

## Greenwich LifeSciences, Inc.

Mar 18, 2026

Healthcare

**GLSI**

NCM

Rating

**Outperform**

Unchanged

Current Price

**\$30.05**

Target Price

**\$45.00**

Market Capitalization

**416.33m**

Shares Outstanding

**13.85m**

Float

**6.72m**

Institutional Holdings

**9.58%**

12-Month Low/High

**\$7.78/\$34.10**

Average 90-Day Volume

**414460**

Fiscal Year End

**12/31/2026**

### **Preliminary Phase 3 FLAMINGO-01 Update Shows Reduction In Breast Cancer Recurrence Rate**

**New Analysis Shows Less Than 1% Recurrence Rate.** Greenwich Pharmaceuticals announced a preliminary update from its FLAMINGO-01 trial. The data from the open-label arm of the trial showed a recurrence rate of less than 1% per year compared to a recurrence rate of 4% per year for patients treated with Kadcyla (ado-trastuzumab emtansine or T-DM1, from Genentech) in the Phase 3 KATHERINE Study. This is a 70% to 80% reduction in the historical recurrence rate for these patients.

**Background On The Phase 3 FLAMINGO-01 Trial.** The trial tests GLSI-100, an immunotherapy to prevent recurrence of HER2-positive breast cancer. Its design has a double-blind portion that enrolls patients with the immune marker HLA-A\*02 to receive either GLSI-100 or placebo, and an open-label arm that enrolls patients that have other HLA types (non-HLA-A\*02). The new data is from the open-label arm of the trial.

**Results Showed A Significant Decrease In Recurrence To Date.** Patients had an average exposure of 1.2 years after the primary immunization series (PIS). The annual recurrence rate for these patients was compared with Kadcyla patients over a similar time period in Phase 3 KATHERINE study. GLSI-100 patients had an annual recurrence rate of 0.7% compared with 4% rate for Kadcyla. This is an 83% reduction in recurrence rate (Chi Square,  $p < 0.005$ ).

**We See This As A Strong Positive For The FLAMINGO-01 Trial.** These data are similar to the 5-year survival rates in the GLSI-100 Phase 2b trial, where the recurrence rate for HLA-A\*02 patients was reduced by 80%. This rate compared with a 50% reduction for products available at that time. The open-label arm reached full enrollment of 250 patients in late December, while the placebo-controlled arms continue toward the 500-patient enrollment target.

**Conclusion.** The new data is consistent with the previous Phase 2b results and shows a significant improvement in recurrence rate over the best published data. We believe this could improve recruitment into the two placebo-controlled arms. We are reiterating our Outperform rating and \$45 price target.

### **Equity Research**

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#### **Revenues (\$ MIL)**

Period	2024A	2025E	2026E
Q1	0.0	0.0A	0.0E
Q2	0.0	0.0A	0.0E
Q3	0.0	0.0E	0.0E
Q4	0.0	0.0E	0.0E
	0.0	0.0E	0.0E

#### **EPS (\$)**

Period	2024A	2025E	2026E
Q1	(0.19)	(0.25)A	(0.35)E
Q2	(0.20)	(0.30)A	(0.36)E
Q3	(0.20)	(0.36)E	(0.37)E
Q4	(0.60)	(0.34)E	(0.40)E
	(1.21)	(1.30)E	(01.48)E

**Summary.** Greenwich Pharmaceuticals announced a preliminary update from its FLAMINGO-01 trial. The data from the open-label arm of the trial showed a recurrence rate of less than 1% per year compared to a recurrence rate of 4% per year for patients treated with Kadcylla (ado-trastuzumab emtansine or T-DM1, from Genentech) in the Phase 3 KATHERINE Study. This is a 70% to 80% reduction in the recurrence rate for these patients.

Kadcyla is an antibody–drug conjugate that combines the targeted therapy trastuzumab (Herceptin) with chemotherapy agent DM1 to deliver the drug into cancer cells. It was tested in the Phase 3 KATHERINE trial, a randomized study that compared Kadcylla against Herceptin (trastuzumab) in HER2-positive breast cancer patients with residual invasive disease.

**Background On GLSI-100 and The Phase 3 FLAMINGO-01 Trial.** The trial tests GLSI-100, an immunotherapy to prevent recurrence of HER2-positive breast cancer. It delivers the antigen GP2, a 9-amino acid segment of the transmembrane peptide HER2. If cancer cells start to recur or metastasize, these immune cells can recognize the HER2-positive cancer cells, start a response, and kill them. For a detailed discussion of GLSI-100 and the FLAMINGO-01 trial, please see [our Initiation of Coverage report](#).

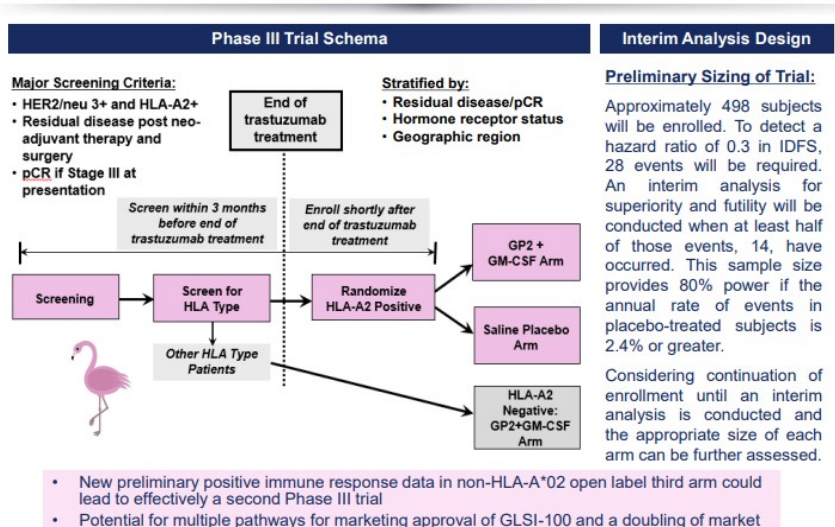
The Phase 3 FLAMINGO-01 trial is testing GLSI-100 for prevention of breast cancer recurrence in patients with residual disease or at high-risk of recurrence. Patients enrolled in the trial are screened for their level of HER2 expression and by HLA type, an immune criteria. HLA antigens are a common cell surface marker found on most cells in the body and are part of the immune response.

Patients with the immune marker HLA-A\*02 are randomized into a double-blind portion and receive either GLSI-100 or placebo. Patients with other HLA types (non-HLAA\*02) are enrolled into an open label arm. Each arm has a target enrollment of about 250 patients, for a total of roughly 750 patients.

The Primary Endpoint is a hazard ratio of 0.3 in invasive breast cancer-free survival, where 28 events will be required. An interim analysis for superiority and futility will be conducted when at least half of those events, 14, have occurred. This sample size provides 80% power if the annual rate of events in placebo-treated subjects is 2.4% or greater.

**Exhibit 1. Phase 3 FLAMINGO Trial Design.** The double-blinded arms of the Phase III trial have a planned enrollment of 500 HLA-A\*02 patients, and about 250 patients of other HLA types have been enrolled in the open-label arm.

### Flamingo-01 - Phase III Trial Schema & Interim Analysis

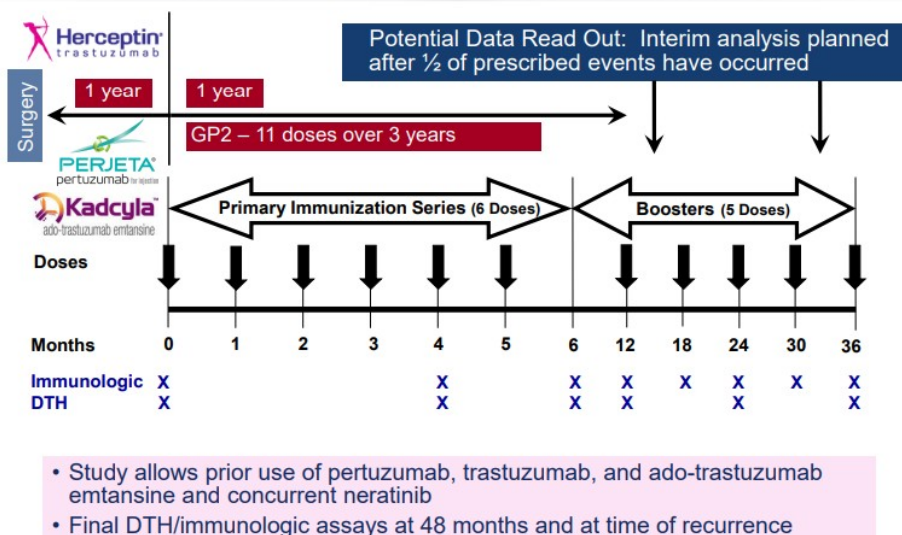


Source: Greenwich LifeSciences, Inc.

**Exhibit 2: Phase 3 FLAMINGO Trial Treatment and Dosing Schedule.** Following surgery, patients complete a standard one-year course of Herceptin (trastuzumab, an anti-HER2 antibody) as both neoadjuvant and postoperative adjuvant-based

treatment. GLSI-100 is given once per month for six months, followed by 5 booster doses every 6 months for a total of 11 doses over 3 years. The first six month period is referred to as the Primary Immunization Series (PIS), in which the immune system starts the process of recognition for its primary immune response. The PIS can be measured by a local skin test and an immunological assay. The primary endpoint of the trial is recurrence-free survival.

### GP2 Phase III Clinical Trial Dosing



Source: Greenwich LifeSciences, Inc.

**Results Showed A Significant Decrease In Recurrence To Date.** Patients in the analysis were non-HLA-A\*02 open-label arm with an average exposure of 1.2 years after the primary immunization series (PIS). The annual recurrence rate for these patients was compared with Kadcyla patients over a similar time period in the Phase 3 KATHERINE study, showing an annual recurrence rate for GLSI-100 patients of 0.7% compared with the 4% rate for Kadcyla patients. This shows an 83% reduction in recurrence rate (Chi Square,  $p < 0.005$ ).

**We See This As A Strong Positive For The FLAMINGO-01 Trial.** This data is similar to the 5-year survival rates in the GLSI-100 Phase 2b trial, in which the recurrence rate for HLA-A\*02 patients was reduced by 80%. This rate compared with a 50% reduction for products available at that time.

**Conclusion.** The new data shows a significant improvement in recurrence rate over the best published data and is consistent with the previous Phase 2b results. The open-label arm of the trial reached full enrollment of 250 patients in late December, while the placebo-controlled arms continue toward the 500-patient full enrollment target. We believe this could improve recruitment into the two placebo-controlled arms. We are reiterating our Outperform rating and \$45 price target.

## Company Profile

**Company Description.** Greenwich LifeSciences is a biotechnology company developing GLSI-100, an immunotherapy to prevent recurrence of breast cancer. GLSI-100 completed four clinical trials before starting the current Phase 3 Flamingo-01 trial. The trial began in January 2023 and is currently enrolling patients in the US and Europe.

## Valuation Summary

Our valuation is based on completion of the Phase 3 Flamingo-01 trial, followed by market entry by FY2028. We value the stock based on FY2029 EPS of \$9.90 per share. We believe this to be a conservative estimate for the first full year of sales, which could come earlier. Applying a multiple of 15X to the discounted EPS for a target of \$45 per share.



A - 03/04/2026 Outperform Target \$45.00 Current \$27.00  
 C - 12/10/2025 Outperform Target \$45.00 Current \$10.11  
 E - 08/20/2025 Outperform Target \$45.00 Current \$11.94

B - 12/19/2025 Outperform Target \$45.00 Current \$13.01  
 D - 09/15/2025 Outperform Target \$45.00 Current \$11.68

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Noble intends to seek compensation for investment banking services and non-investment banking services (securities and non-securities related) within the next 3 months.

Noble is not a market maker in the Company.

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

### Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

### The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or underserved needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

### Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

### Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

### Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclical, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

### ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	88%	15%
Market Perform: potential return is -15% to 15% of the current price	12%	2%
Underperform: potential return is >15% below the current price	0%	0%

**NOTE:** On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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