

Halozyyme Therapeutics (HALO)

\$19.98 (As of 02/10/20)

Price Target (6-12 Months): **\$21.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 12/05/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

2-Buy

Zacks Style Scores:

VGM:F

Value: D

Growth: F

Momentum: D

Summary

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. Development of subcutaneous formulation of another blockbuster drug, Darzalex is 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. Rising competition for partnered drugs is also a concern.

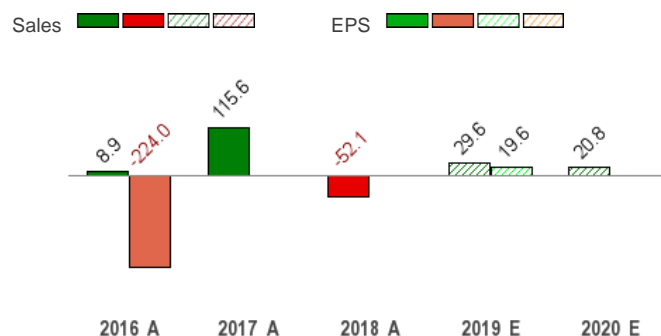
Price, Consensus & Surprise



Data Overview

| | |
|----------------------------|---|
| 52 Week High-Low | \$21.28 - \$14.61 |
| 20 Day Average Volume (sh) | 1,612,110 |
| Market Cap | \$2.9 B |
| YTD Price Change | 12.7% |
| Beta | 2.16 |
| Dividend / Div Yld | \$0.00 / 0.0% |
| Industry | Medical - Biomedical and Genetics |
| Zacks Industry Rank | Top 27% (70 out of 255) |

Sales and EPS Growth Rates (Y/Y %)



| | |
|---------------------------|------------|
| Last EPS Surprise | -41.7% |
| Last Sales Surprise | -21.4% |
| EPS F1 Est- 4 week change | 52.0% |
| Expected Report Date | 02/24/2020 |
| Earnings ESP | -38.9% |
| P/E TTM | NA |
| P/E F1 | 33.3 |
| PEG F1 | NA |
| P/S TTM | 14.5 |

Sales Estimates (millions of \$)

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|------|------|------|------|------|---------|
| 2020 | 36 E | 51 E | 66 E | 84 E | 238 E |
| 2019 | 57 A | 39 A | 46 A | 55 E | 198 E |
| 2018 | 31 A | 35 A | 26 A | 60 A | 152 A |

EPS Estimates

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|------|-----------|-----------|-----------|-----------|-----------|
| 2020 | -\$0.08 E | \$0.08 E | \$0.28 E | \$0.35 E | \$0.60 E |
| 2019 | \$0.01 A | -\$0.10 A | -\$0.17 A | -\$0.18 E | -\$0.45 E |
| 2018 | -\$0.19 A | -\$0.16 A | -\$0.19 A | -\$0.01 A | -\$0.56 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 02/10/2020. The reports text is as of 02/11/2020.

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.

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 \$151.9 million in 2018 compared with \$316.6 million in the year-ago period.



Reasons To Buy:

- ▲ **Shares Outperforming Industry:** Halozyme's shares have gained 20% in the past year against the industry's decrease of 1.1%.
- ▲ **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. In July 2019, J&J submitted regulatory application seeking approval for subcutaneous administration of Darzalex. A potential approval for the subcutaneous formulation of the blockbuster drug is likely to boost Halozyme's royalty revenues. Halozyme's proprietary drug delivery product, Hylenex recombinant, has also been developed using ENHANZE technology. The company also earns revenues from sale of ENHANZE drug product to collaborators.

- ▲ **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 will 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, it will reduce headcount by 55% or 160 employees.

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. The company expects to reach sustainable profitability by the second quarter of 2020. 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 will be completed in the first quarter of 2020. 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 another \$1 billion in annual royalties from its ENHANZE technology by 2027. Moreover, the ENHANZE technology is expected to bring \$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.

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

▼ **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. In 2013, an early-stage study conducted by SWOG, a cancer research cooperative group, on PEGPH20 was halted due to unfavorable data. The candidate, in combination with Folfirinox, failed to improve OS in stage IV PDA patients compared to Folfirinox alone. Moreover, higher gastrointestinal toxicities were observed in the PEGPH20 arm of the study. Any setback in the ongoing late-stage PDA study will significantly impact the company's future prospect.

▼ **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.

Last Earnings Report

Halozyme Earnings & Revenues Miss Estimates in Q3

Halozyme Therapeutics reported third-quarter 2019 loss of 17 cents per share, wider than the Zacks Consensus Estimate of a loss of 12 cents. The company had reported loss of 19 cents in the year-ago quarter.

Total revenues increased 80.5% year over year to \$46.2 million, driven by higher product sales, partially offset by lower royalties. However, the top line missed the Zacks Consensus Estimate of \$58.82 million.

Quarter Ending **09/2019**

| Report Date | Nov 12, 2019 |
|------------------|--------------|
| Sales Surprise | -21.40% |
| EPS Surprise | -41.67% |
| Quarterly EPS | -0.17 |
| Annual EPS (TTM) | -0.27 |

Quarter in Detail

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

Royalty revenues were \$16.6 million in the third quarter, down 11.2% from the year-ago quarter. The decline was due to lower sales of Roche's breast cancer drug, Herceptin SC, which was partially offset by higher sales of Roche's Rituxan Hycela and Takeda's (TAK) HyQvia. These drugs are developed using Halozyme's ENHANZE drug delivery technology.

Product sales, solely from the sale of bulk rHuPH20 to collaborators using the ENHANZE platform for drug development, increased 365% to \$29.2 million in the third quarter. The significant increase was primarily attributable to sales of \$20.1 million to Janssen, a subsidiary of J&J. Revenues under collaborative agreements were \$0.4 million compared with \$0.6 million in the prior-year quarter.

Research and development expenses declined 14.1% to \$30.5 million primarily due to lower expenses related to clinical studies, as the company progressed toward the completion of HALO-301 study on its lead pipeline candidate, PEGPH20. However, the study was discontinued in November following failure to meet primary endpoint.

General and administrative expenses were up 20.8% to \$18 million in the reported quarter primarily due to costs related to commercialization initiatives to support oncology operations.

2019 Guidance

Halozyme lowered its revenue guidance for 2019 to \$195-\$205 million from \$205-\$215 million mentioned earlier. The guidance was lowered due to delay in the initiation of a planned phase III study on a partnered candidate, partially offset by new unplanned target nomination. These activities generate revenues for the company either through product sales or milestone payments. It also lowered its guidance for royalty revenues to \$67-\$69 million from \$72-\$74 million stated previously.

The company maintained its expectation for year-end cash, cash equivalents and marketable securities of \$220-\$230 million. It increased the outlook for operating expenses to \$255-\$265 million from previously mentioned \$215-\$225 million. The increase was led by anticipated one-time restructuring costs of \$25-\$27 million, which will be incurred in the fourth quarter.

Recent News

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 up 12.7% in the year-to-date period and 20% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are up 0.6% and 1.1% in the year-to-date period. Over the past year, stocks in the sub-industry are down 1.1% while stocks in the sector are up 2.2%.

The S&P 500 Index is up 3.2% in the year-to-date period and 20.3% in the past year.

The stock is currently trading at 14.42X trailing 12-month sales per share, which compares to 2.82X for the Zacks sub-industry, 3.16X for the Zacks sector and 3.97X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 32.55X and as low as 6.78X, with a 5-year median of 12.3X. Our Neutral recommendation indicates that the stock will perform better than the market. Our \$21.00 price target reflects 15.16X forward 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 | 14.42 | 2.82 | 3.16 | 3.97 |
| | 5-Year High | 32.55 | 5.03 | 4.16 | 3.98 |
| | 5-Year Low | 6.78 | 2.15 | 2.75 | 2.54 |
| | 5-Year Median | 12.3 | 2.65 | 3.28 | 3.13 |
| P/B TTM | Current | 11.93 | 3.88 | 4.59 | 4.29 |
| | 5-Year High | 157.39 | 5.79 | 5.03 | 4.42 |
| | 5-Year Low | 8.24 | 2.46 | 3.49 | 2.9 |
| | 5-Year Median | 29.03 | 3.27 | 4.3 | 3.62 |

As of 02/10/2020

Industry Analysis Zacks Industry Rank: Top 27% (70 out of 255)



Top Peers

| | |
|--|--------------|
| Alkermes plc (ALKS) | Neutral |
| Amphastar Pharmaceuticals, Inc. (AMPH) | Neutral |
| Ascendis Pharma A/S (ASND) | Neutral |
| Bausch Health Cos Inc. (BHC) | Neutral |
| Eli Lilly and Company (LLY) | Neutral |
| Merck & Co., Inc. (MRK) | Neutral |
| Nektar Therapeutics (NKTR) | Neutral |
| Ligand Pharmaceuticals Incorporated (LGND) | Underperform |

| Industry Comparison Industry: Medical - Biomedical And Genetics | | | | Industry Peers | | |
|---|--------------|------------|-----------|----------------|-------------------|--------------|
| | HALO Neutral | X Industry | S&P 500 | ALKS Neutral | LGND Underperform | NKTR Neutral |
| VGM Score | F | - | - | D | F | C |
| Market Cap | 2.93 B | 206.50 M | 24.17 B | 3.01 B | 1.69 B | 3.93 B |
| # of Analysts | 4 | 3 | 13 | 8 | 1 | 7 |
| Dividend Yield | 0.00% | 0.00% | 1.77% | 0.00% | 0.00% | 0.00% |
| Value Score | D | - | - | C | C | B |
| Cash/Price | 0.08 | 0.22 | 0.04 | 0.20 | 0.64 | 0.38 |
| EV/EBITDA | -43.22 | -3.59 | 13.89 | -342.61 | 4.63 | 3.84 |
| PEG Ratio | NA | 1.84 | 2.05 | 1.70 | 1.84 | NA |
| Price/Book (P/B) | 11.91 | 3.89 | 3.27 | 2.82 | 2.21 | 2.63 |
| Price/Cash Flow (P/CF) | NA | 13.76 | 13.60 | 30.87 | 28.92 | 5.59 |
| P/E (F1) | 33.30 | 29.59 | 19.00 | 35.30 | 27.53 | NA |
| Price/Sales (P/S) | 14.45 | 14.12 | 2.66 | 2.80 | 14.07 | 32.62 |
| Earnings Yield | 3.00% | -15.16% | 5.26% | 2.83% | 3.63% | -10.96% |
| Debt/Equity | 0.04 | 0.02 | 0.71 | 0.26 | 0.85 | 0.26 |
| Cash Flow (\$/share) | -0.56 | -1.08 | 6.89 | 0.62 | 3.33 | 4.00 |
| Growth Score | F | - | - | B | F | D |
| Hist. EPS Growth (3-5 yrs) | NA% | 16.51% | 10.85% | NA | 24.48% | NA |
| Proj. EPS Growth (F1/F0) | 233.71% | 7.19% | 7.22% | 2.34% | 13.27% | 4.24% |
| Curr. Cash Flow Growth | -225.01% | 19.21% | 8.88% | 126.78% | -70.63% | -1,067.24% |
| Hist. Cash Flow Growth (3-5 yrs) | 0.03% | 7.72% | 8.36% | -9.18% | 16.16% | 46.22% |
| Current Ratio | 3.17 | 5.12 | 1.22 | 2.69 | 66.09 | 12.60 |
| Debt/Capital | 3.66% | 3.95% | 42.90% | 20.46% | 45.82% | 20.90% |
| Net Margin | -19.73% | -201.70% | 11.81% | -18.71% | 523.19% | -352.83% |
| Return on Equity | -15.76% | -64.16% | 16.98% | -6.08% | 4.34% | -26.60% |
| Sales/Assets | 0.49 | 0.21 | 0.54 | 0.61 | 0.07 | 0.06 |
| Proj. Sales Growth (F1/F0) | 12.55% | 17.19% | 4.06% | -8.41% | 2.91% | 37.39% |
| Momentum Score | D | - | - | F | D | B |
| Daily Price Chg | 1.45% | 0.17% | 0.45% | 0.74% | 1.12% | -1.11% |
| 1 Week Price Chg | 3.77% | 1.53% | 2.47% | 8.90% | 8.50% | 13.68% |
| 4 Week Price Chg | 6.45% | 0.00% | 0.95% | 0.42% | 6.83% | -18.39% |
| 12 Week Price Chg | 5.80% | 14.99% | 5.05% | -5.26% | -6.93% | 24.15% |
| 52 Week Price Chg | 21.98% | -5.88% | 16.18% | -39.13% | -18.34% | -51.76% |
| 20 Day Average Volume | 1,612,110 | 189,021 | 1,999,386 | 1,452,285 | 327,014 | 2,371,837 |
| (F1) EPS Est 1 week change | -3.26% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| (F1) EPS Est 4 week change | 51.97% | 0.00% | 0.00% | -19.05% | -19.39% | 2.39% |
| (F1) EPS Est 12 week change | 293.88% | 0.00% | -0.18% | -19.05% | -19.39% | 5.27% |
| (Q1) EPS Est Mthly Chg | -6.67% | 0.00% | 0.00% | 0.00% | NA | 16.78% |

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 | D |
| 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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