

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **April 14, 2021**

**Greenwich LifeSciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**001-39555**

(Commission  
File Number)

**20-5473709**

(I. R. S. Employer  
Identification No.)

**3992 Bluebonnet Dr, Building 14  
Stafford, TX 77477**

(Address of principal executive offices, including ZIP code)

**(832) 819-3232**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common stock, \$0.001 par value	GLSI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒ [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐ [ ]

**Item 8.01 Other Events.**

On April 14, 2021, Greenwich LifeSciences, Inc. (the "Company") issued a press release announcing the publication of a second poster for the GP2 Phase III clinical trial design for recurring breast cancer at the 2021 AACR Annual Meeting. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release dated April 14, 2021</a>

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto

duly authorized.

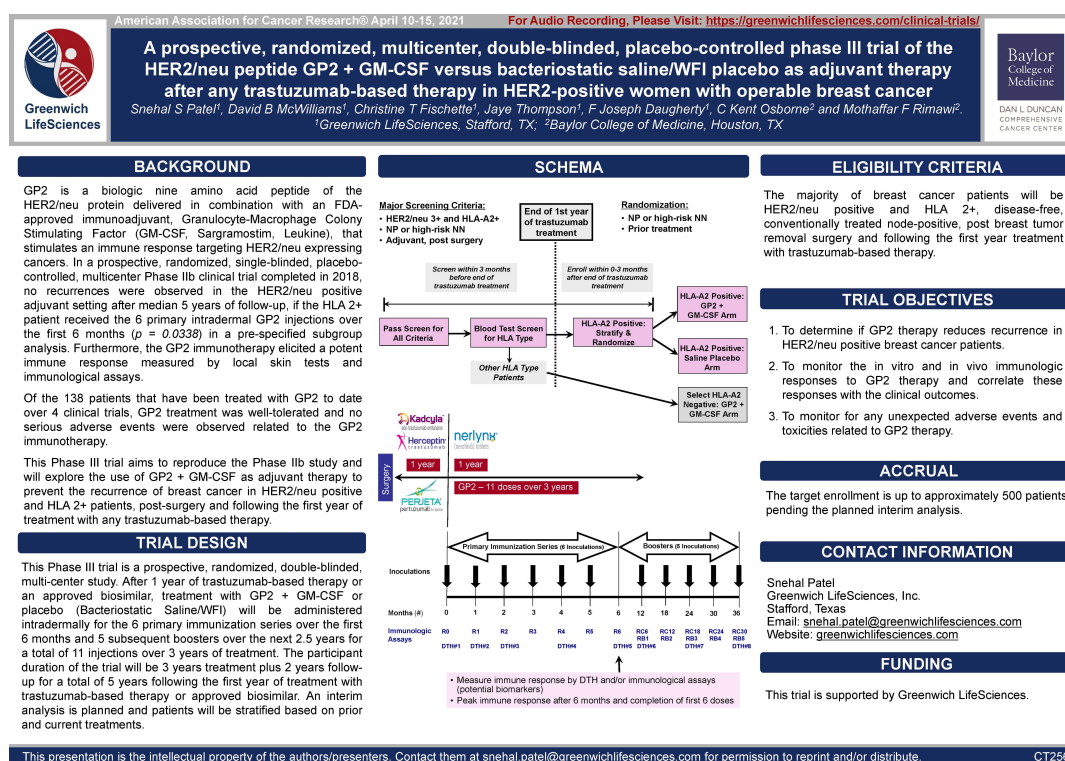
**Greenwich LifeSciences, Inc.**

Date: April 15, 2021

By: /s/ Snehal Patel  
Snehal Patel  
Chief Executive Officer

## Greenwich LifeSciences Announces Update of GP2 Phase III Clinical Trial Design at the 2021 AACR Annual Meeting

- The GP2 Phase III clinical trial design was presented in a poster during the 2021 American Association for Cancer Research (AACR) Annual Meeting, introduced by the Global Principal Investigator, Professor Mothaffar F. Rimawi of Baylor College of Medicine.
- The Company plans to complete manufacturing of GP2 by the end of the 3rd quarter 2021 and plans to commence the Phase III clinical trial thereafter.
- A third open-label arm has been added to the Phase III trial to test GP2 in HLA types other than HLA-A02 and to assess immune response and clinical outcome. This third arm will function similar to a Phase II trial, thus creating potential for early immune response data analysis and proof of concept that GP2 can treat other HLA types, which would expand GP2's market by HLA type from 50% up to 80% or more.
- In some clinical sites for the Phase III trial, up to 8 immune response tests will be taken over time to assess immune response beyond the 2.5 years tracked in the Phase IIb trial, thus providing additional high quality immune response data to help identify responders and correlations to clinical outcome.
- The Phase III trial design will include an event-driven interim analysis for superiority or futility. This analysis will be conducted when approximately half of the expected breast cancer recurrences have occurred, which may allow for submission of a Biologics Licensing Application (BLA) to the FDA for conditional marketing approval of GP2 approximately halfway through the trial.



Poster Presentation CT256 from 2021 AACR Annual Meeting Showing GP2 Phase III Clinical Trial Design for Recurring Breast Cancer

STAFFORD, Texas—(Business Wire)— Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the “Company”), 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, today announced the publication of a second poster for the GP2 Phase III clinical trial design for recurring breast cancer at the 2021 AACR Annual Meeting. The Global Principal Investigator of the GP2 Phase III clinical trial, Dr. Mothaffar F. Rimawi of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, is the lead author of the poster and has recorded an audio track providing an overview.

The AACR published the Phase III trial design abstract on April 9, 2021 and the poster on April 10, 2021. The abstract can be viewed at the bottom of this press release and the full poster with audio can be accessed or downloaded on the Company website at <https://greenwichlifesciences.com/clinical-trials/#Phase-III>.

Snehal Patel, CEO of Greenwich LifeSciences, commented, ‘At present, the Phase III trial is designed to treat up to 500 patients. The data read out for the interim analysis will be event driven and could be completed approximately halfway through the planned 5 year follow-up. The recently reported robust immune response data, which peaked after 6 months in the Phase IIb trial, will help to finalize the Phase III trial design, including the immune response monitoring strategy. We will also assess immune response in an open-label third arm across multiple HLA types to potentially expand the market for GP2. This immune response data could be reported before the interim analysis.’

**Updated Phase III Clinical Trial Design:** The Company and the Baylor College of Medicine presented the updated design of the planned Phase III clinical trial to breast cancer key opinion leaders. The Phase III clinical trial is a prospective, randomized, double-blinded, multi-center trial. The primary efficacy endpoints for the three arms of the Phase III trial are invasive Disease Free Survival (iDFS). The objective is to conservatively reproduce the Phase IIb trial results which demonstrated 100% iDFS with 5 years of

follow-up in the HER2/*neu* 3+ population.

In addition to the trial design updates in the bullet points above, patients meeting all entry criteria will be randomized to receive either GP2 + GM-CSF or placebo. The Phase III trial design includes the use of saline in the placebo arm, instead of GM-CSF, which was used in the placebo arm of the Phase IIb trial. GM-CSF is not the standard of care and may cause immune responses in placebo patients.

Dr. Jaye Thompson, VP of Clinical and Regulatory Affairs, added, “It is critical that the study population and design in the protocol are carefully crafted so that the resulting data provides convincing evidence of safety and efficacy for the BLA submission. We have already engaged a statistician to design the interim analysis and have begun recruiting clinicians and clinical sites for participation in the Phase III trial.”

#### **AACR Abstract CT256**

**Title: A prospective, randomized, multicenter, double-blinded, placebo-controlled phase III trial of the HER2/*neu* peptide GP2 + GM-CSF versus bacteriostatic saline/WFI placebo as adjuvant therapy after any trastuzumab-based therapy in HER2-positive women with operable breast cancer**

**Snehal S Patel<sup>1</sup>, David B McWilliams<sup>1</sup>, Christine T Fischette<sup>1</sup>, Jaye Thompson<sup>1</sup>, F Joseph Daugherty<sup>1</sup>, C Kent Osborne<sup>2</sup> and Mothaffar F Rimawi<sup>2</sup>.**

<sup>1</sup>Greenwich LifeSciences, Stafford, TX; <sup>2</sup>Baylor College of Medicine, Houston, TX

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**Background:** GP2 is a biologic nine amino acid peptide of the HER2/*neu* protein delivered in combination with an FDA-approved immunoadjuvant Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF, Sargramostim, Leukine) that stimulates an immune response targeting HER2/*neu* expressing cancers. In a prospective, randomized, single-blinded, placebo-controlled, multicenter Phase IIb clinical trial completed in 2018, no recurrences were observed in the HER2/*neu* positive adjuvant setting after median 5 years of follow-up, if the HLA 2+ patient received the 6 primary intradermal injections over the first 6 months ( $p = 0.0338$ ) in a pre-specified subgroup analysis. 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 treatment was well tolerated and no serious adverse events were observed related to the GP2 immunotherapy. This Phase III trial aims to reproduce the Phase IIb study and will explore the use of GP2 + GM-CSF as adjuvant therapy to prevent the recurrence of breast cancer in HER2/*neu* positive and HLA 2+ patients, post-surgery and following the first year treatment with any trastuzumab-based therapy.

**Trial Design:** This Phase III trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy or an approved biosimilar, treatment with GP2 + GM-CSF or placebo (Bacteriostatic Saline/WFI) will be administered intradermally for the 6 primary immunization series over the first 6 months and 5 subsequent boosters over the next 2.5 years for a total of 11 injections over 3 years of treatment. The participant duration of the trial will be 3 years treatment plus 2 years follow-up for a total of 5 years following the first year treatment with trastuzumab-based therapy or approved biosimilar. An interim analysis is planned and patients will be stratified based on prior and current treatments, among other factors.

**Eligibility Criteria:** The majority of breast cancer patients will be HER2/*neu* positive and HLA 2+, disease-free, conventionally treated node-positive, post breast tumor removal surgery and following the first year treatment with trastuzumab-based therapy.

#### **Trial Objectives:**

1. To determine if GP2 therapy reduces recurrence in HER2/*neu* positive breast cancer patients.
2. To monitor the in vitro and in vivo immunologic responses to GP2 therapy and correlate these responses with the clinical outcomes.
3. To monitor for any unexpected adverse events and toxicities related to GP2 therapy.

**Accrual:** The target enrollment is up to approximately 500 patients.

**Funding:** This trial is supported by Greenwich LifeSciences.

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#### **About the AACR Annual Meeting 2021**

The AACR is the first and largest cancer research organization dedicated to accelerating the conquest of cancer and has more than 48,000 members residing in 127 countries and territories. The AACR Annual Meeting program covers the latest discoveries across the spectrum of cancer research — from population science and prevention; to cancer biology, translational, and clinical studies; to survivorship and advocacy — and highlights the work of the best minds in research and medicine from institutions all over the world.

#### **About Breast Cancer and HER2/*neu* Positivity**

One in eight 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. HER2/*neu* (human epidermal growth factor receptor 2) protein is 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.

#### **About Greenwich LifeSciences, Inc.**

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* protein. In a randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial, 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 ( $p = 0.0338$ ). Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 treatment was well tolerated and no serious adverse events were observed related to GP2 immunotherapy. Greenwich LifeSciences is planning to commence a Phase III clinical trial using a similar treatment regime as the Phase IIb clinical trial. For more information on Greenwich LifeSciences, please visit the Company's website at [www.greenwichlifesciences.com](http://www.greenwichlifesciences.com) and follow the Company's Twitter at <https://twitter.com/GreenwichLS>.

#### **About GP2 Immunotherapy Immune Response**

As previously reported, GP2 immunotherapy generated GP2-specific immune responses, leading to no metastatic breast cancer recurrence in the HER2/*neu* 3+ population in the Phase IIb clinical trial, thus supporting GP2's mechanism of action. Statistically significant peak immunity was reached after 6 months of GP2 treatment, as measured in both the Dimer Binding Assay and the DTH skin test. HER2/*neu* 3+ population immune response was similar to the HER2/*neu* 1-2+ population immune response, suggesting the potential to treat the HER2/*neu* 1-2+ population (including triple negative breast cancer) with GP2 immunotherapy in combination with trastuzumab (Herceptin) based products and other clinically active agents. The broad based immune response suggests the potential for GP2 to treat other HER2/*neu* 1-3+ expressing cancers. For more information on

#### **Forward-Looking Statement Disclaimer**

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Greenwich LifeSciences Inc.'s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including statements regarding the intended use of net proceeds from the public offering; consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus related to the public offering filed with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Greenwich LifeSciences, Inc. undertakes no duty to update such information except as required under applicable law.

#### **Company Contact**

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