

**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, 2022

☐ **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

(State or other jurisdiction
of incorporation or organization)

20-5473709

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

3992 Bluebonnet Dr., Building 14, Stafford, Texas
(Address of principal executive offices)

77477
(Zip Code)

(832) 819-3232

(Registrant's telephone number, including area code)

Title of each class:

Common Stock

Trading Symbol(s)

GLSI

Name of each exchange on which registered:

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 November 1, 2022, the issuer had 12,848,165 shares of Common Stock issued and outstanding.

GREENWICH LIFESCIENCES, INC.

Table of Contents

	Page
PART I <u>FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Balance Sheets as of September 30, 2022 (Unaudited) and December 31, 2021</u>	3
<u>Statements of Operations for the Three Months and Nine Months Ended September 30, 2022 and 2021 (Unaudited)</u>	4
<u>Statements of Stockholders' Equity for the Nine Months Ended September 30, 2022 and 2021 (Unaudited)</u>	5
<u>Statements of Cash Flows for the Nine Months Ended September 30, 2022 and 2021 (Unaudited)</u>	6
<u>Notes to Financial Statements (Unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	11
Item 4. <u>Controls and Procedures</u>	12
PART II <u>OTHER INFORMATION</u>	12
Item 1. <u>Legal Proceedings</u>	12
Item 1A. <u>Risk Factors</u>	12
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	12
Item 3. <u>Defaults Upon Senior Securities</u>	12
Item 4. <u>Mine Safety Disclosures</u>	12
Item 5. <u>Other Information</u>	12
Item 6: <u>Exhibits</u>	13
<u>SIGNATURES</u>	14

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GREENWICH LIFESCIENCES, INC.
BALANCE SHEETS
AS OF SEPTEMBER 30, 2022 AND DECEMBER 31, 2021 (UNAUDITED)

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash	\$ 15,638,087	\$ 27,204,269
Acquired patents, net	9,906	12,615
Total assets	\$ 15,647,993	\$ 27,216,884
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable & accrued interest	\$ 220,845	\$ 220,845
Unreimbursed expenses	17,034	164,327
Total current liabilities	237,879	385,172
Total liabilities	237,879	385,172
Stockholders' equity		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 12,848,165 and 13,147,829 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	12,848	13,148
Additional paid-in capital	54,079,520	60,466,093
Accumulated deficit	(38,682,254)	(33,647,529)
Total stockholders' equity	15,410,114	26,831,712
Total liabilities and stockholders' equity	\$ 15,647,993	\$ 27,216,884

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF OPERATIONS
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses				
Research and development	1,723,493	657,096	4,017,564	1,495,607
General and administrative	659,568	209,590	1,128,007	725,130
Total operating expenses	2,383,061	866,686	5,145,571	2,220,737
Loss from operations	(2,383,061)	(866,686)	(5,145,571)	(2,220,737)
Interest Income	64,037	3,568	110,846	10,866
Net loss	<u>\$ (2,319,024)</u>	<u>\$ (863,118)</u>	<u>\$ (5,034,725)</u>	<u>\$ (2,209,871)</u>
Per share information:				
Net loss per common share, basic and diluted	\$ (0.18)	\$ (0.07)	\$ (0.39)	\$ (0.17)
Weighted average common shares outstanding, basic and diluted	12,823,447	12,968,891	13,067,620	12,826,249

See accompanied notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Amount	Shares	Par Amount			
Balances, December 31, 2020	12,703,541	\$ 12,704	—	\$ —	\$ 56,695,359	\$ (29,076,953)	\$ 27,631,110
Stock-based compensation	73,356	73	—	—	164,978	—	165,051
Exercise of common stock from Green Shoe of follow-on offering, net of offering costs	70,000	70	—	—	2,547,930	—	2,548,000
Net loss					-	(597,008)	(597,008)
Balances, March 31, 2021	12,846,897	12,847	—	—	59,408,267	(29,673,961)	29,747,153
Stock-based compensation	73,356	73	—	—	164,978	—	165,051
Net loss					-	(749,745)	(749,745)
Balances, June 30, 2021	12,920,253	12,920	—	—	59,573,245	(30,423,706)	29,162,459
Stock-based compensation	73,356	74	—	—	164,977	—	165,051
Net loss					-	(863,118)	(863,118)
Balances, September 30, 2021	<u>12,993,609</u>	<u>\$ 12,994</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 59,738,222</u>	<u>\$ (31,286,824)</u>	<u>\$ 28,464,392</u>
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	<u>12,848,165</u>	<u>\$ 12,848</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 54,079,520</u>	<u>\$ (38,682,254)</u>	<u>\$ 15,410,114</u>

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
STATEMENTS OF CASH FLOWS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021 (UNAUDITED)

	Nine Months Ended September 30,	
	2022	2021
Operating activities:		
Net loss	\$ (5,034,725)	\$ (2,209,871)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Amortization	2,709	2,709
Stock-based compensation	1,149,343	495,153
Changes in operating assets and liabilities:		
Accounts payable	—	(451,732)
Accrued interest	—	36,606
Unreimbursed expenses (accrued)	(147,293)	99,907
Net cash used in operating activities	<u>(4,029,966)</u>	<u>(2,027,228)</u>
Financing activities:		
Proceeds from sale of common stock	—	2,548,000
Repurchase of common stock via stock buy back program, net of costs	(7,536,216)	—
Repayment to related party/shareholder	—	(275,154)
Net cash provided by (used in) financing activities	<u>(7,536,216)</u>	<u>2,272,846</u>
Net increase (decrease) in cash	(11,566,182)	245,618
Cash, beginning of period	27,204,269	28,660,375
Cash, end of period	<u>\$ 15,638,087</u>	<u>\$ 28,905,993</u>

See accompanying notes to unaudited financial statements.

GREENWICH LIFESCIENCES, INC.
NOTES TO 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. 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, 2021 and 2020 as reported in the Company’s Form 10-K have been omitted.

Basic and Diluted Loss per Share

As of September 30, 2022 and 2021, the Company had common stock equivalents related to warrants outstanding to acquire 20,174 and 100,870 shares of the Company’s common stock, respectively.

As of September 30, 2022 and 2021, the Company has no common stock equivalents related to convertible preferred stock issued and outstanding.

The following table sets forth the computation of basic and diluted net loss per common share for the periods indicated:

	Nine Months Ended September 30,	
	2022	2021
Basic and diluted net loss per share calculation:		
Net loss, basic	(5,034,725)	(2,209,871)
Change in fair value of warrants	—	—
Net loss, diluted	(5,034,725)	(2,209,871)
Weighted average common shares outstanding, basic and diluted	13,067,620	12,826,249
Net loss per common share, basic and diluted	\$ (0.39)	\$ (0.17)

3. Related Party Transactions

Unreimbursed expenses have been accrued and incurred by management, which total \$17,034 as of September 30, 2022 and \$164,327 as of December 31, 2021.

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, 2022 and December 31, 2021.

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, 2022, 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 approximately \$34,157 value. An aggregate of 220,164 shares of common stock were vested at approximately \$495,369 value from January through September 2022 in consideration for services rendered.

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 is until 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 June 30, 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.

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). 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, 2022, outstanding warrants to purchase shares of common stock accounted for as equity or liabilities were as follows with an aggregate intrinsic value as of September 30, 2022 of \$38,583 based on the September 30, 2022 closing share price of \$9.10:

Shares Underlying Outstanding Warrants	Exercise Price ⁽¹⁾	Expiration Date ⁽¹⁾
20,174	\$	7.1875
20,174		September 24, 2025

(1) The warrants are exercisable at any time and from time to time, in whole or in part, during a period commencing March 24, 2021 and expiring September 24, 2025. The exercise price of the warrants is \$7.1875 per share or \$6.9718 per share if the warrants are exercised for cash within the first six months of the period in which they are exercisable.

Options

On June 22, 2022, 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 closing share price on June 21, 2022. The options had a fair value on the grant date of \$9,512,356 of which \$653,974 was expensed through September 30, 2022 and \$8,858,382 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 planned 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, 2021, filed on March 21, 2022. 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 \$4.6 million and \$1.9 million for the years ended December 31, 2021 and 2020, respectively and \$5.0 million and \$2.2 million for the nine months ended September 30, 2022 and 2021, 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, 2022 and 2021

Research and Development Expenses

Research and development expenses increased by \$1,066,397, or 162%, to \$1,723,493 for the three months ended September 30, 2022 from \$657,096 for the three months ended September 30, 2021. The increase was primarily the result of an increase in stock compensation, clinical, and manufacturing expenses.

General and Administrative Expenses

General and administrative expenses increased by \$449,978, or 215%, to \$659,568 for the three months ended September 30, 2022 from \$209,590 for the three months ended September 30, 2021. The increase was primarily the result of an increase in stock compensation and financing expenses.

Results of Operations for the Nine Months Ended September 30, 2022 and 2021

Research and Development Expenses

Research and development expenses increased by \$2,521,957, or 169%, to \$4,017,564 for the nine months ended September 30, 2022 from \$1,495,607 for the nine months ended September 30, 2021. The increase was primarily the result of an increase in cash compensation, clinical, and manufacturing expenses.

General and Administrative Expenses

General and administrative expenses increased by \$402,877, or 56%, to \$1,128,007 for the nine months ended September 30, 2022 from \$725,130 for the nine months ended September 30, 2021. The increase was primarily the result of an increase in stock compensation and financing expenses.

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, 2022 and December 31, 2021, our principal source of liquidity was our cash, which totaled \$15,638,087 and \$27,204,269, 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.

Cash Flow Activities for the Nine Months Ended September 30, 2022 and 2021

We incurred net losses of \$5,034,725 and \$2,209,871 during the nine month periods ended September 30, 2022 and 2021, respectively. The increase was primarily the result of an increase in cash compensation, financing, clinical, and manufacturing expenses.

Operating Activities

Net cash used in operating activities was \$4,029,966 for the nine months ended September 30, 2022 and \$2,027,228 for the nine months ended September 30, 2021.

Investing Activities

We did not use or generate cash from investing activities during the nine months ended September 30, 2022 and September 30, 2021.

Financing Activities

We used a total of \$7,536,216 cash for the stock buy back program, net of costs, during the nine months ended September 30, 2022 and used and generated cash netting a total of \$2,272,846 from financing activities during the nine months ended September 30, 2021.

Contractual Obligations and Commitments

As of September 30, 2022, 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, 2022, 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

As of September 30, 2022, there were no recent accounting pronouncements applicable to our business.

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

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2021:

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	<u>Certification of Chief Executive Officer and Principal Financial and Accounting Officer required by Rule 13a-14(a)/15d-14(a) under the Exchange Act.</u>
32.1	<u>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.</u>
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.

November 14, 2022

By: /s/ Snehal Patel

Snehal Patel

Chief Executive Officer (Principal Executive Officer and Principal Accounting and Financial Officer)

**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.

November 14, 2022

/s/ Snehal Patel

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

**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, 2022 (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.

November 14, 2022

/s/ Snehal Patel

Snehal Patel

Chief Executive Officer

(Principal Executive Officer and Principal Financial and Accounting Officer)
