August 2019	August 2019
Time difference between PFS and OS events	**16 months**	**6-8 Months**

Higher Than Projected PFS Event Censoring Resulting in Longer Time to Target PFS Events

- Multiple definitions are used for PFS in oncology registration trials
- HALO-301 PFS definition (determined acceptable by FDA):
  - The time from randomization until the first occurrence of radiological disease progression, as determined by a blinded CIV based on RECIST v 1.1 criteria, or death from any cause during treatment period
- PFS censoring rate was higher than planned and historically reported, at ~40%, resulting in longer time to target PFS events

Agreement Reached with FDA to Change the Primary Endpoint of HALO-301 to a Single Endpoint, Overall Survival

- Agreement reached with FDA, to change the primary endpoint of HALO-301 to a single primary endpoint, Overall Survival (OS)
- Additional statistical plan changes:
  - No interim analysis
  - 2-sided alpha of 0.05 for OS primary endpoint
  - Target number of OS events for final analysis, unchanged at 330, projected August - November 2019
  - Enrollment will be ~500 patients, assuring a mature dataset
    - All patients expected to be followed for at least 8.5 months and only 9% will have less than ~13 months follow-up
  - FDA provided feedback that these details appear acceptable with a final determination pending review of amended protocol and statistical plan to be submitted in December 2018

Final Analysis Plan for HALO-301

Analysis	Sample Size Events (%)	Alpha Level (2-sided)	Significant HR (minimal observable difference in months for statistical significance)	Statistical Power	Projected Events Achieved (~500 enrolled)
Final OS	330 (100%)	0.05	0.795 (2.2)	93% for HR=0.67	Aug. - Nov. 2019

Potential benefits

- Allows for 100% of alpha spend on OS
- Expected mature dataset with patient follow up of at least 8.5 months
- Timing difference between a PFS interim analysis and OS final analysis is 6 -11 months
- Supports the commercial opportunity

Final Analysis Approach: Potential Benefits

- Full FDA and MAA approval pathway, with Overall Survival endpoint
- Mature data set, maximizing ability to observe treatment effect
- High probability of definitive HALO-301data in 2H 2019