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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **November 18, 2020**

Greenwich LifeSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-39555

(Commission
File Number)

20-5473709

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

3992 Bluebonnet Dr, Building 14
Stafford, TX 77477

(Address of principal executive offices, including ZIP code)

(832) 819-3232

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value	GLSI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Other Events

Greenwich LifeSciences, Inc. (the “Company”) intends to conduct meetings with third parties in which its corporate slide presentation will be presented. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the document attached as Exhibit 99.1 are being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On November 18, 2020, the Company announced the publication of an abstract at the San Antonio Breast Cancer Symposium (SABCS). The abstract will be displayed as a poster on Wednesday, December 9, 2020 in a virtual format. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	<u>Greenwich LifeSciences, Inc. Corporate Presentation</u>
99.2	<u>Press release dated November 18, 2020</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Greenwich LifeSciences, Inc.

Date: November 19, 2020

By: /s/ Snehal Patel

Snehal Patel

Chief Executive Officer

GREENWICH LIFESCIENCES

Planned GP2 Phase III Clinical Trial

**A Breakthrough Targeted
Immunotherapy to Prevent
Breast Cancer Recurrences**

NASDAQ: **GLSI**

Snehal Patel, CEO
David McWilliams, Chairman



Greenwich
LifeSciences



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Image: T-cells targeting cancer cell



Safe Harbor Statement

This document is the property of Greenwich LifeSciences, Inc., (the "Company" or "Greenwich LifeSciences"). This document is non-directive in nature (contains no recommendations regarding financial actions related to the Company). This document is not to be copied or delivered to any other person or used for any other purpose without the prior consent of the Company.

This presentation contains "forward-looking statements" within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995.

These statements are identified by the use of words "could", "believe", "anticipate", "intend", "estimate", "expect", "may", "continue", "predict", "potential" and similar expressions that are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that could cause the actual results of the Company to differ materially from the results expressed or implied by such statements including, but not limited to: risks associated with the success of clinical trials, research and development programs, regulatory approval processes for clinical trials, competitive technologies and products, intellectual property rights and the need for additional financing.

Accordingly, although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. Except as required by law, the Company disclaims any obligations to publicly update or release any revisions to the forward-looking information contained in this presentation, whether as a result of new information, future events or otherwise, after the date of this presentation or to reflect the occurrence of unanticipated events.

The information contained herein is based on sources, which we believe to be reliable, but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data. Although every effort has been made to assure the accuracy of the statements in this presentation, we make no representation or warranty as to the accuracy or completeness of the statements in this presentation. Furthermore, we make forward-looking statements in this report about the Company's plans, objectives, expectations, and intentions.

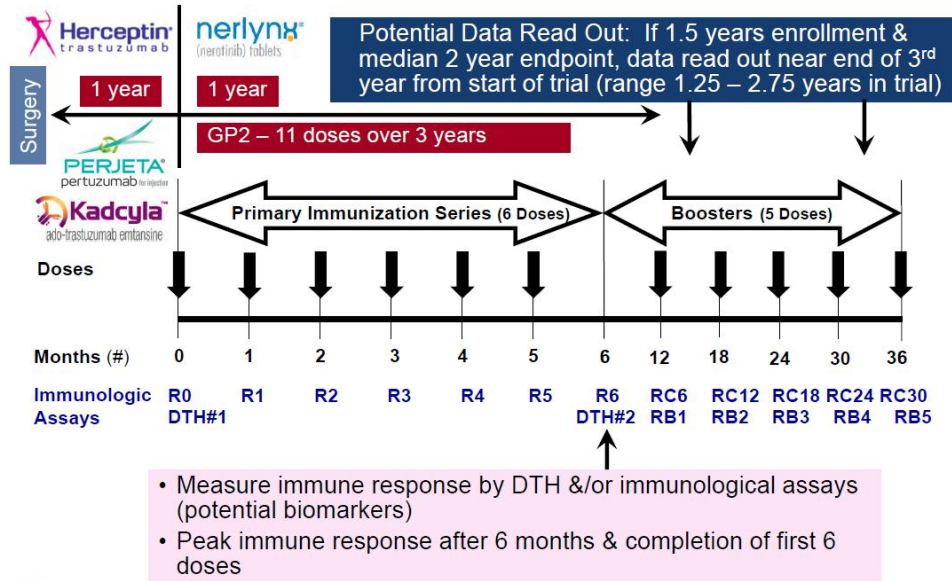
This presentation is not an offer to sell any securities of the Company and is not to be used in connection with any offer to sell or any inquiry about or evaluation of any securities of the Company. Any such sale, or opportunity, will be subject to appropriate documentation and due diligence.



GP2 Executive Summary

- **Planned Phase III Trial:** 9 amino acid HER2/neu peptide + GM-CSF immunotherapy for breast cancer in adjuvant/neoadjuvant setting (post-surgery) in HER2/neu 3+, HLA-A2 patients in Y2 following Herceptin or Kadcyla
- **Phase IIb Trial Results:** No recurrences, if fully immunized, versus 11% placebo recurrence rate in 96 patients, with minimal to no side effects, no SAEs ($p = 0.0338$)
 - Randomized, multi-center (16 centers), placebo-controlled, closed in 2018 with median 5 years follow-up led by MD Anderson
- **Regulatory:** FDA reviewed Phase III trial protocol and CMC - final revisions to the Phase III trial protocol are under way
- **Manufacturing:** Straight forward, completing scale-up, started Phase III lot
- **Multiple Phase II Trial Opportunities to Expand Market:**
 - HER2/neu 1-2+ patients with Herceptin - increase market from 25% to 75%
 - Other HLA types – increase from 40-50% up to 80% of all patients
 - Combination with CD4/CD8 peptides and checkpoints
 - Other HER2/neu cancers
- **NASDAQ Ticker “GLSI”:** Closed IPO on September 29, 2020

GP2 Phase III Clinical Trial Dosing



Breast Cancer – *Still* a Substantial Unmet Need

- *Unmet Need is to address the 50% of recurring patients who do not respond to Herceptin or Kadcyla – an opportunity for GP2.*
- *Adjuvant Setting: Following breast cancer surgery, HER2/neu 3+ patients receive Herceptin in the first year and then hope that their breast cancer will not recur, with the odds of recurrence slowly decreasing over the first 5 years. Herceptin reduces recurrence rates from 25% to 12%.*
- *Neoadjuvant Setting: Kadcyla was just approved for use in patients with residual disease determined via pCR at time of surgery. Kadcyla reduces recurrence rates from 22% to 11%.*
- *Neither Perjeta or Nerlynx fully address this unmet need, even in their most efficacious subpopulations.*

GP2 Addresses Unmet Need: GP2 & GM-CSF starting in Year 2 act synergistically with Herceptin to prevent cancer recurrences, if fully immunized, reducing recurrence rates from **11%** to **0%** at median 5 years follow-up ($p = 0.0338$), with minimal to no side effects & no SAEs.

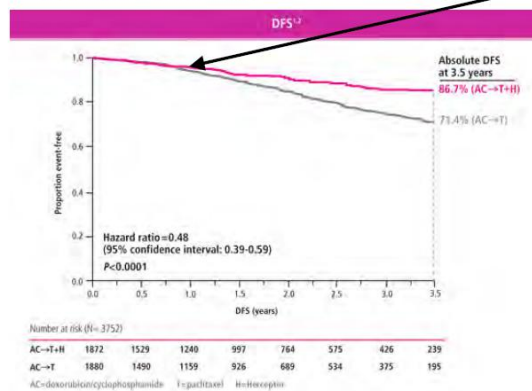
In the initial GP2 indication, approximately 17,000 new patients could be treated per year, saving up to 1,500 to 2,000 lives per year.



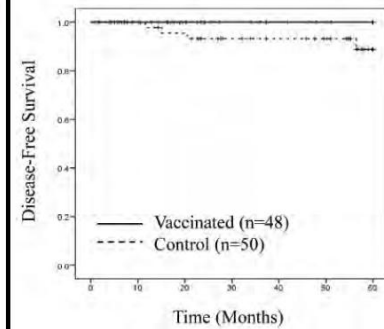
pCR = pathologic complete response, the lack of all signs of cancer in tissue samples remove during surgery or biopsy due to Neoadjuvant treatment.

Synergy with Herceptin & No Recurrences if Fully Immunized

Herceptin Approved for Adjuvant
Treatment of HER2/neu 3+ Breast Cancer



Phase IIb Results for GP2 Target
Population, if Fully Immunized
(median 34 month follow-up)



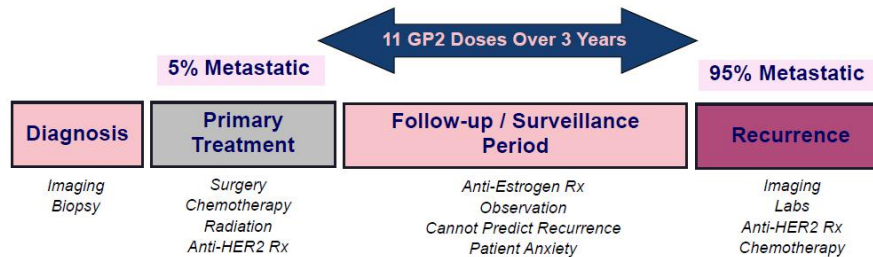
Joint Analysis Trial

*DFS – Disease Free Survival



GP2 Market Positioning & Feedback from KOLs

- As only injection site reactions were observed (which speaks to the immunogenicity of GP2) and no SAEs, GP2 can be positioned as the final treatment for patients post surgery
- Patients are seeking a de-escalation and a return to normal life free of toxic treatments, especially if the chance of recurrence is reduced to substantially
- GP2 can be the treatment that will naturally overlap with or follow Herceptin, Kadcyla, or Enhertu or any of the other Herceptin derivatives being developed





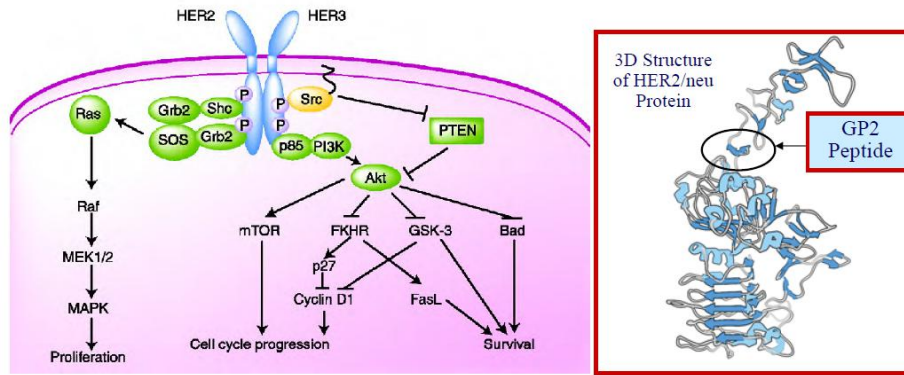
GP2 Clinical Data:

***GP2 is Immunogenic &
Clinically Effective***



HER2/neu Signaling Pathway Well Studied

- HER2/neu pathway activates cancer cell proliferation
- Overexpression of HER2/neu correlates strongly with aggressive cancers



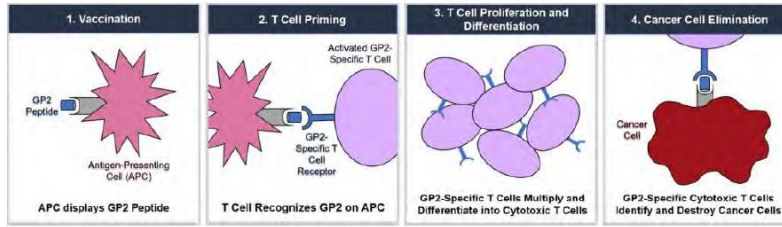
GP2 Product Description & Mechanism of Action

- 9 amino acid transmembrane peptide segment of HER2/neu protein
- Intradermal injection in combination with an FDA-approved immunoadjuvant GM-CSF, following 1st year of Herceptin treatment in Adjuvant Setting

Leukine®
sargramostim

Herceptin®
trastuzumab

- Given once per month for six months followed by 5 booster doses every 6 months = 11 doses over 3 years
- Mechanism of Action: 4 primary steps, followed by a secondary epitope spreading & broader immune response

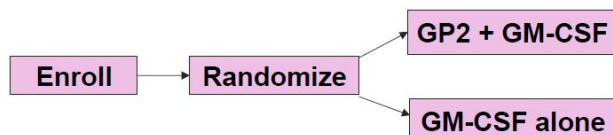


Summary of All GP2 Trials – 3 Phase I & 1 Phase IIb (Total N=138 Patients Treated to Date with No SAEs)

Protocol No./ Protocol Title	Status
Protocol No. C.2007.098/IRBNet# 363083 <ul style="list-style-type: none"> • Prospective, Randomized, Single-Blinded, Multi-Center Phase II Trial of the HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine versus GM-CSF Alone in HLA-A2+ Node-Positive and High-Risk Node-Negative Breast Cancer Patients to Prevent Recurrence • 89 patients treated with GP2 + GM-CSF, 91 placebo patients treated with GM-CSF 	Trial Completed
Protocol No. C.2008.146/ IRBNet# 363196 <ul style="list-style-type: none"> • Phase Ib Trial of Combination Immunotherapy with HER2/<i>neu</i> Peptide GP2 + GM-CSF Vaccine and Trastuzumab in Breast Cancer Patients • 17 patients treated with GP2 + GM-CSF + trastuzumab 	Trial Completed
Conducted at Brooke Army Medical Center and Mary Crowley Medical Research Center <ul style="list-style-type: none"> • Phase I Safety Trial of the GP2 + GM-CSF Vaccine in Combination with the Helper Peptide AE37 + GM-CSF Vaccine • 14 patients treated with GP2 + AE37 + GM-CSF 	Trial Completed
Protocol No. 04-20017 / IRBNet ID 20307 <ul style="list-style-type: none"> • Phase Ib Trial of HER2/<i>neu</i> Peptide (GP2) Vaccine in Breast Cancer Patients • 18 patients treated with GP2 + GM-CSF 	Trial Completed

Design of Phase IIb Clinical Trial

- Prospective, randomized, single-blinded, placebo-controlled phase IIb clinical trial of GP2 + GM-CSF or GM-CSF alone in 180 intent to treat HER2/neu 1-3+, HLA-A2 patients at 16 civilian/military clinical sites, led by MD Anderson
- High-risk breast cancer patients (Node Positive, High Risk Node Negative) who were disease-free and immunocompetent after having completed standard of care therapy
- A recurrence is defined as either a pathologically confirmed recurrence or a new radiographic finding during standard of care follow-up



Primary Objective

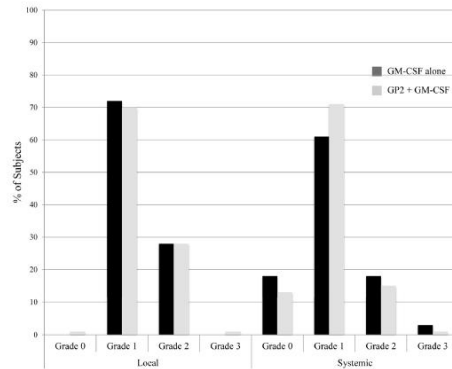
- Determine if GP2+GM-CSF treatment reduces recurrence rates vs. GM-CSF alone

Secondary Objective

- Monitor immune response and correlate with clinical outcomes
- Monitor for any unexpected toxicities

Phase IIb Clinical Data – No SAEs

- Maximum local and systemic toxicities were primarily grade 1 and grade 2
- Toxicities ranged from redness at injection site to flu-like symptoms and can be largely attributed to GM-CSF, not GP2

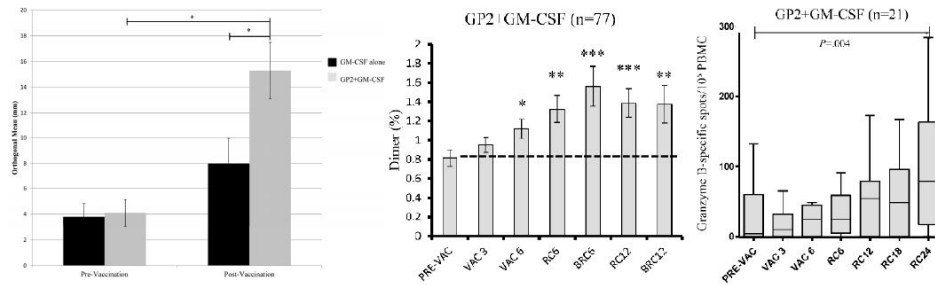


Toxicity: The maximum local and systemic toxicity experienced by patients administered the GP2+GM-CSF vaccine were comparable to those experienced by patients receiving GM-CSF alone. For patients receiving GP2 + GM-CSF, maximum local toxicities experienced during the PVS were grade 1 (70%), grade 2 (28%), or grade 3 (1%). The most common toxicities included erythema, induration and pruritis; the grade 3 toxicity was induration. Maximum systemic toxicities were grade 0 (13%), grade 1 (71%), grade 2 (15%), or grade 3 (1%). The most common systemic toxicities included fatigue, headache, and myalgias; the grade 3 toxicity was a diffuse maculopapular rash. The toxicities were comparable for patients receiving GM-CSF only, with maximum local toxicities being grade 1 (75%) or grade 2 (25%); and maximum systemic toxicities being grade 0 (21%), grade 1 (60%), grade 2 (15%), or grade 3 (3%). The grade 3 systemic toxicities in this group included diffuse urticarial reactions, syncope and extremity pain.

No SAEs. Primarily injection site reactions which are caused by GM-CSF & can be mitigated by reducing GM-CSF dose (and then GP2, if necessary)

Phase IIb – GP2 is Clinically & Immunologically Effective

- Immune response was observed peaking after 6 months compared to baseline, measured by Delayed Type Hypersensitivity (DTH skin test using GP2) and immunological assay. DTH response rate for treated patients is very high. Orthogonal mean baseline vs 6 months: $4.1 \pm 1.1\text{mm}$ versus $15.3 \pm 2.2\text{mm}$ (\pm standard error)
- Boosters administered every 6 months to sustain immunity
- Per treatment: 96 HER2/neu 3+, HLA-A2 patients - No recurrences if fully immunized at 6 months following 1st year of Herceptin treatment => target population for Phase III trial
- Per treatment: 72 HER2/neu 1-2+, HLA-A2 patients - No reduction in recurrence rate, but Herceptin was not administered to these patients => pursue in future with Herceptin combination therapy



Immune response peaks after 6 months of 6 doses, thereafter reducing recurrence rates from **11%** to **0%** at median 5 years follow-up



GP2 Planned Phase III Trial:

***Strategy – Conservatively Reproduce
Phase IIb Trial in Larger Population***



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Phase III Clinical Trial – Protocol Reviewed by FDA

Title: “Study Evaluating The Reduction Of Recurrences Using HER2/neu Peptide GP2 + GM-CSF Vaccine After Adjuvant Trastuzumab In HLA-A2-Positive, HER2-Positive (3+) Women With Operable Breast Cancer”

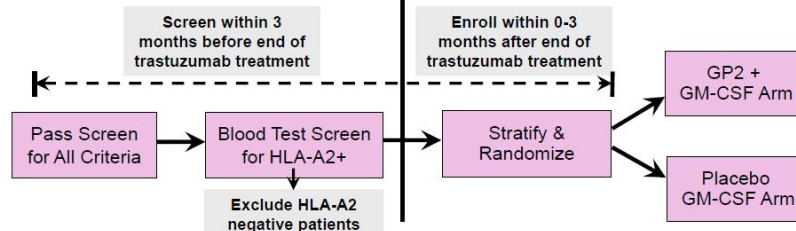
Major Screening Criteria:

- HER2/neu 3+ and HLA-A2+
- NP or high-risk NN
- Adjuvant, post surgery

End of 1st year
of trastuzumab
treatment

Randomization:

- NP or high-risk NN
- Prior pertuzumab (Perjeta),
Planned neratinib (Nerlynx),
trastuzumab Biosimilar
- By site if possible



- Plan to start trial in late 2020 or early 2021
- Enrollment period: 1.5 to 2 yrs
- Primary endpoint: Compare recurrence rate of GP2-treated vs. placebo at median 2, 3, 4, & 5 years follow-up using standard of care

Manufacturing / Regulatory / IP

- GP2 manufactured by straightforward amino acid chemistry
 - Manufactured by FDA-approved commercial facility with multiple back-up facilities
 - Detailed CMC plan reviewed by FDA
 - Commenced engineering scale-up run for commercial scale manufacturing
 - Phase III trial lot commenced in 2019
 - GM-CSF is commercially available, along with Saline/WFI, which will all be sold independently
- Discussing potency assay / HLA companion diagnostic
- GP2 registered as biologic with CBER – 10-12 years exclusivity in US
- GP2 issued patents provide protection through 2032 in the major markets (US, EU, Canada, Australia, & Japan), including ongoing prosecution in emerging markets



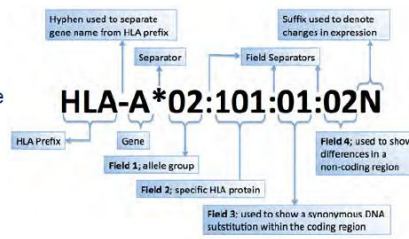
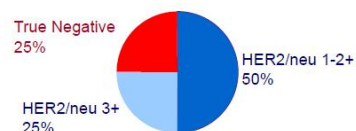
GP2 Commercial Opportunity



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Potential Additional Indications of GP2 & Herceptin in Various Populations in Adjuvant Setting

- HER2/neu 3+ protein over-expression (25%) & 1-2+ expression (50%)
 - All breast cancer patients are tested for HER2/neu expression by immunohistochemistry (IHC) or fluorescence in situ hybridisation (FISH)
- Node Positive (60%) & High Risk Node Negative (40%)
 - Node positive – cancer has spread to lymph nodes
 - High risk node negative – no cancer in lymph nodes but at high risk for recurrence
 - The more lymph node involvement the more aggressive the cancer
- Hormone Receptor Positive (60%) & Hormone Receptor Negative (40%)
- HLA Type: HLA-A2 (40-50%) & HLA-A3,A24 (additional 30%)
 - Human leukocyte antigen presents peptide from inside cancer cell to killer T-cells
 - HLA also presents injected peptide to create killer T-cells following intradermal injection



Commercial Opportunity for GP2 in Breast Cancer


- 1 in 8 U.S. women (12.4%) will develop invasive breast cancer over her lifetime, with 266k new breast cancer patients per year in 2018
- GP2's target market is 6-30% of available breast cancer market or up to 2.4x that of Herceptin in adjuvant setting
- GP2 could be a long term treatment that treats survivors (3.1m as of 2018)
- Herceptin/Perjeta/Nerlynx/Kadcyla pricing from \$75k - \$125k per patient per year
- 11 doses over 3 years in initial indication

	Herceptin	GP2
US Market Potential (Size = 3.1m current breast cancer survivors and 266k new patients per year)		
HER2/neu Expressors (1-3+)	25% (3+)	25-75% (1-3+)
HLA Type	100%	50-80% (2/3/24/26)
Node Positive (NP) or High Risk Node Negative (HRNN)	50%	50%
Target Market Potential	12.5%	6.25 - 30%
Theoretical New Patients per Year	33,250	16,750 – 79,800
Adjuvant Patients Treated per Year (est. from sales)	27,000 – 40,000	
Estimated Adjuvant Setting US Revenue (\$ billions)		
Estimated Price (first year)	\$74,500	TBD (6 primary + 1 booster)
Estimated Price (booster)	Not Approved	TBD (4 boosters over 2 years)
Estimated 2017 Global Revenue (\$ billions)		
Adjuvant Setting	\$2-3	
Metastatic Breast Cancer	\$4-5	

Multi \$ Billion
Revenue
Potential




GP2 Acts Synergistically with Herceptin, Perjeta, Nerlynx, & the Newest Entrants Kadcyra and Enhertu




Herceptin
trastuzumab

- Genentech's Herceptin (trastuzumab) in Y1 post-surgery
 - Reduces recurrence rates from **25% to 12%** by Y4 post-surgery
 - Node Positive and High Risk Node Negative
 - **Side Effects:** Cardiotoxic, 1 year treatment only
- Genentech's Perjeta (pertuzumab) in Y1 with Herceptin
 - Reduces recurrence rates in Node Positive from **13% to 10%** & in Hormone Receptor Negative from **11% to 9%** by Y4 post-surgery
 - **Side Effects:** Adverse reactions (>30%) - diarrhea, nausea, alopecia, fatigue, peripheral neuropathy and vomiting.
- Puma's Nerlynx (neratinib) in Y2 post-Herceptin
 - Reduces recurrence rates overall from **12% to 10%** & in Hormone Receptor Positive from **13% to 9%** by Y6 post-surgery
 - **Side Effects:** 95% all-grade diarrhea & 40% grade 3/4 (reduced 20% with loperamide prophylaxis), nausea (43%), fatigue (27%), vomiting (26%), & abdominal pain (24%).



Kadcyla
ado-trastuzumab emtansine


Herceptin
ADC 4:1




ENHERTU
tado-trastuzumab emtansine

Herceptin
ADC 8:1

Approved on Y3
Post-Surgery Data



PERJETA
pertuzumab

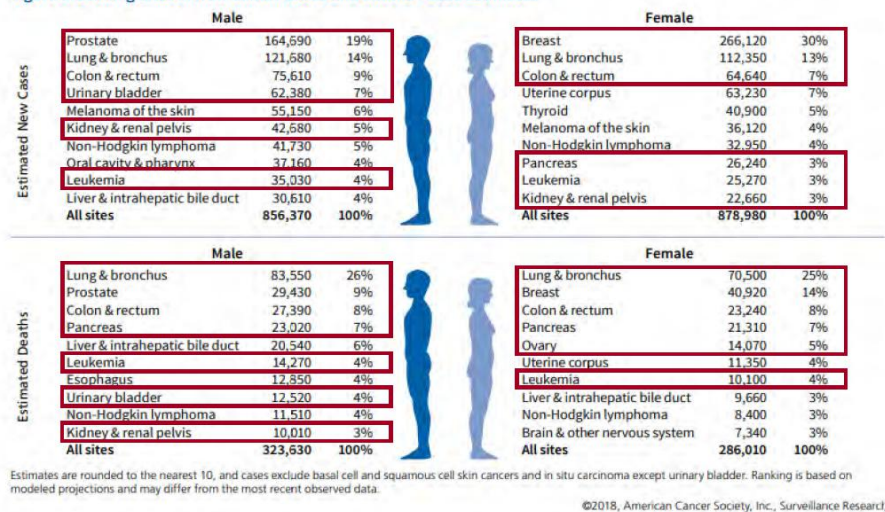


nerlynx
(neratinib) tablets

Substantial Unmet Need: GP2 & GM-CSF starting in Y2 act synergistically with Herceptin to prevent cancer recurrences, if fully immunized, reducing recurrence rates from **11% to 0% at median 5 years follow-up, minimal to no side effects, & no SAEs**

Potential Commercial Opportunities / Additional Indications for GP2 : HER2/neu Expressed in Multiple Cancers

Figure 3. Leading Sites of New Cancer Cases and Deaths – 2018 Estimates



Denotes cancers where HER2/neu over expression has been reported

Trading & Transaction Comparables

Trading Comparables

As of market close on 11/17/20

Symbol	Name	Price	Change	Volume	Day Range	52Wk Range	Market Cap	Comments
Late Stage Breast Cancer / ImmunoOncology								
PBYI	PUMA BIOTECHNOLOGY	9.38	▲ +0.30 +3.30 %	370.61k	8.91-9.49	5.50-15.00	372.97M	Pure play comp with Nerlynx not as effective and more toxic than GP2
CVM	CEL-SCI CORPORATION	11.61	▼ -0.63 -5.15 %	426.62k	11.40-12.21	6.35-18.00	449.72M	Pure play comp with Phase III cancer immunotherapy with promising Phase II data
GTHX	G1 THERAPEUTICS	13.78	▲ +0.59 +4.47 %	400	13.14-14.05	8.80-31.38	524.27M	Recently announced positive Phase II & III data
SGEN	SEATTLE GENETICS	173.17	▼ -4.02 -2.27 %	640.46k	172.57-177.25	90.57-213.94	31.22B	Recently announced Phase II data, tucatanib just approved
Early to Mid-stage ImmunoOncology								
BNTX	BioNTech SE	86.93	▼ -4.59 -5.02 %	10.70k	86.65-92.00	18.60-115.00	20.93B	Cancer and infectious diseases, including Coronavirus
GRTS	GRITSTONE ONCOLOGY	2.69	▼ -0.18 -6.27 %	349.81k	2.62-2.85	2.54-12.96	101.59M	Neoantigens - early stage clinical trials
IMV	IMV	3.41	▼ -0.15 -4.21 %	249.99k	3.41-3.57	1.35-6.82	299.91M	Antigen based early/mid stage trials

Note: Excludes Marker Therapeutics, Genex Biotechnology, & Sellas Life Sciences as their breast cancer programs are not reflected in the company valuation.

Breast Cancer & Peptide Immunotherapy Transaction Comparables

- Genentech secures a global license to neoantigen cancer vaccines developed by Vaccibody, committing \$200m in upfront and near-term payments, plus up to \$515m in future milestones.
- Merck invests \$1b in equity in Seattle Genetics. For breast cancer drug #1, which is still in development, Merck is paying \$600m upfront plus another \$2.6b over time. For breast cancer drug #2, Tukysa, which is now approved for metastatic breast cancer with toxicity, Merck is paying \$125m upfront plus another \$65m over time for marketing rights outside of the U.S., Canada and Europe.
- Gilead acquires Immunomedics for \$21b gaining access to Trodelvy, or sacituzumab govitecan-hziy, an FDA-approved drug designed to treat metastatic triple-negative breast cancer.



Veteran Management Team / Board

- David McWilliams, MBA – Chairman, Board
 - 40 years of start-up / CEO experience
 - CEO of 2 private and 3 public biotech companies
- Snehal Patel, MS, MBA – CEO, Board
 - 30 years of biopharma / Wall Street experience
 - Large pharma operations / management experience
- Joe Daugherty, M.D. – CMO, Board
 - 35+ years of biopharma experience
 - Assisted over 20 public and private companies
- Jaye Thompson, Ph.D. – VP Clinical & Regulatory
 - 30 years of active involvement in over 200 clinical trials for drugs, biologics and devices
 - Founder of multiple CROs
- Eric Rothe – Board & Founder of GLSI
- Ken Hallock – Board & Major Investor



Capitalization (as of 9/30/20)

CASH	\$6.2m
COMMON SHARES	11,970,185
WARRANTS AND OPTIONS	100,870
FULLY DILUTED SHARES	12,071,055
OWNERSHIP (TIGHTLY HELD: 76% Insiders + 14% Family Trusts)	90%
LIABILITIES	\$1.6m

Over \$20M in private capital and grants
have been invested in GP2 prior to IPO

GP2 Conclusions: A Breakthrough Targeted Immunotherapy for Prevention of HER2/neu Cancer

- Phase IIb trial: No breast cancer recurrences post-surgery, if fully immunized, ($p = 0.0338$), with minimal to no side effects, at median 5 years follow-up, randomized, placebo-controlled, multi-center (16 sites, 96 patients), study led by MD Anderson
- Conservative design of Phase III trial to reproduce Phase IIb results
- Planned Phase III Trial: Breast cancer post-surgery adjuvant/neoadjuvant setting, HER2/neu 3+, HLA-A2 patients starting in Y2 following Herceptin or Kadcyla
- FDA-reviewed Phase III trial protocol & CMC, Initiated scale-up manufacturing for Phase III trial, & Finalizing CRO selection/budget
- Multiple Phase II trial opportunities to expand breast cancer market:
 - HER2/neu 1-2+ patients with Herceptin - increase market from 25% to 75%
 - Other HLA types – increase from 40-50% up to 80% of all patients
 - Combination with CD4/CD8 peptides and checkpoints
 - Other HER2/neu cancers
- NASDAQ Ticker “GLSI”: Closed IPO on September 29, 2020



For Additional Information, Please Contact:

Snehal Patel
CEO

Telephone: 832.819.3232

E-mail: info@greenwichlifesciences.com

Website: greenwichlifesciences.com

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November 18, 2020

Greenwich LifeSciences Announces Publication of Positive Phase IIb Clinical Trial Data for GP2, Its Lead Drug Candidate for the Prevention of Recurring Breast Cancer

- Company now preparing to enter a phase III clinical trial
- Phase IIb clinical trial was a prospective, randomized, single-blinded, placebo-controlled, multi-center (16 sites) trial led by MD Anderson and completed in 2018
- No recurrences were observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$)
- GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays

STAFFORD, Texas—(Business Wire)— Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the “Company”), a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery, today announced the publication of an abstract at the San Antonio Breast Cancer Symposium (SABCS). The abstract will be displayed as a poster on Wednesday, December 9, 2020 in a virtual format.

The study met all of its clinical endpoints for HER2/*neu* 3+ patients, concluding that the first 6 intradermal injections of GP2+GM-CSF safely elicited a potent immune response and reduced recurrence rates to 0% in HER2/*neu* 3+ patients, who received a standard course of trastuzumab after surgery, and this reduction of recurrence rate was maintained over the gold standard of 5 years of follow-up. A pivotal Phase III trial is being initiated to treat HER2/*neu* 3+ patients in the neoadjuvant setting. GP2 may also be effective when used in parallel to trastuzumab based therapeutics or in combination with trastuzumab based therapeutics in HER2/*neu* 1-2+ or other HER2/*neu* expressing cancers.

Snehal Patel, CEO of Greenwich LifeSciences, commented, “Approximately 50% of recurring patients do not respond to Herceptin or Kadcyla and still recur with metastatic breast cancer and a poor prognosis, where approximately 80-85% of recurring patients do not survive.”

“The publication of this abstract shows that we met all of the endpoints for our Phase IIb clinical trial for HER2/*neu* 3+ patients, including safety, where no serious adverse events were observed. By substantially reducing the recurrence rate of the non-responders, we are addressing a large unmet need of women. If we are successful in reproducing our Phase IIb clinical trial data in a Phase III clinical trial, we could make a major impact in reducing metastatic breast cancer recurrence in this patient population, potentially saving thousands of lives per year. We are excited to begin our Phase III clinical trial.”

“Based on our analysis of the potential market in our IPO prospectus, GP2 could initially treat 17,000 newly diagnosed patients per year in the US or approximately 50% of the Herceptin adjuvant market of \$2-3 billion, and could expand to 2.4x that of the Herceptin market through additional Phase II trials and indications, reaching a potential peak revenue exceeding \$5 billion. Not included in these estimates are the 3 million breast cancer survivors in the US of whom 25% are HER2/*neu* 3+. These survivors could also be candidates for a safe and effective preventative therapy,” Patel concluded.

The abstract highlights the final 5 year follow-up efficacy and demographic data across all patient populations from the completed prospective, randomized, placebo-controlled, single-blinded, multicenter, Phase IIb clinical trial evaluating the reduction of recurrences. The poster presentation includes the disease-free survival curves for both HER2/*neu* 3+ and HER2/*neu* 1-2+ patient populations, including the demographics for stage of cancer, hormone receptor status, node status, and prior treatment with chemotherapy, radiation, endocrine therapy, or trastuzumab.

This 168 patient (ITT: n=180) basket trial across 16 clinical sites explored 96 HER2/*neu* 3+ patients, who received a standard course of trastuzumab after surgery and subsequently completed the first 6 intradermal injections or placebo, starting GP2 treatment at median 17.1 months after surgery, and 72 HER2/*neu* 1-2+ patients, who did not receive trastuzumab after surgery and subsequently completed the first 6 intradermal injections or placebo, starting the GP2 treatment at median 10.8 months after surgery.

Since GP2 is synergistic with trastuzumab, and the HER2/*neu* 1-2+ patients did not receive trastuzumab, it was prespecified to compare recurrence rates ITT versus per protocol in these 2 distinct, independently reported populations, excluding those patients who did not complete the first 6 intradermal injections. GP2 was shown to be well tolerated with no SAEs and elicited a potent immune response measured by local skin tests and immunological assays, which suggest peak immunity is reached at 6 months upon completion of the first 6 intradermal injections.

After 5 years of follow-up, the Kaplan-Meier estimated 5-year DFS rate in the 46 HER2/*neu* 3+ patients treated with GP2+GM-CSF, if the patient completed the first 6 intradermal injections, was 100% versus 89.4% (95% CI:76.2, 95.5%) in the 50 placebo patients treated with GM-CSF ($p = 0.0338$). The treated versus placebo HER2/*neu* 3+ patients were well-matched, where approximately 53% were stage T1, 41% were stages T2-T4, 55% were node positive, 58% were HR positive and received endocrine therapy, 77% received adjuvant radiation, 77% received adjuvant chemotherapy, and 89% received trastuzumab. There was no benefit to GP2 treatment in the HER2/*neu* 1-2+ patients where trastuzumab was not administered.

Abstract PS10-23 is entitled: Five year median follow-up data from a prospective, randomized, placebo-controlled, single-blinded, multicenter, Phase IIb study evaluating the reduction of recurrences using HER2/*neu* peptide GP2 + GM-CSF vs. GM-CSF alone after adjuvant trastuzumab in HER2/*neu* positive women with operable breast cancer. The full abstract can be viewed here on page 654.

About SABCS

The 43rd annual SABCS has grown to be the industry's premier breast cancer conference for basic, translational, and clinical cancer research professionals. It is well-known for presenting the latest breast cancer data from all over the world. More than 7,500 health care professionals from more than 90 countries attend annually. Baylor College of Medicine became a joint sponsor of SABCS in 2005. The Cancer Therapy & Research Center at UT Health Science Center San Antonio and American Association for Cancer Research began collaborations with SABCS in 2007. For more information, please visit the conference website at: <https://www.sabcs.org/>

About Breast Cancer and HER2/*neu* Positivity

One in eight U.S. women will develop invasive breast cancer over her lifetime, with approximately 266,000 new breast cancer patients and 3.1 million breast cancer survivors in 2018. HER2/*neu* (human epidermal growth factor receptor 2) protein is a cell surface receptor protein that is expressed in a variety of common cancers, including in 75% of breast cancers at low (1+), intermediate (2+), and high (3+ or over-expressor) levels.

About Greenwich LifeSciences, Inc.

Greenwich LifeSciences is a clinical-stage biopharmaceutical company focused on the development of GP2, an immunotherapy to prevent breast cancer recurrences in patients who have previously undergone surgery. GP2 is a 9 amino acid transmembrane peptide of the HER2/*neu* protein. In a randomized, single-blinded, placebo-controlled, multi-center (16 sites led by MD Anderson Cancer Center) Phase IIb clinical trial, no recurrences were observed in the HER2/*neu* 3+ adjuvant setting after median 5 years of follow-up, if the patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$). Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 treatment was well tolerated and no serious adverse events were observed related to GP2 immunotherapy. Greenwich LifeSciences is planning to commence a Phase III clinical trial using a similar treatment regime as the Phase IIb clinical trial. For more information on Greenwich LifeSciences, please visit the company's website: www.greenwichlifesciences.com

Forward-Looking Statement Disclaimer

Statements in this press release contain “forward-looking statements” that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “target,” “aim,” “should,” “will” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Greenwich LifeSciences Inc.’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the final prospectus related to the public offering filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Greenwich LifeSciences Inc. undertakes no duty to update such information except as required under applicable law.

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Company Contact

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

Investor & Public Relations Contact for Greenwich LifeSciences Inc.:

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

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