

**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 19, 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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

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 19, 2021, Greenwich LifeSciences, Inc. issued a press release announcing the appointment of Christine Fischette, Ph.D., to Vice President of Business Development. 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.

Exhibit No.	Description
99.1	Press release dated April 19, 2021

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 20, 2021

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



April 19, 2021

Greenwich LifeSciences Hires Industry Expert Dr. Christine Fischette to Lead Business Development & Advise on Commercialization

- Previously led partnering transactions and strategic analyses for multiple companies, including Roche, Pfizer, and Novartis
- Dr. Fischette will focus on out-licensing the Company's lead drug candidate for recurring breast cancer, GP2, and building a clinical pipeline to complement GP2
- Dr. Fischette has 25+ years of experience in research, clinical development, commercialization, and business development at Big Pharma, leveraging her Ph.D. in Biology and Physiology

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 appointment of Christine Fischette, Ph.D., to Vice President of Business Development.

Dr. Fischette commented, "I am very excited to lead the effort in building an expanded pipeline for the Company. The release of our final 5 year safety data from our Phase IIb trial at the upcoming ASCO conference, combined with our previously released clinical outcome and immune response data at SABCS 2020 and AACR 2021, will give us a complete data package to present to Big Pharma for the out-licensing of GP2. The GP2 Phase IIb clinical data showed no breast cancer recurrences in HER2+ patients over 5 years and a peak immune response after 6 months of treatment. If the final safety data is positive, which we expect it to be, we will have a compelling product profile which compares favorably to commercialized breast cancer drugs as well as those currently under development. Breast cancer survivors seek safe and effective drugs to prevent metastatic breast cancer recurrence. GP2 may represent a paradigm shift in the way we treat recurring breast cancer. I look forward to developing a partnership with Big Pharma to help us maximize the potential of GP2."

CEO Snehal Patel added, "We are thrilled that Dr. Fischette is joining the Company. While she was invaluable in advising the Company in the past through our engagement with Torrey Partners, her expanded role and responsibilities inside the Company will not only include exploring strategic partnerships with Big Pharma for GP2, but will also include adding additional products to our clinical pipeline. Both of these activities are high priorities for the Company. We also look forward to Dr. Fischette's contributions to our management team as we seek to expand the GP2 market from HER 2+ breast cancer to triple negative breast cancer and other HER2 expressing cancers, where the market potential of GP2 may exceed \$5 billion."

-1-

Dr. Fischette has over 30 years of experience in strategic and operational roles within research, drug development, commercialization, business development, and general management in the BioPharma industry. She has advised companies on growth strategies, business development, licensing, and drug development. She has also consulted for investment banks, biotech companies, academic institutions, non-profits, and she was a faculty member for BIO's Business Development Fundamentals Course offered annually by BIO. Previously, Dr. Fischette worked at Torrey Partners, Novartis, Pfizer, and Roche. She served as Head of Negotiation and Board Director for several therapeutic business units at Novartis. At Pfizer, she orchestrated the entire drug development/marketing process of a therapeutic from formulation selection to successful commercialization with net sales eventually reaching \$350 million. She has authored over 50 publications in peer-reviewed publications, including *Science* while at Rockefeller University and other institutions. Dr. Fischette received a B.A. in Biology Education from Rutgers University and a Ph.D. in Physiology from Rutgers Biomedical Health Sciences, formerly known as the University of Medicine and Dentistry of New Jersey.

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 and follow the Company's Twitter at <https://twitter.com/GreenwichLS>.

-2-

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 GP2 immune response and clinical data, please visit the Company's clinical trial tab at <https://greenwichlifesciences.com/clinical-trials/#Phase-IIb-AACR>.

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

Snehal Patel
Investor Relations
(832) 819-3232
info@greenwichlifesciences.com

Investor & Public Relations Contact for Greenwich LifeSciences

Dave Gentry
RedChip Companies Inc.
Office: 1-800-RED CHIP (733 2447)
Cell: (407) 491-4498
dave@redchip.com