

**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) **July 12, 2022**

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

Common stock, \$0.001 par value

Trading Symbol(s)

GLSI

Name of each exchange on which registered

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 July 12, 2022, Greenwich LifeSciences, Inc. issued a press release announcing that the Food and Drug Administration has removed the previously disclosed clinical hold on the Flamingo-01 Phase III clinical trial and is allowing the clinical trial to proceed. 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

99.1 [Press release dated July 12, 2022.](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: July 12, 2022

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



July 12, 2022

Greenwich LifeSciences Announces Removal of Clinical Hold Permitting Phase III Clinical Trial to Proceed

STAFFORD, Texas—(Business Wire)— Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the “Company”), a clinical-stage biopharmaceutical company focused on the development of GLSI-100, announced that the Food and Drug Administration (FDA) has removed the clinical hold permitting the Flamingo-01 Phase III clinical trial to proceed.

As previously announced, the Phase III clinical trial was placed on clinical hold by the FDA related to manufacturing and the pharmacy process. The Company through discussions with the FDA and testing of GP2 in the pharmacy process has satisfactorily addressed the clinical hold issues. The Company has committed to additional testing of GP2 in the pharmacy process. On July 11, 2022, the FDA formally removed the clinical hold and thus the Flamingo-01 Phase III clinical trial may proceed as planned. The Company has begun site initiation visits and will provide further updates on the progress of Flamingo-01 in the future.

Company Contact

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