

COMPANY PROFILE

Business Description: Greenwich LifeSciences (the “Company”) is a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery. GP2 is a 9 amino acid transmembrane peptide of the HER2/*neu* (human epidermal growth factor receptor 2) protein, a cell surface receptor protein that is expressed in a variety of common cancers, including in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or “over-expressor”) levels.

Substantial Unmet Need: 1 in 8 U.S. women will develop invasive breast cancer over her lifetime. There are approximately 700,000 new breast cancer patients and 9.5 million breast cancer survivors in the US and EU in 2025. In the adjuvant setting, a HER2/*neu* positive patient typically receives Herceptin in the first year following breast cancer surgery, with the hope that their breast cancer will not recur, and with the odds of recurrence slowly decreasing over the first 5 years following surgery. Herceptin has been shown to reduce recurrence rates by 50%, from 25% to 12%, in the adjuvant setting. In the neoadjuvant setting, a HER2/*neu* 3+ patient receives treatment before surgery and based on the results of a biopsy at surgery, will receive Herceptin or Kadcyla, a more potent form of Herceptin, following surgery. Kadcyla has been shown to reduce recurrence rates by 50%, from 22% to 11%, in the neoadjuvant setting. Accordingly, the Company believes that GP2 immunotherapy may be effective in safely addressing the 50% of recurring patients who do not respond to either Herceptin or Kadcyla.

Phase IIb Clinical Data in HER2/*neu* 3+ Over-Expressors: In a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) Phase IIb clinical trial led by MD Anderson and completed in 2018, an 80% or greater reduction in recurrences was observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patient was treated, followed, and remained disease free over the first 6 months, which is the time required to reach peak immunity and thus maximum efficacy and protection. Furthermore, the GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays. Of the 146 patients who have been treated with GP2 immunotherapy to date over 4 clinical trials, no serious adverse events were reported related to GP2 immunotherapy, and GP2 immunotherapy was well tolerated. The Phase IIb clinical trial results can be summarized as:

- 80% or greater reduction in metastatic breast cancer recurrence rate over 5 years of follow-up compared to 20-50% reduction in recurrence rate by other approved products
- Peak immunity at 6 months
- No serious adverse events attributable to treatment
- A well tolerated safety profile

Ongoing Phase III Clinical Trial: Greenwich LifeSciences is currently advancing GLSI-100 through its global Phase III clinical trial, called Flamingo-01, in which up to 750 patients are planned to be treated. In alignment with top-tier research networks — US (US Oncology), Spain (GEICAM), Italy (GIM), France (Unicancer), Germany (GBG), and Polish network— and prestigious institutions across 150 clinical sites, Greenwich LifeSciences is striving to build on the promising results of the Phase IIb clinical trial.

MANAGEMENT TEAM

Snehal S. Patel

Chief Executive Officer

F. Joseph Daugherty, M.D.

Chief Medical Officer

Jaye Thompson, Ph.D.

VP Clinical & Regulatory Affairs

Christine Fischette, Ph.D.

VP Business Development

BOARD OF DIRECTORS

David B. McWilliams

Chairman of the Board

Eric Rothe

Board Member, Founder

Kenneth Hallock

Board Member

Snehal S. Patel

Board Member

F. Joseph Daugherty, M.D.

Board Member

STOCK OVERVIEW

Symbol	GLSI
Exchange	Nasdaq
Last Price	\$11.15
52-Week Low	\$8.06
52-Week High	\$15.50

09/17/2025 08:00 PM EDT

CONTACT

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DISCLAIMER

Except for the historical information contained here in, the matters discussed in this document are forward-looking statements that involve risks and uncertainties, including but not limited to business conditions and the amount of growth in our industry and general economy, competitive factors, and other risks detailed from time to time in the Company's SEC reports, including but not limited to its annual reports on form 10-K and its quarterly reports on Form 10-Q. The company does not undertake any obligation to update forward-looking statements. All trademarks and brand name are the property of their respective companies.

Greenwich LifeSciences' GLSI-100 Granted US FDA Fast Track Designation

Sep 10 2025, 6:00 AM EDT

Noble Capital Markets Initiates Equity Research Coverage on Greenwich LifeSciences

Aug 20 2025, 9:25 AM EDT

Greenwich LifeSciences Announces Plan to Build Out Internal Clinical Operations Team

Aug 19 2025, 6:00 AM EDT