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 23, 2021

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number 001-32335

Delaware	**88-0488686**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
11388 Sorrento Valley Road **San Diego** **California**	**92121**
(Address of principal executive offices)	*(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 February 23, 2021, Halozyme Therapeutics, Inc. issued a press release to report its financial results for the fourth quarter end December 31, 2020. 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.

Exhibit No.	Description
99.1	Press release dated February 23, 2021
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

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.

February 23, 2021

By: */s/ Masaru Matsuda*

Name: Masaru Matsuda, Esq.
Title: Senior Vice President, General Counsel and Corporate Secretary

Exhibit 99.1

HALOZYME REPORTS FOURTH QUARTER 2020 RESULTS AND FULL YEAR 2020 RESULTS

– Reports Fourth Quarter 2020 Revenue of $121.7 million and Earnings Per Share of $0.50 –

– Reports Full Year 2020 Revenue of $267.6 million and Earnings Per Share of $0.91 –

– Successful Launch of DARZALEX® SC with ENHANZE® Drives 86% Year-over-year and 34% Sequential Growth in Royalties in the Fourth Quarter –

– 2021 Revenue Guidance of $375 Million to $395 Million Representing 40% to 48% Growth over 2020 Revenue –

– 2021 Royalties Projected to Double versus 2020 Royalties –

– 2021 EPS Guidance of $1.40 to $1.55 Representing 54%-70% Growth over 2020 EPS –

SAN DIEGO, February 23, 2021 - Halozyme Therapeutics, Inc. (NASDAQ: HALO) today reported financial results for the fourth quarter and full year ended December 31, 2020 and provided an update on its recent corporate activities and outlook.

“The fourth quarter capped an extraordinary year for Halozyme during which we transitioned to a profitable, high-growth company with strong prospects for continued growth over the long-term,” said Dr. Helen Torley, president and chief executive officer. “Our strong growth prospects are fueled by recent product approvals for subcutaneous DARZALEX® (daratumumab) and Phesgo® (pertuzumab, trastuzumab and hyaluronidase) utilizing our ENHANZE® technology. Building on our portfolio of 5 commercialized partner products, we project the expansion of our development pipeline, including 4 products being evaluated in 7 phase 3 studies utilizing our ENHANZE® technology. We believe this advancing pipeline of products utilizing our ENHANZE® technology is setting the potential for multiple waves of future product launches that will deliver long-term growth in revenues, profitability and cash flow.”

Fourth Quarter 2020 and Recent Highlights Include:

- In February 2021, argenx announced a “go” decision for its ADHERE trial evaluating subcutaneous (SC) efgartigimod with ENHANZE® technology in chronic inflammatory demyelinating polyneuropathy (CIDP). argenx plans to continue enrollment to include approximately 130 patients to support potential registration of SC efgartigimod for the treatment of CIDP.

- In January 2021, ENHANZE® partner Janssen Biotech, Inc. (Janssen) received U.S. Food and Drug Administration (FDA) accelerated approval of DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. AL amyloidosis is a rare and potentially fatal disease that develops when plasma cells in the bone marrow generate abnormal light chains, which form amyloid deposits in vital organs and lead to organ deterioration. There were previously no approved therapies for the disease.
- In January 2021, argenx initiated a Phase 3 study of ARGX-113 with ENHANZE® technology in pemphigus vulgaris and pemphigus foliaceus, rare autoimmune diseases that cause painful blisters on the skin and mucous membranes.
- In December 2020, argenx initiated a Phase 3 study of ARGX-113 with ENHANZE® technology for patients with immune thrombocytopenia (ITP), an immune disorder in which the blood does not clot normally, resulting in a $15 million payment to Halozyme.
- In December 2020, Roche initiated a Phase 3 study in patients with non-small cell lung cancer for Tecentriq® (atezolizumab) with ENHANZE® technology, resulting in a $17 million payment to Halozyme.
- In December 2020, the Company announced that the European Commission approved Roche's Phesgo®, a fixed-dose combination of Perjeta® (pertuzumab) and Herceptin® (trastuzumab) with ENHANZE® technology, administered by SC injection for the treatment of patients with early and metastatic HER2-positive breast cancer. This was the first time the European Commission approved a product combining two monoclonal antibodies that can be administered by a single SC injection utilizing ENHANZE® technology.
- In November 2020, the Company announced a global collaboration and license agreement that provides Horizon Therapeutics plc exclusive access to ENHANZE® technology for SC formulation of medicines targeting IGF-1R for which the Company received an upfront payment of $30 million. Horizon intends to use ENHANZE® technology to develop a SC formulation of TEPEZZA® (teprotumumab-trbw), indicated for the treatment of Thyroid Eye Disease, a serious, progressive and vision-threatening rare autoimmune disease, potentially shortening drug administration time, reducing healthcare practitioner time and offering additional flexibility and convenience for patients.
- In November 2020, Janssen initiated a Phase 1 study of amivantamab utilizing ENHANZE® technology in advanced solid tumors.
- In November 2020, the Company announced that Janssen submitted regulatory applications to the FDA and European Medicines Agency (EMA) seeking approval of DARZALEX FASPRO® in the U.S. and as DARZALEX® SC in the European Union (EU) utilizing ENHANZE® technology in combination with pomalidomide and dexamethasone (D-Pd) for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy.
- In November 2020, Janssen submitted a Type II variation application to the EMA seeking European approval for DARZALEX® SC utilizing ENHANZE® technology to be used in the treatment of patients with AL amyloidosis.
- In October 2020, the Company announced that argenx expanded its existing global collaboration and license agreement that was signed in February 2019. Under the expansion, argenx gained the ability to exclusively access Halozyme's ENHANZE® drug delivery technology for three additional targets upon nomination for a total of up to six targets. To date, argenx has nominated two targets including the human neonatal Fc receptor FcRn, which is blocked by efgartigimod, and complement component C2.

- During the fourth quarter, the Company repurchased approximately 1.1 million shares of common stock for $37.6 million at an average price per share of $34.36, bringing the total 2020 repurchases to $150.0 million at an average price of $23.05.

Fourth Quarter and Full Year 2020 Financial Highlights

- Revenue for the fourth quarter was $121.7 million compared to $53.7 million for the fourth quarter of 2019. The year-over-year increase was primarily driven by a $30.0 million upfront payment from Horizon, a $15.0 million sales milestone from Janssen, an increase in royalty revenue following the strong DARZALEX FASPRO® launch during the second quarter and an increase in product sales. Revenue for the quarter included $32.0 million in royalties, an increase of 86% compared to $17.2 million in the prior year period.

  Total revenues for the full year were $267.6 million, compared with $196.0 million in 2019, representing growth of 37% year over year.

- Research and development expenses for the fourth quarter were $7.4 million, compared to $45.1 million for the fourth quarter of 2019. The decrease in expenses was due to a decrease in clinical trial activities-related costs as a result of the Company halting its oncology drug development efforts beginning in November 2019 and one-time restructuring charges of $17.2 million in the prior year related to the shift in strategic focus to the Company's ENHANZE® technology.

  Research and development expenses for the full year were $34.2 million, compared with $140.8 million in 2019.

- Selling, general and administrative expenses for the fourth quarter were $10.4 million, compared to $23.9 million for the fourth quarter of 2019. The decrease was due to lower compensation and commercial-related expenses related to the corporate restructuring announced in November 2019 and a one-time restructuring charge of $11.2 million in the prior year.

  Selling, general and administrative expenses for the full year were $45.7 million, compared with $77.3 million in 2019.

- Operating income for the fourth quarter was $77.6 million, compared to an operating loss of $32.1 million in the fourth quarter of 2019.

  Operating income for the full year was $144.3 million, compared to an operating loss of $67.6 million in 2019.

- Net income for the fourth quarter was $73.2 million, or $0.50 per share, compared to a net loss in the fourth quarter of 2019 of $34.4 million, or loss of $0.24 per share.

  Net income for the full year was $129.1 million or $0.91 per share, compared to a net loss of $72.2 million or loss of $0.50 per share in 2019.

- Cash, cash equivalents and marketable securities were $368.0 million at December 31, 2020, compared to $421.3 million at December 31, 2019.

- During 2020, the Company repurchased 6.5 million shares of common stock for $150 million at an average price of $23.05, bringing the total for share repurchases since the announcement of the Company's three-year share repurchase program to $350.0 million at an average price of $19.88.

Financial Outlook for 2021

Based on the latest information from collaboration partners and planned expenditures for the year, the Company expects:

- Revenues of $375 million to $395 million, representing year-over-year growth of 40%-48%, with revenues from royalties projected to approximately double versus 2020;
- Operating Income of $215 million to $235 million, representing year-over-year growth of 49%-63%;
- Earnings per share on a GAAP basis of $1.40 to $1.55, representing year-over-year growth of 54%-70%.

The Company plans to repurchase up to $125 million in common stock during 2021 as part of the $550 million three-year share repurchase plan authorized by Halozyme's board of directors in 2019. The amount and timing of shares to be repurchased in 2021 will be subject to a variety of factors including market conditions, other business considerations and applicable legal requirements.

Webcast and Conference Call

Halozyme will webcast its Quarterly Update Conference Call for the fourth quarter of 2020 today, Tuesday, February 23, 2021 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 register for this conference call, please use this link:http://www.directeventreg.com/registration/event/7096809. After registering, you will receive an email confirmation that includes dial in details and unique conference call codes for entry. Registration is open through the live call. However, to ensure you are connected for the full call, we suggest registering a day in advance or at minimum 10 minutes before the start of the call.

About Halozyme

Halozyme is a biopharmaceutical company bringing disruptive solutions to significantly improve patient experiences and outcomes for emerging and established therapies. Halozyme advises and supports its biopharmaceutical partners in key aspects of new drug development with the goal of improving patients' lives while helping its partners achieve global commercial success. As the innovators of the ENHANZE® technology, which can reduce hours-long treatments to a matter of minutes, Halozyme's commercially-validated solution has positively impacted more than 400,000 patient lives via five commercialized products across more than 100 global markets. Halozyme and its world-class partners

are currently advancing multiple therapeutic programs intended to deliver innovative therapies, with the potential to improve the lives of patients around the globe. Halozyme's proprietary enzyme rHuPH20 forms the basis of the ENHANZE® technology and is used to facilitate the delivery of injected drugs and fluids, potentially reducing the treatment burden of other drugs to patients. Halozyme has licensed its ENHANZE® technology to leading pharmaceutical and biotechnology companies including Roche, Baxalta, Pfizer, Janssen, AbbVie, Lilly, Bristol-Myers Squibb, Alexion, argenx and Horizon Therapeutics. 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®. 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 in this press release include forward-looking statements including, without limitation, statements concerning the Company's expected future financial performance (including the Company's financial outlook for 2021) and expectations for future growth, profitability, revenue, operating income, cash flow, expenses and earnings-per-share and the Company's plans to continue its share repurchase program. Forward-looking statements regarding the Company's ENHANZE® drug delivery technology may include the possible activity, benefits and attributes of ENHANZE®, the possible method of action of ENHANZE®, its potential application to aid in the dispersion and absorption of other injected therapeutic drugs and facilitating more rapid delivery of injectable medications through subcutaneous delivery. Forward-looking statements regarding the Company's ENHANZE® business may include potential growth driven by our partners' development and commercialization efforts, the size and growth prospects of our partners' drug franchises, potential new ENHANZE® collaborations and collaborative targets and regulatory review and potential approvals of new ENHANZE® products. These 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 and involve risk and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Actual results could differ materially from the expectations contained in these forward-looking statements as a result of several factors, including unexpected levels of revenues, expenditures and costs, inability to sustain profitability, unexpected delays in the execution of the Company's share repurchase program, unexpected results or delays in the growth of the Company's ENHANZE® business, or in the development, regulatory review or commercialization of ENHANZE® products, including any potential delays caused by the current COVID-19 global pandemic, regulatory approval requirements, unexpected adverse events or patient outcomes and competitive conditions. These and other factors that may result in differences are discussed in greater detail in the Company's most recently filed Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Contact:
Al Kildani
Vice President, Investor Relations and Corporate Communications
858-704-8122
ir@halozyme.com

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Royalties	$ 31,997	$ 17,230	$ 88,596	$ 69,899
Product sales, net	32,455	22,693	55,987	66,048
Revenues under collaborative agreements	57,251	13,742	123,011	60,045
Total revenues	121,703	53,665	267,594	195,992
Operating expenses:				
Cost of product sales	26,272	16,687	43,367	45,546
Research and development	7,380	45,111	34,236	140,804
Selling, general and administrative	10,427	23,929	45,736	77,252
Total operating expenses	44,079	85,727	123,339	263,602
Operating income (loss)	77,624	(32,062)	144,255	(67,610)
Other income (expense):				
Investment and other income, net	661	1,333	5,425	6,986
Interest expense	(5,036)	(3,731)	(20,378)	(11,627)
Net income (loss) before income taxes	73,249	(34,460)	129,302	(72,251)
Income tax expense	85	(63)	217	(11)
Net income (loss)	$ 73,164	$ (34,397)	$ 129,085	$ (72,240)
Net income (loss) per share:				
Basic	$ 0.54	$ (0.24)	$ 0.95	$ (0.50)
Diluted	$ 0.50	$ (0.24)	$ 0.91	$ (0.50)
Shares used in computing net income (loss) per share:				
Basic	135,107	141,046	136,206	144,329
Diluted	145,122	141,046	141,463	144,329

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 147,703	$ 120,179
Marketable securities, available-for-sale	220,310	301,083
Accounts receivable, net and other contract assets	97,730	59,442
Inventories	60,747	29,359
Prepaid expenses and other assets	28,274	33,373
Total current assets	554,764	543,436
Property and equipment, net	10,593	10,855
Prepaid expenses and other assets	14,067	11,083
Restricted cash	500	500
Total assets	$ 579,924	$ 565,874
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,928	$ 6,434
Accrued expenses	20,483	55,649
Deferred revenue, current portion	1,746	4,012
Current portion of long-term debt, net	397,228	19,542
Total current liabilities	421,385	85,637
Deferred revenue, net of current portion	4,026	1,247
Long-term debt, net	—	383,045
Other long-term liabilities	3,466	4,180
Stockholders' equity:		
Common stock	135	137
Additional paid-in capital	625,483	695,066
Accumulated other comprehensive income (loss)	22	240
Accumulated deficit	(474,593)	(603,678)
Total stockholders' equity	151,047	91,765
Total liabilities and stockholders' equity	$ 579,924	$ 565,874