



Market Data

Greenwich LifeSciences

NASDAQ: GLSI

Fiscal Year December

Industry Biopharma

Recent Price \$9.97

52-Wk Range \$6.82- \$45.23

Market Cap \$130M

Shares Out. 13.0M

Float 2.9M

Avg. Volume (90-day) 67,924

Cash (mrq) \$17.2M

As of September 16, 2022greenwichlifesciences.com

Company Overview

Greenwich LifeSciences 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.

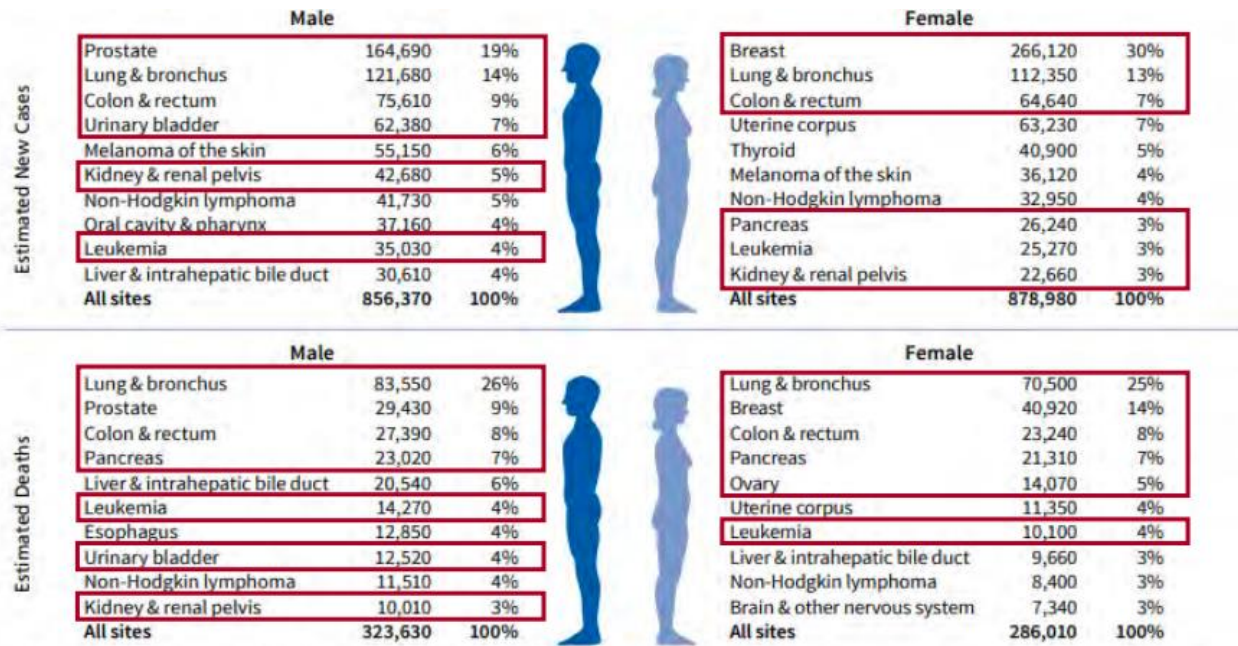
Value Proposition

One in 8 U.S. women will develop invasive breast cancer over her lifetime, with approximately 266,000 new breast cancer patients and 3.1 million breast cancer survivors in 2018. Following breast cancer surgery in the adjuvant setting, a HER2/neu 3+ patient typically receives Herceptin® in the first year, with the hope that their breast cancer will not recur, and with the odds of recurrence slowly decreasing over the first 5 years after surgery. Herceptin® has been shown to reduce recurrence rates from 25% to 12% in the adjuvant setting. In the neoadjuvant setting, a patient receives treatment before surgery and based on the results of a biopsy at surgery, will receive the same or more potent treatment after surgery. Kadcyla® has been shown to reduce recurrence rates from 22% to 11% in the neoadjuvant setting. Accordingly, we believe that GP2 may be used to address the 50% of recurring patients who do not respond to either Herceptin® or Kadcyla®.

In a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) Phase IIb clinical trial led by MD Anderson, no recurrences were observed in the HER2/neu 3+ adjuvant setting after median 5 years of follow-up, if the patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$). Furthermore, the GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays. Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 immunotherapy was well tolerated, and no serious adverse events were reported related to the GP2 immunotherapy.

- No cancer recurrences if fully immunized
- No reported serious adverse events
- A well tolerated safety profile

In August 2022, Greenwich LifeSciences officially launched its Phase III clinical trial that is conservatively designed to reproduce the Phase IIb clinical trial results. The Company is now transitioning to pre-commercialization activities, including working with the FDA in preparation for a BLA submission and product launch, as well as global strategy development for markets outside the EU and US, and large-scale manufacturing, packing, and marketing initiatives.



Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Ranking is based on modeled projections and may differ from the most recent observed data.

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Denotes cancers where HER2/neu over expression has been reported

Investment Highlights

- ✓ **Activated FDA-reviewed Phase 3 trial of GP2, the Company's lead candidate and a breakthrough targeted immunotherapy to prevent breast cancer recurrences, in August 2022**
- ✓ **Completed manufacturing for multi-center Phase 3 trial**
- ✓ **Successfully completed three Phase 1 and one Phase 2b trials for GP2; Phase 2b resulted in no recurrences, if fully immunized, vs. 11% placebo recurrence rate in 96 patients, with minimal to no side effects**
- ✓ **Multiple Phase 2 trial opportunities to expand market: HER2/neu 1-2+ patients with Herceptin, other HLA types, combination with CD4/CD8 peptides and checkpoints, other HER2/neu cancers**
- ✓ **Over \$20M in private capital and grants invested in GP2 prior to IPO**
- ✓ **Veteran management team and board**