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 11, 2022**

Greenwich LifeSciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39555**	**20-5473709**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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

We previously committed to not commencing Flamingo-01 without first submitting manufacturing information to the U.S. Food and Drug Administration ("FDA"), which was incomplete at the time we amended our Investigational New Drug Application, due to our initial lots being tested at such time. As previously disclosed in our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, the FDA placed our evaluation of GLSI-100 in certain HER2*/neu* positive patients and Flamingo-01 on clinical hold prohibiting us from commencing Flamingo-01 until we provided such manufacturing information. All hold issues in the clinical hold letter we received were associated with manufacturing. We have completed the last steps of manufacturing GP2 and released three clinical lots of GP2 drug product that we believe meet all release specifications. The FDA is currently reviewing the manufacturing data and has sent us follow up questions to which we have responded. The third lot was manufactured in a commercial facility on an automated filling line. We are also scheduling site initiation visits to do the final training of the clinicians, nurses, coordinators, and pharmacists to activate and open clinical sites.

We are supplementing our risk factors disclosed in our Form 10-K for the year ended December 31, 2021 as follows:

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, including the risk of a clinical trial being placed on clinical hold. Our proposed Phase III clinical trial to evaluate GLSI-100 in certain HER2/neu positive patients is currently on clinical hold and there can be no assurances as to when or if the hold will be removed.

Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of our product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidate in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well as IND-enabling toxicology studies. These experiments and studies may be time-consuming and expensive to complete. The necessary preclinical testing may not be completed successfully for a preclinical product candidate and a potentially promising product candidate may therefore never be tested in humans. Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We may experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our product candidate. In particular, clinical trials of our product candidate may produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of GP2 administered in combination with GM-CSF. Clinical trials also require the review and oversight of an institutional review board ("IRB"). An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

We previously committed to not commencing Flamingo-01 without first submitting manufacturing information to the U.S. Food and Drug Administration ("FDA"), which was incomplete at the time we amended our Investigational New Drug Application, due to our initial lots being tested at such time. As previously disclosed in our Quarterly Report on Form 10-Q for the three months ended March 31, 2022, the FDA placed our evaluation of GLSI-100 in certain HER2/*neu* positive patients and Flamingo-01 on clinical hold prohibiting us from commencing Flamingo-01 until we provided such manufacturing information. All hold issues in the clinical hold letter we received were associated with manufacturing. There can be no assurance as to when the FDA will release the clinical hold or if they ever will release the clinical hold. In addition, there can be no assurance that the FDA will not place future clinical trials of our product candidate on additional clinical holds in the future. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a clinical trial design and protocols that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable patients to participate in a clinical trial;
- delay or failure in patients completing a clinical trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from clinical trial protocol, failing to conduct the clinical trial in accordance with regulatory requirements, or dropping out of a clinical trial;
- inability to identify and maintain a sufficient number of clinical trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third-party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new clinical trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of clinical trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, the IRB or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a clinical trial;
- a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate to start or to use in clinical trials;

- lack of adequate funding to continue a clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs and other third parties; or

- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidate, the approval and commercial prospects of our product candidate will be harmed, delaying our ability to generate product revenues from such product candidate and our costs will most likely increase. The required regulatory approvals may also be delayed, thereby jeopardizing our ability to commence product sales and generate revenues and the period of commercial exclusivity for our product may be decreased. Regulatory approval of our product candidate may be denied for the same reasons that caused the delay.

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 11, 2022

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