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

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2023

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

COMMISSION FILE NUMBER 001-39555

GREENWICH LIFESCIENCES, INC.
(Exact Name of registrant as specified in its charter)

Delaware	**20-5473709**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3992 Bluebonnet Dr., Building 14, Stafford, Texas	**77477**
(Address of principal executive offices)	(Zip Code)

(832) 819-3232
(Registrant's telephone number, including area code)

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	GLSI	Nasdaq Capital Market

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ 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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 16, 2023, the issuer had 12,848,165 shares of Common Stock issued and outstanding.

GREENWICH LIFESCIENCES, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GREENWICH LIFESCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
AS OF SEPTEMBER 30, 2023 AND DECEMBER 31, 2022 (UNAUDITED)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash	$ 9,143,619	$ 13,468,026
Non-current assets		
Acquired patents, net	6,294	9,003
Total assets	$ 9,149,913	$ 13,477,029
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable & accrued interest	$ 230,902	$ 220,845
Unreimbursed expenses	66,385	42,060
Total current liabilities	297,287	262,905
Total liabilities	297,287	262,905
Stockholders' equity		
Common stock, $0.001 par value; 100,000,000 shares authorized; 12,848,165 shares issued and outstanding as of September 30, 2023 and December 31, 2022	12,848	12,848
Additional paid-in capital	56,457,608	54,674,042
Accumulated deficit	(47,617,830)	(41,472,766)
Total stockholders' equity	8,852,626	13,214,124
Total liabilities and stockholders' equity	$ 9,149,913	$ 13,477,029

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022 (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	2,158,167	1,723,493	5,365,641	4,017,564
General and administrative	344,758	659,568	1,126,192	1,128,007
Total operating expenses	2,502,925	2,383,061	6,491,833	5,145,571
Loss from operations	(2,502,925)	(2,383,061)	(6,491,833)	(5,145,571)
Interest Income	111,136	64,037	346,769	110,846
Net loss	$ (2,391,789)	$ (2,319,024)	$ (6,145,064)	$ (5,034,725)
Per share information:				
Net loss per common share, basic and diluted	$ (0.19)	$ (0.18)	$ (0.48)	$ (0.39)
Weighted average common shares outstanding, basic and diluted	12,848,165	12,823,447	12,848,165	13,067,620

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022 (UNAUDITED)

	Common Stock		Additional		Total
	Shares	Par Amount	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balances, December 31, 2021	13,147,829	$ 13,148	$ 60,466,093	$ (33,647,529)	$ 26,831,712
Stock-based compensation	73,452	74	165,193	—	165,267
Repurchase of common stock via stock buy back program, net of costs	(269,828)	(270)	(5,513,441)	—	(5,513,711)
Net loss			—	(1,969,628)	(1,969,628)
Balances, March 31, 2022	12,951,453	12,952	55,117,845	(35,617,157)	19,513,640
Stock-based compensation	73,356	73	224,430	—	224,503
Repurchase of common stock via stock buy back program, net of costs	(250,000)	(250)	(2,022,255)	—	(2,022,505)
Net loss			—	(746,073)	(746,073)
Balances, June 30, 2022	12,774,809	12,775	53,320,020	(36,363,230)	16,969,565
Stock-based compensation	73,356	73	759,500	—	759,573
Net loss			—	(2,319,024)	(2,319,024)
Balances, September 30, 2022	12,848,165	$ 12,848	$ 54,079,520	$ (38,682,254)	$ 15,410,114
Balances, December 31, 2022	12,848,165	$ 12,848	$ 54,674,042	$ (41,472,766)	$ 13,214,124
Stock-based compensation	—	—	594,522	—	594,522
Net loss			—	(2,124,902)	(2,124,902)
Balances, March 31, 2023	12,848,165	12,848	55,268,564	(43,597,668)	11,683,744
Stock-based compensation			594,522	—	594,522
Net loss			—	(1,628,373)	(1,628,373)
Balances, June 30, 2023	12,848,165	12,848	55,863,086	(45,226,041)	10,649,893
Stock-based compensation	—	—	594,522	—	594,522
Net loss			—	(2,391,789)	(2,391,789)
Balances, September 30, 2023	12,848,165	$ 12,848	$ 56,457,608	$ (47,617,830)	$ 8,852,626

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022 (UNAUDITED)

	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	$ (6,145,064)	$ (5,034,725)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	2,709	2,709
Stock-based compensation	1,783,566	1,149,343
Changes in operating assets and liabilities:		
Accounts payable	10,057	—
Unreimbursed expenses (accrued)	24,325	(147,293)
Net cash used in operating activities	(4,324,407)	(4,029,966)
Financing activities:		
Repurchase of common stock via stock buy back program, net of costs	—	(7,536,216)
Net cash provided by (used in) financing activities	—	(7,536,216)
Net increase (decrease) in cash	(4,324,407)	(11,566,182)
Cash, beginning of period	13,468,026	27,204,269
Cash, end of period	$ 9,143,619	$ 15,638,087

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Organization and Description of the Business

Greenwich LifeSciences, Inc. (the "Company") was incorporated in the state of Delaware in 2006 under the name Norwell, Inc. In March 2018, Norwell,

Inc. changed its name to Greenwich LifeSciences, Inc. In February 2023, Greenwich LifeSciences Europe Limited was incorporated as a wholly owned subsidiary in Ireland. The Company is developing a breast cancer immunotherapy focused on preventing the recurrence of breast cancer following surgery.

2. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission and should be read in conjunction with the audited financial statements and notes thereto of the Company contained elsewhere herein.

In the opinion of management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of financial position and the results of operations for the interim periods presented have been reflected herein. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year. Notes to the financial statements that would substantially duplicate the disclosures contained in the audited financial statements of the Company for the years ended December 31, 2022 and 2021 as reported in the Company's Form 10-K have been omitted.

Leases

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02-Leases (Topic 842), which significantly amends the way companies are required to account for leases. Under the updated leasing guidance, some leases that did not have to be reported previously are now required to be presented as an asset and liability on the balance sheet. In addition, for certain leases, what was previously classified as an operating expense must now be allocated between amortization expense and interest expense. The Company elected to adopt this update using the modified retrospective transition method and prior periods have not been restated. The current monthly rent is approximately $2,555. The month-to-month sub-lease is from a related party and the underlying lease expires in May of 2024. Any right of use asset and liability is deemed to be nominal as of September 30, 2023 and December 31, 2022.

Basic and Diluted Loss per Share

Basic EPS is computed by dividing net loss (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method. Diluted EPS excludes all dilutive potential shares if their effect is antidilutive. During periods of net loss, all common stock equivalents related to 1,498,128 options and 20,174 warrants outstanding as of September 30, 2023 and 2022 are excluded from the diluted EPS calculation because they are antidilutive.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 effective January 1, 2023. The Company determined that the update applied to trade receivables, but that there was no material impact to the consolidated financial statements from the adoption of ASU 2016-13.

3. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total $ 66,385 as of September 30, 2023 and $ 42,060 as of December 31, 2022.

4. Commitments and Contingencies

License Obligation, Legal Expenses, and Manufacturing Agreements

The Company entered into an exclusive license agreement with The Henry M. Jackson Foundation ("HJF") in April 2009, as amended, pursuant to which it acquired exclusive marketing rights to GP2, the Company's product candidate. In consideration for such licensed rights, the Company issued HJF 202,619 shares of the Company's common stock valued at $ 0.267 per share, which is amortized over 15 years at $3,607 per year. Pursuant to the exclusive license agreement, the Company is required to pay an annual maintenance fee, milestone payments and royalty payments based on sales of GP2 and to reimburse HJF for patent expenses related to GP2. The Company currently depends on third-party contract manufacturers for all required raw materials, active pharmaceutical ingredients, and finished product candidate for the Company's clinical trials.

Accounts payable includes accrued interest obligations to HJF which total $ 220,845 as of September 30, 2023 and December 31, 2022.

Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of business. Any of these claims could subject the Company to costly legal expenses and, while management generally believes that there will be adequate insurance to cover different liabilities at such time the Company becomes a public company and commences clinical trials, the Company's future insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the results of operations and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. The Company is currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, could have a material adverse effect on our results of operations or financial position.

5. Stockholders' Equity

As of September 30, 2023, 893,181 shares of the 908,362 shares of the common stock grant, which includes an additional grant of 120 shares issued during the vesting period due to rounding up of fractional shares, had vested at approximately $2,009,657 value and 15,181 shares remain unvested and unrecognized at $34,157 value. There were no shares vested during the nine months ended September 30, 2023.

On January 23, 2022, the Board of Directors authorized the Company's management to implement a stock repurchase program for up to $ 10 million of the Company's common stock at any time. The term of the Board of Directors authorization of the repurchase program ended on March 31, 2023. The repurchase program may be suspended or discontinued at any time and will be funded using the Company's working capital. As of September 30, 2023 and 2022, approximately 519,828 shares of the Company's common stock has been repurchased and cancelled at an aggregate purchase price,

including all transactions costs, of approximately $7,536,216. There were no shares repurchased during the nine months ended September 30, 2023.

On January 23, 2022, the Board of Directors extended the lock-up of the shares owned by the Company's directors, officers, and existing pre-IPO investors to March 24, 2023 (30 months from date of the Company's IPO) from March 24, 2022 (18 months from date of the Company's IPO). On November 30, 2022, the Board of Directors further extended the lock-up of the shares owned by the Company's directors, officers, and existing pre-IPO investors to December 31, 2023 (approximately 39 months from date of the Company's IPO) from March 24, 2023 (30 months from date of the Company's IPO). During this period, current officers, directors and certain shareholders will not be able to sell their shares of the Company's common stock unless otherwise modified by the Board of Directors.

Warrants

At September 30, 2023, outstanding warrants to purchase shares of common stock were as follows with an aggregate intrinsic value as of September 30, 2023 of $33,338 based on the September 29, 2023 closing share price of $ 8.84:

Shares Underlying Outstanding Warrants		Exercise Price	Expiration Date
20,174	$	7.1875	September 24, 2025
20,174			

Options

On June 22, 2022, prior to the close of the Nasdaq market, 1,498,128 shares of common stock were granted to employees, consultants, and directors issuable upon exercise of outstanding stock options under the Company's 2019 Equity Incentive Plan at an exercise price of $7.63 per share, which was the most recent prior closing share price on June 21, 2022. The options had a fair value on the grant date of $9,512,356, based on a risk-free rate of 3.2% and an annualized volatility of 106%, of which $3,032,062 was expensed through September 30, 2023 and $ 6,480,294 will be expensed in the future if and as vesting occurs. Vesting will be based on time of service over a four year period and certain additional performance milestones for senior management, primarily related to the Phase III clinical trial.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions.

In addition, our business and financial performance may be affected by the factors that are discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 31, 2023 and updated in Item 1A below. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

The following discussion and analysis is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best present assessment of our management.

Overview

We are 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, a cell surface receptor protein that is expressed in a variety of common cancers, including expression in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels. The combination of GP2 + GM-CSF is called GLSI-100. In a completed randomized, single-blinded, placebo-controlled, multi-center Phase IIb clinical trial led by MD Anderson Cancer Center, no recurrences were observed in patients treated with GLSI-100 in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patients were treated, followed, and remained disease free over the first 6 months, which is the time required to reach peak immunity and thus maximum efficacy and protection ($p = 0.0338$). For the 146 patients who have been treated with GLSI-100 to date over 4 clinical trials, treatment was well tolerated and no serious adverse events were observed related to the immunotherapy.

We have commenced Flamingo-01, a Phase III clinical trial with Baylor College of Medicine as the global primary investigator site. Flamingo-01 is designed to evaluate the safety and efficacy of GLSI-100 in HER2/*neu* positive patients with residual disease or high-risk pathologic complete response at surgery and who have completed both neoadjuvant and postoperative adjuvant trastuzumab based treatment.

To date, we have not generated any revenue and we have incurred net losses. Our net losses were approximately $7.8 million and $4.6 million for the years ended December 31, 2022 and 2021, respectively and $6.1 million and $5.0 million for the nine months ended September 30, 2023 and 2022, respectively.

Our net losses have resulted from costs incurred in developing the drug in our pipeline, planning and preparing for clinical trials and general and administrative activities associated with our operations. We expect to continue to incur significant expenses and corresponding increased operating losses for the foreseeable future as we continue to develop our pipeline. Our costs may further increase as we conduct clinical trials and seek regulatory approval for and prepare to commercialize our product candidate. We expect to incur significant expenses to continue to build the infrastructure necessary to support our expanded operations, clinical trials, commercialization, including manufacturing, marketing, sales and distribution functions. We will also experience increased costs associated with operating as a public company.

Results of Operations for the Three Months Ended September 30, 2023 and 2022

Research and Development Expenses

Research and development expenses increased by $434,674, or 25%, to $2,158,167 for the three months ended September 30, 2023 from $1,723,493 for the three months ended September 30, 2022. The increase was primarily the result of an increase in clinical expenses.

General and Administrative Expenses

General and administrative expenses decreased by $314,810, or 48%, to $344,758 for the three months ended September 30, 2023 from $659,568 for the three months ended September 30, 2022. The decrease was primarily the result of a decrease in compensation, financing, and corporate expenses.

Results of Operations for the Nine Months Ended September 30, 2023 and 2022

Research and Development Expenses

Research and development expenses increased by $1,348,077, or 34%, to $5,365,641 for the nine months ended September 30, 2023 from $4,017,564 for the nine months ended September 30, 2022. The increase was primarily the result of an increase in clinical expenses.

General and Administrative Expenses

General and administrative expenses decreased by $1,815 to $1,126,192 for the nine months ended September 30, 2023 from $1,128,007 for the nine months ended September 30, 2022.

Liquidity and Capital Resources

Since our inception in 2006, we have devoted most of our cash resources to research and development and general and administrative activities. We have not yet achieved commercialization of our product and have a cumulative net loss from our operations. We will continue to incur net losses for the foreseeable future. Our financial statements have been prepared assuming that we will continue as a going concern.

We will require additional capital to meet our long-term operating requirements. We expect to raise additional capital through the sale of equity and/or debt securities; however, there is no assurance that we will be successful at raising additional capital in the future. If our plans are not achieved and/or if significant unanticipated events occur, we may have to further modify our business plan, which may require us to raise additional capital. As of September 30, 2023 and December 31, 2022, our principal source of liquidity was our cash, which totaled $9,143,619 and $13,468,026, respectively, and additional loans and accrued unreimbursed expenses from related parties. Historically, our principal sources of cash have included proceeds from the sale of common stock and preferred stock and related party loans. Our principal uses of cash have included cash used in operations. We expect that the principal uses of cash in the future will be for continuing operations, funding of research and development, including our clinical trials, and general working capital requirements. The Company's existing cash resources are expected to provide sufficient funds to carry the Company's planned operations over the next 12 months from the date these financial statements were issued.

Cash Flow Activities for the Nine Months Ended September 30, 2023 and 2022

We incurred net losses of $6,145,064 and $5,034,725 during the nine month periods ended September 30, 2023 and 2022, respectively. The increase was primarily the result of an increase in clinical expenses.

Operating Activities

Net cash used in operating activities was $4,324,407 for the nine months ended September 30, 2023 and $4,029,966 for the nine months ended September 30, 2022.

Investing Activities

We did not use or generate cash from investing activities during the nine months ended September 30, 2023 and September 30, 2022.

Financing Activities

We used a total of $0 and $7,536,216 cash for the stock buy back program, net of costs, during the nine months ended September 30, 2023 and September 30, 2022, respectively.

Contractual Obligations and Commitments

As of September 30, 2023, we did not have any material contractual obligations, other than employment and shareholder agreements, license for GP2 from HJF, and manufacturing and clinical trial obligations.

Off-Balance Sheet Arrangements

As of September 30, 2023, we did not have any off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

Our financial statements are prepared in conformity with U.S. GAAP, which require the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses in the periods presented.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of expenses that are not readily apparent from other sources. Actual results could differ from those estimates, particularly given the significant social and economic disruptions and

uncertainties associated with the ongoing coronavirus pandemic and the COVID-19 control responses.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 effective January 1, 2023. The Company determined that the update applied to trade receivables, but that there was no material impact to the consolidated financial statements from the adoption of ASU 2016-13.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standard Board or other standard setting bodies that the Company adopts as of the specified effective date. The Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on the Company's financial position or results of operations upon adoption.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("Securities Act") for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal accounting and financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal accounting and financial officer has concluded that as of September 30, 2022, our disclosure controls and procedures were not effective as of such date as a result of material weaknesses in our internal control over financial reporting due to inadequate segregation of duties within account processes due to limited personnel and insufficient written policies and procedures for accounting, IT and financial reporting and record keeping. Under the direction of our principal executive officer and principal financial and accounting officer, we are developing a plan to remediate the material weaknesses.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during our most recent fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all errors and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse

effect on our business, operating results, cash flows or financial condition.

ITEM 1A. RISK FACTORS

The Company is updating its risk factors disclosed in its Form 10-K for the year ended December 31, 2022 as follows:

Risks associated with out-licensing GP2 or future product candidates in foreign countries could materially adversely affect the commercialization of our products.

We may not be able to market products abroad if we cannot complete out-licensing transactions of GP2 or future product candidates by signing licensing agreements with regional companies in countries where we plan to commercialize our products but where we do not have any operations. Risks associated with out-licensing transactions of our products in foreign countries include:

- failure to obtain regulatory approval or intellectual property rights in any country which could lead to the termination of a licensing transaction in that country;
- the inability to obtain the issuance of patent claims or regulatory status in a foreign country that provide periods of market exclusivity or data exclusivity prior to the entry of generic or biosimilar forms of our products;
- the difficulty of pursuing legal remedies to disputes or to secure monetary damages in foreign countries;
- the inability to repatriate income from a licensing transaction in a foreign country to the U.S. or to other foreign countries where cash is needed; and
- the potential to not realize or to delay development or commercialization milestone payments due to unanticipated outcomes that prevent or delay the milestone.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We may conduct future clinical trials in countries outside of the U.S. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the U.S., *e.g.*, General Data Protection Regulation in the European Union;
- difficulty in exporting patient samples or patient data back to the U.S. to conduct research and analyze clinical trial results due to exportation and data protection requirements;
- difficulty and costs associated with shipping drugs, clinical supplies, and patient samples in controlled temperature conditions over long distances;
- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Our future success is dependent on the regulatory approval of our product candidate.

Our business is dependent on our ability to obtain regulatory approval for our product candidate in a timely manner. We cannot commercialize our product candidate in the U.S. without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize our product candidate outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA and foreign regulatory authorities may not allow patient data from all countries to be used to satisfy their specific country requirements for various reasons such as concerns of varying genetics and thus treatment responses by race or country of origin or differences in standard of care by country or regions within countries. The most recent U.S. approved breast cancer drugs may not be approved, available, affordable, or reimbursed in all countries in the world or in countries in which we may conduct clinical trials. Before obtaining regulatory approvals for the commercial sale of our product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Additional time may be required to do more manufacturing testing as well as to make multiple lots of commercial drug product, including the packaging of the drug product, based on the commercial requirements of each country.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval clinical trial or risk management requirements. Also, any regulatory approval of our current product candidate or any future product candidates we may pursue, once obtained, may be withdrawn.

A new EU regulatory software system was implemented in 2023 to facilitate the submission of applications to conduct clinical trials in the EU. This new Clinical Trials Information System (CTIS) supports the flow of information between clinical trial sponsors, EU Member States, European Economic Area countries and the European Commission. This new unproven process for seeking approval to conduct clinical trials in EU member

countries is based on new software, is conducted without direct interaction with EU regulators, and thus may create unexpected outcomes or delays, misunderstandings based on written interpretations and language differences, repeated submissions, protracted timelines based on staffing and EU holidays, and limited negotiations that can only take place in writing without any voice or video discussions.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidate from being marketed and out-licensed abroad.

In addition to regulations in the U.S., to market and sell our product candidate in the European Union, United Kingdom, many Asian countries or other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. We may not be able to obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product in any market. If we are unable to obtain approval of any of our current product candidate or any future product candidates we may pursue by regulatory authorities in the European Union, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline, we may not be able to complete out-licensing transactions, and this could materially adversely affect our business, results of operations and financial condition.

In the clinical trials using GP2, improper intradermal injections or poor HLA binding by GP2 may potentially jeopardize the outcome of the trials.

GP2 is administered intradermally to patients with and without the HLA-A*02 allele. The effectiveness of GP2 is dependent upon attracting sufficient antigen presenting cells in the patient's intradermal space and the association of GP2 with the HLA type of a patient to adequately train T cells to kill cancer cells, which may or may not be possible or consistent across all HLA types. It is possible that nurses may not successfully inject GP2 in the intradermal space or that certain HLA types may form weak or no association with GP2, potentially leading to weak or no immune response to GP2 and thus no benefit to patients with some or any HLA type.

In the clinical trials using GP2, GM-CSF is also administered and its availability is dependent upon a third-party manufacturer, which may or may not reliably provide GM-CSF in the U.S. or in any other country, thus potentially jeopardizing the completion of the trials.

GP2 is administered in combination with GM-CSF which is available in a lyophilized form exclusively from one manufacturer who only has marketing approval for sale of GM-CSF (Leukine) in the U.S, and not in any other country. We will need to export GM-CSF to any countries in which we conduct clinical trials relying on the U.S. registration, which may not always be successful. We will continue to be dependent on such manufacturer for our supply of GM-CSF in combination with GP2 in the ongoing GP2 trials and upon the potential commercialization of GP2. To successfully commercialize GP2 outside of the U.S., GM-CSF will need to be available in those countries, through a customized process that allows for individual patient use based on a doctor's prescription or through registration of GM-CSF in those countries. We have not entered into a supply agreement with the manufacturer for GM-CSF, and instead rely on purchase orders to meet our supply needs. Any temporary interruptions or discontinuation of the availability of GM-CSF could have a material adverse effect on our operations.

We are periodically involved in various litigation and/or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition, and results of operations.

We are periodically party to or the subject of litigation, investigations, regulatory proceedings or other disputes. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. While we intend to pursue any claims made by us, or vigorously defend against any claims brought against us, we cannot predict the outcomes of such claims. Any failure to prevail in any claims made by us or any adverse determination against us in these legal and/or regulatory proceedings, or even the allegations contained in such proceedings, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions, fines, penalties, or damages that could have a material adverse effect on our business, financial condition and results of operations.

We may hold cash and cash equivalents at various foreign subsidiaries and in countries outside of the US that may not be readily available to meet cash requirements.

Currently a majority of our cash and cash equivalents is held by our U.S. parent company, however, our foreign subsidiary may in the future hold cash. Our U.S. parent company or our foreign subsidiary may hold cash balances outside the United States which may not be readily available, or may not be available without an additional tax burden, to meet our domestic or foreign cash requirements. U.S. tax laws may allow for reductions to the potential tax burden on repatriation of foreign cash; however, such actions would require us to record additional income tax expense and remit additional taxes, which could have a material adverse effect on our results of operations, cash flows and financial condition. In addition, foreign exchange rates may fluctuate leading to unexpected losses and inefficient utilization of cash in countries outside of the U.S.

The COVID-19 coronavirus could adversely impact our business in the U.S. and in other countries, including several key activities, including clinical trial activities, manufacturing of drugs and clinical supplies, exportation of drug and supplies, and management of international payments and cash flow that are critical to our success.

The global outbreak of COVID-19 continues to rapidly evolve, including the emergence of new strains that could have the potential to be as harmful as or more harmful than the original strains in 2020. As a result, businesses may close, staffing may be reduced, including clinical staffs, and limits may be placed on travel. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate impact of the disease on specific geographies, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The spread of COVID-19 throughout the world has also created global economic uncertainty, which may cause partners, suppliers and potential customers to closely monitor their costs and reduce their spending budget. Any of the foregoing could materially adversely affect our research and development activities, clinical trials, supply chain, financial condition and cash flows.

If the COVID-19 outbreak continues to spread and evolve, we may need to limit operations or implement other limitations on our activities. There is a risk that countries or regions outside the United States may be less effective at vaccinations and containing COVID-19, in which case the risks

described herein could be elevated significantly.

We may be adversely affected by the effects of** inflation **and a potential recession.

Inflation has the potential to adversely affect our liquidity, business, financial condition, and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates, and other similar effects. As a result of inflation, we have experienced and may continue to experience, cost increases. In addition, poor economic and market conditions, including a potential recession, may negatively impact market sentiment, which would adversely affect our results of operations. If we are unable to take effective measures in a timely manner to mitigate the impact of the inflation as well as a potential recession, our business, financial condition, and results of operations could be adversely affected.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None**.**

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
31.1	Certification of Chief Executive Officer and Principal Financial and Accounting Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
104	Cover Page Interactive Data File - the cover page from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 is formatted in Inline XBRL

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, thereunto duly authorized.

GREENWICH LIFESCIENCES, INC.

October 19, 2023

By: */s/ Snehal Patel*
Snehal Patel
Chief Executive Officer (Principal Executive Officer and Principal Accounting and Financial Officer)

Exhibit 31.1

Certification of Chief Executive Officer and Principal Financial and Accounting Officer of Greenwich LifeSciences, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Snehal Patel, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Greenwich LifeSciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 19, 2023

/s/ Snehal Patel

Snehal Patel,
Chief Executive Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 32.1

Statement of Chief Executive Officer and Principal Financial and Accounting Officer
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Snehal Patel, the Chief Executive Officer and Principal Financial and Accounting Officer of Greenwich LifeSciences, Inc. (the "Company"), hereby certifies that based on the undersigned's knowledge:

1. The Company's quarterly report on Form 10-Q for the period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

October 19, 2023

/s/ Snehal Patel
Snehal Patel
Chief Executive Officer
(Principal Executive Officer and Principal Financial and Accounting Officer)