

Halozyyme Therapeutics (HALO)

\$16.25 (As of 04/03/20)

Price Target (6-12 Months): **\$18.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 12/05/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:F

Value: D

Growth: F

Momentum: A

Summary

Halozyyme reported dismal fourth-quarter results, wherein both earnings and sales missed estimates. Halozyyme has promising collaboration deals related to its ENHANZE technology with several small and large pharma companies. These deals generate the majority of revenues for the company. Blockbuster drugs like Herceptin and Rituxan use ENHANZE for subcutaneous administration, which boosts Halozyyme's royalties. Potential approval for subcutaneous formulation of Darzalex will be encouraging. Restructuring initiatives following failure of late-stage candidate PEGPH20 is also encouraging. Halozyyme's shares have outperformed the industry in the past year. However, the company's dependence on collaboration partners for revenues remains a concern. Failure and discontinuation of PEGPH20 development in 2019 was a major setback.

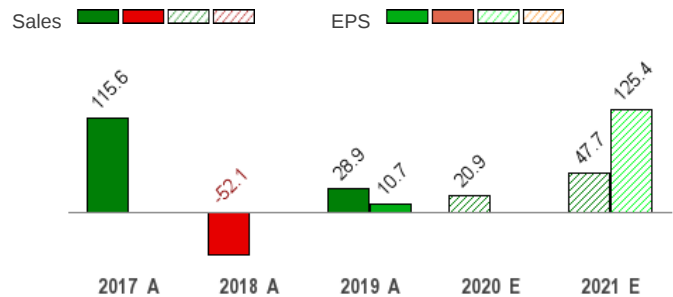
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$22.06 - \$12.71
20 Day Average Volume (sh)	2,162,798
Market Cap	\$2.2 B
YTD Price Change	-8.4%
Beta	1.71
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 11% (29 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	-33.3%
Last Sales Surprise	-2.8%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	05/05/2020
Earnings ESP	0.0%
P/E TTM	NA
P/E F1	25.8
PEG F1	NA
P/S TTM	11.5

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	84 E	105 E	127 E	159 E	350 E
2020	39 E	58 E	71 E	69 E	237 E
2019	57 A	39 A	46 A	54 A	196 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.26 E	\$0.34 E	\$0.45 E	\$0.60 E	\$1.42 E
2020	-\$0.01 E	\$0.16 E	\$0.25 E	\$0.24 E	\$0.63 E
2019	\$0.01 A	-\$0.10 A	-\$0.17 A	-\$0.24 A	-\$0.50 A

*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 04/03/2020. The reports text is as of 04/06/2020.

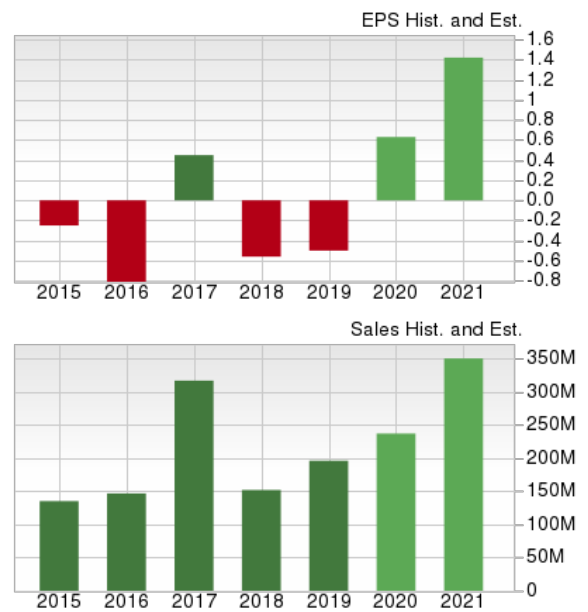
Overview

San Diego, CA-based Halozyme Therapeutics is a biopharmaceutical company, focused on the development and commercialization of novel treatments for oncology indications by targeting tumor microenvironment. The company also licenses its novel drug delivery technology, ENHANZE, for subcutaneous administration of drugs.

The company's ENHANZE drug delivery technology helps in developing subcutaneous administration of drugs. Several companies including Roche, Takeda, J&J, AbbVie, Lilly, Bristol-Myers and others are using this technology for developing subcutaneous formulation of their currently marketed drugs. The company has nine collaborations and three marketed partnered drugs based on this technology. It also recognizes revenues from sale of drug products to its collaboration partners for development of drugs using its ENHANZE platform. The platform was developed based on the company's patented recombinant human hyaluronidase enzyme (rHuPH20).

The company also has one approved product in its portfolio – Hylenex recombinant as an adjuvant to facilitate subcutaneous fluid administration. The company halted all oncology clinical activities following the failure of the late-stage study evaluating its sole pipeline candidate, PEGPH20, in November 2019.

Although Halozyme has one marketed product, it derives the majority of its revenues from royalties on sales of partnered drugs. The company generated total revenues of \$196 million in 2019 compared with \$151.9 million in the year-ago period.



Reasons To Buy:

- ▲ **Shares Outperforming Industry:** Halozyme's shares have lost 5.6% in the past year against the industry's decrease of 15.4%.
- ▲ **ENHANZE Technology Brings Majority Revenues:** Halozyme's ENHANZE drug delivery technology has been used in the development of subcutaneous formulation of three approved drugs through partnerships with Roche and Takeda. Moreover, the company's technology has attracted several other pharma/biotech companies, which use it for developing subcutaneous formulation of their pipeline candidates. These deals generate royalties on sales of marketed drugs, milestone payments for pipeline candidates and annual license fees. The company is also focused on signing new collaboration deals.

We are positive on Halozyme's collaboration deals with large pharma companies related to ENHANZE technology. The company's restructuring initiatives are also encouraging.

Roche's cancer drugs, Rituxan Hycela (subcutaneous formulation of Rituxan) and Herceptin SC, and Takeda's immunodeficiency drug, HyQvia, are the three marketed drugs developed using ENHANZE technology. These drugs generate the majority of revenues for the company. Roche is also developing subcutaneous formulation of Tecentriq and Perjeta. Apart from these drugs, Halozyme has collaborations with Pfizer, J&J, AbbVie, Lilly, Bristol-Myers, Alexion Pharma and ARGENX. Per the agreements, the companies have worldwide license to develop and commercialize products using Halozyme's ENHANZE technology. Regulatory applications seeking approval for subcutaneous administration of J&J's Darzalex is under review in the United States and Europe. A potential approval, expected in July 2020, for the subcutaneous formulation of the blockbuster drug is likely to boost Halozyme's royalty revenues. In February 2020, the FDA accepted biologics license application (BLA) seeking approval for subcutaneous administration of the fixed-dose combination of Perjeta and Herceptin. A decision is expected by Oct 18, 2020. Halozyme anticipates its collaboration partners using the ENHANZE technology to initiate at least three new phase III, one phase 2 clinical and at least five phase I clinical studies in 2020.

- ▲ **Encouraging Restructuring Initiatives:** Following the failure of its lead pipeline candidate, PEGPH20, in phase III HALO-301 study, Halozyme initiated an operational review to support future growth in November 2019. This should enable Halozyme to solely focus on its high-growth, high-margin ENHANZE technology. The company has discontinued all clinical developmental activities related to PEGPH20 and oncology operations. As part of the plan, the company has started workforce reduction to cut headcount by 55% or 160 employees. On its fourth-quarter earnings call, the company stated that it has completed the majority of the restructuring and anticipates to achieve sustainable profitability by the second quarter of 2020.

The restructuring and cost saving efforts are likely to generate savings of \$130 to \$140 million in 2020. Halozyme is anticipating operating expenses, excluding cost of goods sold, to significantly decline to the range of \$65 million and \$75 million in 2020, most likely driven by lower research & development expenses following PEGPH20 development discontinuation. It also authorized the initiation of share repurchase program worth \$550 million to be completed over the next three years, of which \$200 million worth of repurchase has been completed. Additional repurchase of up to \$150 million will be done in rest of 2020. These initiatives are encouraging and pushed share prices higher despite clinical study failure.

- ▲ **Potential in Targeted Indications:** The majority of Halozyme's partnered drugs, under development or being marketed, have blockbuster status. This can lead to significant royalties for Halozyme if the subcutaneous administration of these drugs sees strong uptake. The company expects to generate \$1 billion in annual royalties from its ENHANZE technology by 2027. Moreover, the ENHANZE technology is expected to bring \$350 million to \$450 million through 2020 to 2022 and \$1 billion in milestone payments over its lifetime.
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Reasons To Sell:

- ▼ **Overdependence on Partners:** A significant portion of Halozyme's revenues comes from its partners who are developing or marketing subcutaneous formulation of their drugs using ENHANZE drug delivery technology. The revenues are recorded as royalties or product revenues. Meanwhile, Roche's Herceptin and Rituxan, which generate the majority of royalties for the company, are facing rising biosimilar competition. This is likely to unfavorably impact Halozyme's royalty revenues going forward. The company also sells the bulk of rHuPH20 and ENHANZE drug product to its collaborators for use in clinical studies or drug manufacturing. Thus, the failure of clinical studies by partners, completion or termination of studies or collaborations and lower sales of partnered drugs will result in a decline in Halozyme's product revenues.
- ▼ **Pipeline Setbacks:** Gaining approval for pipeline candidates has become more difficult with an increasingly stringent regulatory environment. We note that Halozyme is no stranger to pipeline setbacks. In November 2019, Halozyme discontinued all clinical activities for PEGPH20 and oncology operations, following the failure of phase III HALO-301 study. The study evaluated a combination regimen of PEGPH20 first-line pancreatic cancer patients.
- ▼ **Product Sales Not Encouraging:** Halozyme's marketed product, Hylenex does not generate significant revenues for the company. In the first nine months of 2019, total sales from Hylenex were less than 10% of total revenues. Moreover, the company expects sales of Hylenex to remain flat or decline in the future as it faces intense rising competition in its targeted market.

Halozyme's dependence on partners for revenues remains a concern. Any setback to collaborations or partnered drugs will have an unfavorable impact.

Last Earnings Report

Halozyyme Q4 Earnings & Revenues Miss Estimates

Halozyyme reported fourth-quarter 2019 loss of 24 cents per share, wider than the Zacks Consensus Estimate of a loss of 18 cents. The company had reported loss of 1 cent in the year-ago quarter.

Total revenues declined 10.9% year over year to \$53.7 million, due to lower royalties and collaboration revenues, partially offset by higher product sales. The top line also missed the Zacks Consensus Estimate of \$55.22 million.

Quarter Ending **12/2019**

Report Date	Feb 24, 2020
Sales Surprise	-2.82%
EPS Surprise	-33.33%
Quarterly EPS	-0.24
Annual EPS (TTM)	-0.50

Quarterly Highlights

Halozyyme's top line comprises product sales, royalties and revenues under collaborative agreements.

Royalty revenues were \$17.2 million in the fourth quarter, down 10.9% from the year-ago quarter. Product sales, solely from the sale of bulk rHuPH20 to collaborators using the ENHANZE platform for drug development, increased 112.5% to \$22.7 million in the fourth quarter.

Revenues under collaborative agreements were \$13.7 million compared with \$30.2 million in the prior-year quarter. The significant decline was due to recognition of \$25 million upfront payment from Roche related to the expansion of their collaboration agreement in the year-ago quarter.

Full-Year Results

Halozyyme reported total revenues of \$196 million in 2019, up 29.1% year over year. The company reported a loss of 50 cents per share, compared with a loss of 56 cents in the year-ago period.

Business Developments

In December 2019, Janssen, a subsidiary of J&J, selected to develop JNJ-61186372 using ENHANZE technology, targeting EGFR and cMET in solid tumors.

In October 2019, Halozyyme's partner Roche nominated one new undisclosed target for evaluation in clinical study, utilizing the ENHANZE technology. This triggered a \$10-million milestone payment to Halozyyme. Its another partner, Bristol-Myers Squibb initiated a phase I study to evaluate relatlimab in combination with Opdivo, utilizing the ENHANZE technology in the same month.

2020 Guidance

Halozyyme reiterated its outlook for revenues and earnings in 2020, provided in January 2020. The company expects total revenues in 2020 to lie between \$230 million and \$245 million, indicating year-over-year growth of 17-25%. It expects reported earnings to be in the range of 60-70 cents per share.

Recent News

FDA Accepts BLA for Subcutaneous Combination of Perjeta-Herceptin – Feb 25

Halozyne announced that the FDA has accepted a BLA submitted by Roche seeking approval for subcutaneous administration of the fixed-dose combination of Perjeta and Herceptin for treating HER2-positive breast cancer. A decision is expected by Oct 18, 2020.

Announces Business Updates, Issues '20 Guidance – Jan 14

Halozyne announced key events related to its ENHANZE technology scheduled for 2020. The company also issued guidance for 2020 revenues.

In July 2019, Janssen, a subsidiary of J&J, submitted regulatory application in the United States and Europe seeking approval for a subcutaneous formulation of Darzalex (Darzalex SC) as a treatment for certain patients with multiple myeloma. Halozyne anticipates regulatory decisions related to approval for Darzalex SC, which uses ENHANZE drug delivery technology, in 2020. The company expects Roche to submit regulatory applications seeking approval for the fixed-dose combination of Perjeta and Herceptin utilizing ENHANZE technology in the first quarter of 2020. It also anticipates its collaboration partners using the ENHANZE technology to initiate at least three new Phase III, one Phase 2 clinical and at least five phase I clinical studies this year. These potential regulatory updates and clinical study initiations will likely generate significant milestone payments for the company in 2020.

Halozyne anticipates total revenues in 2020 to lie between \$230 million and \$245 million, indicating year-over-year growth of 18-26%.

The company also expects to complete share repurchase worth \$200 million in the first quarter of 2020, as part of its previously announced \$550 million share repurchase program. It also plans to repurchase shares worth up to \$150 million in the rest of 2020.

Valuation

Halozyne's shares are down 8.3% in the year-to-date period and 5.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 11.6% and 16.7% in the year-to-date period. Over the past year, stocks in the sub-industry and sector are down 15.4% and 16.5%, respectively.

The S&P 500 Index is down 22.6% in the year-to-date period and 14.2% in the past year.

The stock is currently trading at 11.69X trailing 12-month sales per share, which compares to 2.85X for the Zacks sub-industry, 2.61 X for the Zacks sector and 2.69X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 33.7X and as low as 6.25X, with a 5-year median of 12.35X. Our Neutral recommendation indicates that the stock will perform better than the market. Our \$18.00 price target reflects 12.95X trailing 12-month sales per share.

The table below shows summary valuation data for HALO

Valuation Multiples - HALO					
		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	11.69	2.85	2.61	2.69
	5-Year High	33.7	4.69	4.17	3.69
	5-Year Low	6.25	2.16	2.31	2.43
	5-Year Median	12.35	2.68	3.26	3.19
P/B TTM	Current	24.45	3.44	3.21	3.31
	5-Year High	162.86	5.46	5.05	4.55
	5-Year Low	NA	2.45	2.9	2.84
	5-Year Median	11.73	3.34	4.3	3.63

As of 04/06/2020

Industry Analysis Zacks Industry Rank: Top 11% (29 out of 253)



Top Peers

Acorda Therapeutics, Inc. (ACOR)	Outperform
Amicus Therapeutics, Inc. (FOLD)	Neutral
Guardant Health, Inc. (GH)	Neutral
IVERIC bio, Inc. (ISEE)	Neutral
Pharming Group NV (PHGUF)	Neutral
PHARMA MAR SA (PHMMF)	Neutral
Retrophin, Inc. (RTRX)	Neutral
ANI Pharmaceuticals, Inc. (ANIP)	Underperform

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	HALO Neutral	X Industry	S&P 500	ACOR Outperform	PHGUF Neutral	PHMMF Neutral
VGM Score	F	-	-	C	D	B
Market Cap	2.24 B	146.26 M	16.73 B	41.89 M	663.43 M	1.11 B
# of Analysts	4	3	13	3	3	1
Dividend Yield	0.00%	0.00%	2.53%	0.00%	0.00%	0.00%
Value Score	D	-	-	A	C	C
Cash/Price	0.17	0.30	0.06	2.78	NA	0.03
EV/EBITDA	-39.01	-2.01	10.55	1.96	NA	NA
PEG Ratio	NA	1.52	1.71	NA	NA	NA
Price/Book (P/B)	25.95	2.75	2.28	0.13	NA	NA
Price/Cash Flow (P/CF)	NA	12.95	8.96	0.18	NA	NA
P/E (F1)	26.71	26.60	14.34	NA	11.78	4.42
Price/Sales (P/S)	11.45	11.45	1.78	0.22	NA	NA
Earnings Yield	3.88%	-21.56%	6.84%	-118.39%	8.49%	22.60%
Debt/Equity	4.17	0.02	0.70	0.78	NA	-6.39
Cash Flow (\$/share)	-0.47	-1.03	7.01	4.83	-0.16	-0.05
Growth Score	F	-	-	F	C	A
Hist. EPS Growth (3-5 yrs)	NA%	18.12%	10.95%	NA	NA	NA
Proj. EPS Growth (F1/F0)	226.00%	5.00%	1.08%	40.12%	50.00%	969.23%
Curr. Cash Flow Growth	-14.25%	12.32%	5.92%	107.17%	NA	NA
Hist. Cash Flow Growth (3-5 yrs)	-0.94%	8.83%	8.55%	30.74%	NA	NA
Current Ratio	6.35	4.77	1.24	2.33	NA	0.84
Debt/Capital	80.67%	4.30%	42.29%	43.70%	NA	NA
Net Margin	-36.86%	-227.76%	11.69%	-141.87%	NA	NA
Return on Equity	-33.71%	-65.06%	16.74%	-22.18%	NA	NA
Sales/Assets	0.44	0.20	0.54	0.19	NA	NA
Proj. Sales Growth (F1/F0)	20.88%	8.86%	1.56%	-22.10%	19.00%	324.47%
Momentum Score	A	-	-	B	F	C
Daily Price Chg	-3.68%	-0.33%	-1.59%	3.28%	0.00%	0.00%
1 Week Price Chg	12.40%	7.46%	12.26%	6.81%	8.89%	11.00%
4 Week Price Chg	-18.87%	-24.52%	-22.86%	-24.77%	-20.30%	11.36%
12 Week Price Chg	-15.58%	-28.05%	-30.01%	-61.72%	-37.65%	17.65%
52 Week Price Chg	-3.90%	-40.59%	-23.87%	-93.33%	15.66%	168.82%
20 Day Average Volume	2,162,798	272,854	4,256,776	1,190,970	8,032	5,569
(F1) EPS Est 1 week change	0.00%	0.00%	-0.04%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	-4.29%	0.00%	-10.00%	0.00%
(F1) EPS Est 12 week change	48.82%	-1.43%	-5.40%	20.19%	-10.00%	0.00%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-5.90%	0.00%	NA	NA

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	D
Growth Score	F
Momentum Score	A
VGM Score	F

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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